HANDBOOK HANDBOOK

2019 Interim Meeting Manchester Grand Hyatt San Diego Nov. 16–19

Access the handbook online: ama-assn.org/hod-2019-business

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MEMBERSHIP MOVES MEDICINE

MEMORANDUM FROM THE SPEAKER OF THE HOUSE OF DELEGATES

- All Delegates, Alternate Delegates and others receiving this material are reminded that it refers only to items to be considered by the House.
- No action has been taken on anything herein contained, and it is informational only.
- Only those items that have been acted on finally by the House can be considered official.
- The Interim Meeting is focused on advocacy issues. A resolution committee (see AMA Bylaw 2.13.3) considers each resolution and recommends that the item be considered or not considered at the Interim Meeting. Items that meet the following definition of advocacy or that are considered urgent are recommended for acceptance:

Active use of communication and influence with public and private sector entities responsible for making decisions that directly affect physician practice, payment for physician services, funding and regulation of education and research, and access to and delivery of medical care.

Resolutions pertaining to ethics should also be included in the agenda. Remaining items are recommended against consideration, but any delegate may request consideration when resolutions are presented for consideration (during Sunday's "Second Opening" Session). A simple majority of those present and voting is required for consideration.

• REMINDER: Only the Resolve portions of the resolutions are considered by the House of Delegates. The Whereas portions or preambles are informational and explanatory only.



UNDERSTANDING THE RECORDING OF AMERICAN MEDICAL ASSOCIATION POLICY

Current American Medical Association (AMA) policy is catalogued in PolicyFinder, an electronic database that is updated after each AMA House of Delegates (HOD) meeting and available online. Each policy is assigned to a topical or subject category. Those category headings are alphabetical, starting with "abortion" and running to "women"; the former topic was assigned the number 5, and "women" was assigned 525. Within a category, policies are assigned a 3 digit number, descending from 999, meaning that older policies will *generally* have higher numbers within a category (eg, 35.999 was initially adopted before 35.984). A policy number is not affected when it is modified, however, so a higher number may have been altered more recently than a lower number. Numbers are deleted and not reused when policies are rescinded.

AMA policy is further categorized into one of four types, indicated by a prefix:

- "H" for statements that one would consider positional or philosophical on an issue
- "D" for statements that direct some specific activity or action. There can be considerable overlap between H and D statements, with the assignment made on the basis of the core nature of the statement.
- "G" for statements related to AMA governance
- "E" for ethical opinions, which are the recommendations put forward in reports prepared by the Council on Ethical and Judicial Affairs and adopted by the AMA-HOD

AMA policy can be accessed at ama-assn.org/go/policyfinder.

The actions of the AMA-HOD in developing policy are recorded in the *Proceedings*, which are available <u>online</u> as well. Annotations at the end of each policy statement trace its development, from initial adoption through any changes. If based on a report, the annotation includes the following abbreviations:

BOT – Board of Trustees CME – Council on Medical Education CCB – Council on Constitution and Bylaws CMS – Council on Medical Service

CEJA – Council on Ethical and Judicial Affairs CSAPH – Council on Science and Public Health

CLRPD - Council on Long Range Planning and Development

If a resolution was involved, "Res" is indicated. The number of the report or resolution and meeting (A for Annual; I for Interim) and year (two digits) are also included (eg, BOT Rep. 1, A-14 or Res. 319, I-12).

AMA policy is recorded in the following categories, and any particular policy is recorded in only a single category.

5.000 Abortion	10.000 Accident Prevention/Unintentional Injuries
15.000 Accident Prevention: Motor Vehicles	20.000 Acquired Immunodeficiency Syndrome
25.000 Aging	30.000 Alcohol and Alcoholism
35.000 Allied Health Professions	40.000 Armed Forces
45.000 Aviation Medicine	50.000 Blood
55.000 Cancer	60.000 Children and Youth
65.000 Civil and Human Rights	70.000 Coding and Nomenclature
75.000 Contraception	80.000 Crime
85.000 Death and Vital Records	90.000 Disabled
95.000 Drug Abuse	100.000 Drugs
105.000 Drugs: Advertising	110.000 Drugs: Cost
115.000 Drugs: Labeling and Packaging	120.000 Drugs: Prescribing and Dispensing
125.000 Drugs: Substitution	130.000 Emergency Medical Services
135.000 Environmental Health	140.000 Ethics
145.000 Firearms: Safety and Regulation	150.000 Foods and Nutrition

155.000 Health Care Costs	160.000 Health Care Delivery
165.000 Health Care/System Reform	170.000 Health Education
175.000 Health Fraud	180.000 Health Insurance
185.000 Health Insurance: Benefits and Coverage	190.000 Health Insurance: Claim Forms and Claims Processing
195.000 Health Maintenance Organizations	200.000 Health Workforce
205.000 Health Planning	210.000 Home Health Services
215.000 Hospitals	220.000 Hospitals: Accreditation Standards
225.000 Hospitals: Medical Staff	230.000 Hospitals: Medical Staff - Credentialing and Privileges
235.000 Hospitals: Medical Staff - Organization	240.000 Hospitals: Reimbursement
245.000 Infant Health	250.000 International Health
255.000 International Medical Graduates	260.000 Laboratories
265.000 Legal Medicine	270.000 Legislation and Regulation
275.000 Licensure and Discipline	280.000 Long-Term Care
285.000 Managed Care	290.000 Medicaid and State Children's Health Insurance
	Programs
295.000 Medical Education	300.000 Medical Education: Continuing
305.000 Medical Education: Financing and Support	310.000 Medical Education: Graduate
315.000 Medical Records and Patient Privacy	320.000 Medical Review
330.000 Medicare	335.000 Medicare: Carrier Review
340.000 Medicare: PRO	345.000 Mental Health
350.000 Minorities	355.000 National Practitioner Data Bank
360.000 Nurses and Nursing	365.000 Occupational Health
370.000 Organ Donation and Transplantation	373.000 Patients
375.000 Peer Review	380.000 Physician Fees
383.000 Physician Negotiation	385.000 Physician Payment
390.000 Physician Payment: Medicare	400.000 Physician Payment: Medicare - RBRVS
405.000 Physicians	406.000 Physician-Specific Health Care Data
410.000 Practice Parameters	415.000 Preferred Provider Arrangements
420.000 Pregnancy and Childbirth	425.000 Preventive Medicine
430.000 Prisons	435.000 Professional Liability
440.000 Public Health	445.000 Public Relations
450.000 Quality of Care	455.000 Radiation and Radiology
460.000 Research	465.000 Rural Health
470.000 Sports and Physical Fitness	475.000 Surgery
478.000 Technology - Computer	480.000 Technology - Medical
485.000 Television	490.000 Tobacco Use, Prevention and Cessation
495.000 Tobacco Products	500.000 Tobacco: AMA Corporate Policies and Activities
505.000 Tobacco: Federal and International Policies	510.000 Veterans Medical Care
515.000 Violence and Abuse	520.000 War
525.000 Women	600.000 Governance: AMA House of Delegates
605.000 Governance: AMA Board of Trustees and Officers	610.000 Governance: Nominations, Elections, and Appointments
615.000 Governance: AMA Councils, Sections, and Committees	620.000 Governance: Federation of Medicine
625.000 Governance: Strategic Planning	630.000 Governance: AMA Administration and Programs
635.000 Governance: Membership	640.000 Governance: Advocacy and Political Action
1	<u> </u>

LIST OF MATERIAL INCLUDED IN THIS HANDBOOK (I-19)

Resolutions and reports have been collated by referral according to reference committee assignment. In the listing below, referral is indicated by letter in parenthesis following the title of the report. Resolutions have been numbered according to referrals (i.e., those referred to the Reference Committee on Amendments to Constitution and Bylaws begin with 001, Reference Committee B begins with 201, etc.).

The informational reports contain no recommendations and will be filed on Sunday, November 17, unless a request is received for referral and consideration by a Reference Committee (similar to the use of a consent calendar).

- 1. Memorandum from the Speaker
- 2. Understanding the Recording of American Medical Association Policy
- 3. Declaration of Professional Responsibility Medicine's Social Contract with Humanity
- 4. Delegate / Alternate Delegate Job Description, Roles and Responsibilities
- 5. Seating Allocation and Seating Chart for the House of Delegates
- 6. Hotel Maps
- 7. Official Call to the Officers and Members of the AMA Listing of Delegates and Alternate Delegates Officials of the Association and AMA Councils House of Delegates Reference Committee Members
- 8. Note on Order of Business
- 9. Summary of Fiscal Notes

FOLLOWING COLLATED BY REFERRAL

- 10. Report(s) of the Board of Trustees Jesse M. Ehrenfeld, MD, MPH, Chair
 - 01 Legalization of the Deferred Action for Legal Childhood Arrival (DALCA) (B)
 - 02 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings (B)
 - 03 Restriction on IMG Moonlighting (B)
 - 04 Involvement of Women in AMA Leadership, Recognition and Research Opportunities (Info. Report)
 - 05 Restrictive Covenants of Large Health Care Systems (Info. Report)
 - 06 Physician Health Policy Opportunity (F)
 - 07 2019 AMA Advocacy Efforts (Info. Report)
 - 08 Implementing AMA Climate Change Principles Through JAMA Paper Consumption Reduction and Green Health Care Leadership (F)
 - 09 Opioid Mitigation (B)
 - 11 Re-establishment of National Guideline Clearinghouse (Info. Report)
 - 12 Distracted Driver Education and Advocacy (Info. Report)
 - 13 Hospital Closures and Physician Credentialing (Info. Report)

14 Redefining AMA's Position on ACA and Healthcare Reform (Info. Report)

11. Report(s) of the Council on Constitution and Bylaws - Patricia L. Austin, MD, Chair

- 01 Parity in our House of Delegates (Amendments to C&B)
- 02 Bylaw Consistency--Certification Authority for Societies represented in our AMA House of Delegates and Advance Certification for those Societies (Amendments to C&B)
- 03 AMA Delegate Apportionment (Amendments to C&B)

12. Report(s) of the Council on Ethical and Judicial Affairs - Kathryn L. Moseley, MD, Chair

- 01 Competence, Self-Assessment and Self-Awareness (Amendments to C&B)
- 02 Amendment to E-1.2.2., "Disruptive Behavior by Patients" (Amendments to C&B)

13. Report(s) of the Council on Long Range Planning and Development - James A. Goodyear, MD, Chair

01 Academic Physicians Section Five-Year Review (F)

14. Report(s) of the Council on Medical Education - Jacqueline A. Bello, MD, Chair

- 01 For-Profit Medical Schools or Colleges (Info. Report)
- 02 Healthcare Finance in the Medical School Curriculum (C)
- 03 Standardization of Medical Licensing Time Limits Across States (C)
- 04 Board Certification Changes Impact Access to Addiction Medicine Specialists (C)
- 05 The Transition from Undergraduate Medical Education to Graduate Medical Education (Info. Report)
- 06 Veterans Health Administration Funding of Graduate Medical Education (C)

15. Report(s) of the Council on Medical Service - W. Alan Harmon, MD, Chair

- 01 Established Patient Relationships and Telemedicine (J)
- 02 Addressing Financial Incentives to Shop for Lower-Cost Health Care (J)
- 03 Improving Risk Adjustment in Alternative Payment Models (J)
- 04 Mechanisms to Address High and Escalating Pharmaceutical Prices (J)

16. Report(s) of the Council on Science and Public Health - Michael M. Miller, MD, Chair

- 01 Mandatory Reporting of Diseases and Conditions (K)
- 02 Real-World Data and Real-World Evidence in Medical Product Decision Making (K)
- 03 Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals (K)

17. Report(s) of the HOD Committee on Compensation of the Officers - Richard A. Evans, MD, Chair

01* Report of the HOD Committee on Compensation of the Officers (F)

18. Report(s) of the Speakers - Bruce A. Scott, MD, Speaker; Lisa Bohman Egbert, MD, Vice Speaker

01* Speakers' Report: Task Force on Election Reform (Info. Report)

19. Resolutions

- 001 Support for the Use of Psychiatric Advance Directives (Amendments to C&B)
- 002 Endorsing the Creation of a Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) Research
- IRB Training (Amendments to C&B)
- 003 Accurate Collection of Preferred Language and Disaggregated Race and Ethnicity to Characterize Health Disparities (Amendments to C&B)
- 004 Improving Inclusiveness of Transgender Patients Within Electronic Medical Record Systems (Amendments to C&B)
- 005 Removing Sex Designation from the Public Portion of the Birth Certificate (Amendments to C&B)
- 006 Transparency Improving Informed Consent for Reproductive Health Services (Amendments to C&B)

- 007 Addressing the Racial Pay Gap in Medicine (Amendments to C&B)
- 009 Data for Specialty Society Five-Year Review (Amendments to C&B)
- 010 Ban Conversion Therapy of LGBTQ Youth (Amendments to C&B)
- 011 End Child Marriage (Amendments to C&B)
- 201 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities (B)
- 202 Support for Veterans Courts (B)
- 203 Support Expansion of Good Samaritan Laws (B)
- 204 AMA Position on Payment Provisions in Health Insurance Policies (B)
- 205 Co-Pay Accumulators (B)
- 206 Improvement of Healthcare Access in Underserved Areas by Retaining and Incentivizing IMG Physicians (B)
- 207 Pharmaceutical Advertising in Electronic Health Record Systems (B)
- 208 Net Neutrality and Public Health (B)
- 209 Federal Government Regulation and Promoting Patient Access to Kidney Transplantation (B)
- 210 Federal Government Regulation and Promoting Renal Transplantation (B)
- 211 Effects of Net Neutrality on Public Health (B)
- 212 Centers for Medicare and Medicaid Services Open Payments Program (B)
- 213 Data Completeness and the House of Medicine (B)
- 214 AMA Should Provide a Summary of its Advocacy Efforts on Surprise Medical Bills (B)
- 215* Board Certification of Physician Assistants (B)
- 216* Legislation to Facilitate Corrections-to-Community Healthcare Continuity via Medicaid (B)
- 217* Promoting Salary Transparency Among Veterans Health Administration Employed Physicians (B)
- 218* Private Payers and Office Visit Policies (B)
- 219* OPP and the Immediate Availability of Results in CEHRTs (B)
- 301 Engaging Stakeholders for Establishment of a Two-Interval, or Pass/Fail, Grading System of Non-Clinical Curriculum in U.S. Medical Schools (C)
- 302 Strengthening Standards for LGBTQ Medical Education (C)
- 303 Investigation of Existing Application Barriers for Osteopathic Medical Students Applying for Away Rotations (C)
- 304 Issues with the Match, The National Residency Matching Program (NRMP) (C)
- 305 Ensuring Access to Safe and Quality Care for our Veterans (C)
- 306 Financial Burden of USMLE Step 2 CS on Medical Students (C)
- 307 Implementation of Financial Education Curriculum for Medical Students and Physicians in Training (C)
- 308 Study Expediting Entry of Qualified IMG Physicians to US Medical Practice (C)
- 801 Reimbursement for Post-Exposure Protocol for Needlestick Injuries (J)
- 802 Ensuring Fair Pricing of Drugs Developed with the United States Government (J)
- 803 Encourage Federal Efforts to Expand Access to Scheduled Dialysis for Undocumented People (J)
- 804 Protecting Seniors from Medicare Advantage Plans (J)
- 805 Fair Medication Pricing for Patients in United States: Advocating for a Global Pricing Standard (J)
- 806 Support for Housing Modification Policies (J)
- 807 Addressing the Need for Low Vision Aid Devices (J)
- 808 Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs (J)
- 809 AMA Principles of Medicaid Reform (J)
- 810 Hospital Medical Staff Policy (J)

- 811 Require Payers to Share Prior Authorization Cost Burden (J)
- 812* Autopsy Standards as Condition of Participation (J)
- 813* Public Reporting of PBM Rebates (J)
- 814* PBM Value-Based Framework for Formulary Design (J)
- 815* Step Therapy (J)
- 901 Health Impact of Per- and Polyfluoroalkyl Substances (PFAS) Contamination in Drinking Water (K)
- 902 Amending H-490.913, Smoke-Free Environments and Workplaces, and H-409.907, Tobacco Smoke Exposure of Children in Multi-Unit Housing, to Include E-Cigarettes (K)
- 903 Encouraging the Development of Multi-Language, Culturally Informed Mobile Health Applications (K)
- 904 Amendment to AMA Policy H-150.949, "Healthy Food Options in Hospitals" (K)
- 905 Sunscreen Dispensers in Public Spaces as a Public Health Measure (K)
- 906 Ensuring the Best In-School Care for Children with Sickle Cell Disease (K)
- 907 Increasing Access to Gang-Related Laser Tattoo Removal in Prison and Community Settings (K)
- 908 Request for Benzodiazepine-Specific Prescribing Guidelines for Physicians (K)
- 909 Decreasing the Use of Oximetry Monitors for the Prevention of Sudden Infant Death Syndrome (K)
- 910 Ban on Electronic Nicotine Delivery System (ENDS) Products (K)
- 911 Basic Courses in Nutrition (K)
- 912 Improving Emergency Response Planning for Infectious Disease Outbreaks (K)
- 913 Public Health Impacts and Unintended Consequences of Legalization and Decriminalization of Cannabis for Medicinal and Recreational Use (K)
- 914 Nicotine Replacement Therapy for Minors (K)
- 915 Preventing Death and Disability Due to Particulate Matter Produced by Automobiles (K)
- 916 Sale of Tobacco in Retail Pharmacies (K)
- 917 Supporting Research into the Therapeutic Potential of Psychedelics (K)
- 918 Banning Flavors, Including Menthol and Mint, in Combustible and Electronic Cigarettes and Other Nicotine Products (K)
- 919 Raising Awareness of the Health Impact of Cannabis (K)
- 920 Maintaining Public Focus on Leading Causes of Nicotine-Related Death (K)
- 921 Vaping in New York State and Nationally (K)
- 922 Understanding the Effects of PFAS on Human Health (K)
- 923 Support Availability of Public Transit System (K)
- 924 Update Scheduled Medication Classification (K)
- 925* Suspending Sales of Vaping Products/Electronic Cigarettes Until FDA Review (K)
- 927* Climate Change (K)
- 928* CBD Oil and Supplement Use in Treatment (K)
- 929* Regulating Marketing and Distribution of Tobacco Products and Vaping-Related Products (K)

20. Resolutions not for consideration

- 008 Improving the Health and Safety of Consensual Sex Workers (Not for consideration)
- 012* Study of Forced Organ Harvesting by China (Not for consideration)
- 601 Amending AMA Policy G-630.140, "Lodging, Meeting Venues, and Social Functions" (Not for consideration)
- 926* School Resource Officer Qualifications and Training (Not for consideration)

* Contained in Handbook Addendum

DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE'S SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

- 1. Respect human life and the dignity of every individual.
- 2. Refrain from supporting or committing crimes against humanity and condemn all such acts.
- 3. Treat the sick and injured with competence and compassion and without prejudice.
- 4. Apply our knowledge and skills when needed, though doing so may put us at risk.
- 5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
- 6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
- 7. Educate the public and polity about present and future threats to the health of humanity.
- 8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
- 9. Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Adopted by the House of Delegates of the American Medical Association in San Francisco, California on December 4, 2001

Delegate/Alternate Delegate Job Description, Roles and Responsibilities

At the 1999 Interim Meeting, the House of Delegates adopted as amended Recommendation 16 of the final report of the Special Advisory Committee to the Speaker of the House of Delegates. This recommendation included a job description and roles and responsibilities for delegates and alternate delegates. The description and roles and responsibilities were modified at the 2002 Annual Meeting by Recommendation 3 of the Joint Report of the Board of Trustees and Council on Long Range Planning and Development. The modified job description, qualifications, and responsibilities are listed below.

Delegates and Alternate Delegates should meet the following job description and roles and responsibilities:

Job Description and Roles and Responsibilities of AMA Delegates/Alternate Delegates

Members of the AMA House of Delegates serve as an important communications, policy, and membership link between the AMA and grassroots physicians. The delegate/alternate delegate is a key source of information on activities, programs, and policies of the AMA. The delegate/alternate delegate is also a direct contact for the individual member to communicate with and contribute to the formulation of AMA policy positions, the identification of situations that might be addressed through policy implementation efforts, and the implementation of AMA policies. Delegates and alternate delegates to the AMA are expected to foster a positive and useful two-way relationship between grassroots physicians and the AMA leadership. To fulfill these roles, AMA delegates and alternate delegates are expected to make themselves readily accessible to individual members by providing the AMA with their addresses, telephone numbers, and e-mail addresses so that the AMA can make the information accessible to individual members through the AMA web site and through other communication mechanisms. The qualifications and responsibilities of this role are as follows:

A. Qualifications

- AMA member.
- Elected or selected by the principal governing body or the membership of the sponsoring organization.
- The AMA encourages that at least one member of each delegation be involved in the governance of their sponsoring organization.

B. Responsibilities

- Regularly communicate AMA policy, information, activities, and programs to constituents so he/she will be recognized as the representative of the AMA.
- Relate constituent views and suggestions, particularly those related to implementation of AMA policy positions, to the appropriate AMA leadership, governing body, or executive staff.
- Advocate constituent views within the House of Delegates or other governance unit, including the executive staff.
- Attend and report highlights of House of Delegates meetings to constituents, for example, at hospital medical staff, county, state, and specialty society meetings.
- Serve as an advocate for patients to improve the health of the public and the health care system.
- Cultivate promising leaders for all levels of organized medicine and help them gain leadership positions.
- Actively recruit new AMA members and help retain current members.
- Participate in the AMA Membership Outreach Program.

ADDICTION MEDICINE - 2

American Society of Addiction Medicine (ASAM) – 2

AMDA - 2

AMDA - The Society for Post-Acute and Long-Term Care Medicine (AMDA) – 2

AMGA - 4

American Medical Group Association (AMGA) - 4

ANESTHESIOLOGY - 10

American Society of Anesthesiologists (ASA) - 10 Trustee (McDade) - 1

Former Board Chair (Patchin) - 1

Delegates - 7

Resident and Fellow Section Delegate - 1

ARS - 1

American Rhinologic Society (ARS) - 1

CARDIOLOGY - 10

American College of Cardiology (ACC) - 6 American Society of Echocardiography (ASE) - 2 Heart Rhythm Society (HRS) - 1 Society for Cardiovascular Angiography and Interventions

CHEST PHYSICIANS - 3

American College of Chest Physicians (CHEST) (ACCP)

CRITICAL CARE MEDICINE-2

Society of Critical Care Medicine (SCCM) - 2

DERMATOLOGY - 10

American Academy of Dermatology (AAD) - 5 Trustee (Resneck) – 1 Delegates - 4 American College of Mohs Surgery (ACMS) - 1 American Society for Dermatologic Surgery Assn. (ASDS) - 2

American Society of Dermatopathology (ASD) - 1 Society for Investigative Dermatology (SID) - 1

EMERGENCY MEDICINE - 9

American College of Emergency Physicians (ACEP) - 9 Former President (Stack) - 1 Delegates - 7

Resident and Fellow Section Delegate - 1

ENDOCRINOLOGY - 6

American Association of Clinical Endocrinologists (AACE) - 2 American Soc for Reproductive Medicine (ASRM) - 2

The Endocrine Society (ES) - 2

FAMILY PHYSICIANS - 17

American Academy of Family Physicians (AAFP) - 17 Former Board Chair (Langston) - 1 Delegates - 16

GASTROENTEROLOGY - 6

American College of Gastroenterology (ACG) - 2 American Gastroenterological Association (AGA) - 2 American Society for Gastrointestinal Endoscopy (ASGE)

GERIATRIC MEDICINE - 2

American Geriatrics Society (AGS) - 2

GREAT LAKES - 74

Illinois - 21 Trustee (Kobler) - 1

Delegates - 12

Medical Student Regional Delegate- 1 Resident and Fellow Section Delegate - 1

American Acad of Facial Plastic and Reconstructive Surgery (AAFPRS) - 1 American College of Legal Medicine (ACLM) - 1 American Coll of Radiation Oncology (ACRO) - 1 American Med Women's Association (AMWA) - 1

North American Neuro-Ophthalmology Society (NANOS) - 1

Society of Nuclear Medicine and Molecular Imaging (SNMMI) - 1

Indiana - 7

Former Board Chair (Steen) - 1

Delegates-5

Medical Student Regional Delegate- 1

Michigan - 14 Delegates - 13

Medical Student Regional Delegate - 1

Ohio - 14 Delegates (minus Vice Speaker) - 12

Medical Student Regional Delegate - 1 Resident and Fellow Section Delegate - 1 tic Med

(AANEM) - 1 Pennsylvania - 18

Former President (Gurman) - 1 Delegates - 14

Medical Student Regional Delegate- 1

Resident and Fellow Section Delegate - 1 American Association of Physicians of Indian Origin (AAPIO) - 1

HEART OF AMERICA - 9

Kansas - 3

Missouri - 6

Former President (Barbe) - 1 Delegates - 5

HEMATOLOGY - 2

American Society of Hematology (ASH) - 2

HOSPITAL MEDICINE - 2

Society of Hospital Medicine (SHM) - 2

INFECTIOUS DISEASE - 3

Infectious Diseases Society of America (IDSA) - 3 Resident and Fellow Section Delegate - 1

INTERNAL MEDICINE - 24

American College of Physicians (ACP) - 24 Trustee (Fryhofer) – 1 Delegates - 23

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MOBILITY CAUCUS - 16
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American Acad of Orthopaedic Surgeons (AAOS) - 6 Trustee (Suk) - 1

Delegates - 5 American Association for Hand Surgery (AAHS) - 1

American Orthopaedic Association (AOrA) - 1 American Orthopaedic Foot and Ankle Society (AOFAS)

American Society for Surgery of the Hand (ASSH) - 1 American Society of Interventional Pain Physicians (ASIPP) - 2

Delegate - 1

Resident and Fellow Section Delegate - 1 International Academy of Independent Medical Evaluators (IAIME) - 1

International Society for the Advancement of Spine Surgery (ISASS) – 1 North American Spine Society (NASS) - 2

NEUROSCIENCES - 29

American Academy of Child and Adolescent Psychiatry

American Academy of Hospice and Palliative Medicine (AAHPM) - 1

American Academy of Neurology (AAN) - 4 American Academy of Pain Medicine (AAPM) - 1 American Acad of Psychiatry and the Law (AAPL) - 1 American Assoc for Geriatric Psychiatry (AAGP) - 2 American Association of Neurological Surgeons (AANS)

Former President (Carmel) - 1

Delegates-2

Resident and Fellow Section Delegate - 1 American Psychiatric Association (APA) - 9 Delegates - 8

Resident and Fellow Section Delegate - 1 American Society of Neuroimaging (ASNI) - 1 Congress of Neurological Surgeons (CNS) - 1 $\widetilde{\text{GLMA}} - 1$

North American Neuromodulation Society (NANS) - 1 Spine Intervention Society (SIS) - 1

NEW ENGLAND - 30

Connecticut - 7

Delegates - 4

Medical Student Regional Delegates- 3

Maine - 3

Former President (McAfee) - 1

Delegates - 2 Massachusetts - 16

Trustee (Motta) -1

Delegates - 13

Medical Student Regional Delegate- 1

American Soc of Abdominal Surgeons (ASAS) - 1

New Hampshire - 1 Rhode Island - 2 Vermont - 1

NEW YORK - 29

Former President (Nielsen) - 1 Former Board Chair (Cady) - 1 Delegates - 20 Medical Student Regional Delegate - 1 Resident and Fellow Section Delegates - 2 American College of Medical Genetics and Genomics (ACMGG) - 1 American College of Nuclear Medicine (ACNM) - 1 American Society of Neuroradiology (ASN) - 1

Society of Interventional Radiology (SIR) - 1

NORTH CENTRAL - 14

Iowa - 3 Minnesota - 6 Delegates - 5 Medical Student Regional Delegate- 1 Nebraska – 3 Delegates-2Medical Student Regional Delegate- 1 North Dakota - 1

OBSTETRICIANS AND

GYNECOLOGISTS - 16

American Association of Gynecologic Laparoscopists (AAGL) - 2 American College of Obstetricians and Gynecologists

(ACOG) - 14 Delegates - 13

South Dakota - 1

Resident and Fellow Section Delegate - 1

ONCOLOGY - 4

American Society of Clinical Oncology (ASCO) - 4 Delegates - 3 Resident and Fellow Section Delegate - 1

PACWEST CONFERENCE - 72

Alaska - 1 Arizona - 8

Medical Student Regional Delegate- 1

American Institute of Ultrasound in Medicine (AIUM) California - 32

Former Presidents (Bristow, Corlin, Plested) - 3 Delegates - 23

Medical Student Regional Delegate - 1

Resident and Fellow Section Delegates - 2 American Clinical Neurophysiology Soc (ACNS) – 1 American Soc for Radiation Oncology (ASRO) - 2

Delegate - 1 Resident and Fellow Section Delegate - 1

Colorado - 8

Former President (Lazarus) - 1 Delegates - 5

Medical Student Regional Delegate- 1 Obesity Medicine Association (OMA) - 1

Hawaii - 2 Idaho - 1 Montana - 1 Nevada - 4

Delegates - 2 Medical Student Regional Delegate- 1 Resident and Fellow Section Delegate - 1

New Mexico - 3

Delegates - 2

American Academy of Allergy, Asthma & $Immunology\ (AAAAI)-1$

PACWEST CONFERENCE (cont'd)

Oregon - 3 Former President (Reardon) - 1

Delegates - 2

Former Presidents (A. Nelson, J. Nelson) - 2

Delegates - 2 Washington - 4

Wyoming -1PATHOLOGY - 11

American Society for Clinical Pathology (ASCP) -3American Society of Cytopathology (ASC) - 1 College of American Pathologists (CAP) – 4 Delegates - 3

Resident and Fellow Section Delegate - 1 National Association of Medical Examiners (NAME) - 1 United States and Canadian Academy of Pathology (USCAP) - 2

PEDIATRICS - 6

American Academy of Pediatrics (AAP) - 6 Resident and Fellow Section Delegate - 1

PHYSICAL MEDICINE AND **REHABILITATION - 2**

American Academy of Physical Med & Rehabilitation (AAPMR) - 2

PREVENTIVE MEDICINE - 7 Aerospace Medical Association (AsMA) - 1 American Academy of Insurance Medicine (AAIM) - 1 American Association of Public Health Physicians (AAPHP) - 2

Delegate - 1

Resident and Fellow Section Delegate - 1 American College of Medical Quality (ACMQ) - 1 American College of Occupational & Environmental Med

American College of Preventive Medicine (ACPM) - 1

RADIOLOGY - 12 American College of Radiology (ACR) - 8 Delegates - 7 Resident and Fellow Section Delegate - 1 American Roentgen Ray Society (ARRS) - 3

RHEUMATOLOGY - 2

American College of Rheumatology (ACRh) - 2

Association of University Radiologists (AUR) - 1

Radiological Society of North America (RSNA) - 3 **SECTIONS - 12**

RSNA - 3

Academic Physicians Section (APS) - 1 Integrated Physician Practice Section (IPPS) - 1 International Medical Graduates Section (IMG) - 1 Medical Student Section (MSS) - 2 Trustee (Smith) - 1 Delegate - 1 Minority Affairs Section (MAS) - 1

Organized Medical Staff Section (OMSS) - 1 Resident and Fellow Section (RFS) - 2 Delegate - 1 Resident and Fellow Section Delegate - 1 Senior Physicians Section (SPS) - 1

Women Physicians Section (WPS) -1

Young Physicians Section (YPS) - 1

SERVICES - 6 Air Force - 1 Army - 1 AMSUS - Society of Federal Health Professionals - 1 Navy - 1 Public Health Service - 1 Veterans Affairs - 1

SLEEP MEDICINE – 2

American Academy of Sleep Medicine (AASM) - 2

SOUTHEASTERN - 120

Alabama - 5 Delegates - 4 Medical Student Regional Delegate- 1 Arkansas - 4

Trustee (Ferguson) - 1 Delegates - 3 Delaware - 2

Former Board Chair (Permut) - 1 Delegate - 1 District of Columbia - 4

Former Board Chair (Scalettar) - 1 Delegates - 2 Medical Student Regional Delegate- 1

Florida - 23 Former Presidents (Coble, Wilson) - 2 Delegates - 14

Medical Student Regional Delegate- 2 Resident and Fellow Section Delegates - 2 American Osteopathic Association (AOA) – 1 American Vein and Lymphatic Society (AVLS) - 1

The Triological Society (TS) - 1 Kentucky - 5

Former President (Hoven) - 1 Delegates (minus Speaker) - 5 Louisiana - 8

Former Presidents (Johnson, Palmisano) - 2 Delegates - 5 Medical Student Regional Delegate- 1

Maryland - 9 Trustee (Edwards) - 1 Former Board Chair (Lewers) - 1 Delegates - 5

Acad of Physicians in Clinical Research (APCR) - 1 Renal Physicians Association (RPA) - 1 Mississippi - 4 Former President (Hill) - 1

Delegates - 3 New Jersey - 9 Delegates - 8 Medical Student Regional Delegate- 1 North Carolina - 6

Oklahoma - 7 Delegates - 4 Medical Student Regional Delegate- 2 Resident and Fellow Section Delegate - 1

SOUTHEASTERN (cont'd)

Puerto Rico - 2 South Carolina - 8 Trustee (Harmon) - 1 Former President (Smoak) - 1 Delegates - 5 Medical Student Regional Delegate- 1 Tennessee - 7 Trustee (Williams) - 1 Delegates - 5 Medical Student Regional Delegate- 1 Virginia - 10 Former President (Wootton) - 1 Delegates - 8

Medical Student Regional Delegate- 1

SURGEONS - 49

West Virginia – 2

American Academy of Cosmetic Surgery (AACS) - 1 American Academy of Ophthalmology (AAO) - 6 Trustee (Armstrong) - 1 Delegates - 4 Resident and Fellow Section Delegate - 1

American Academy of Otolaryngic Allergy (AAOA) - 1 Amer Acad of Otolaryngology - Head & Neck Surgery (AAOHNS) - 3 American Association for Thoracic Surgery (AATS) - 1 American Association of Plastic Surgeons (AAPS) - 1

American Society for Aesthetic Plastic Surgery (ASAPS) American Society for Metabolic and Bariatric Surgery (ASMBS) - 1

American College of Surgeons (ACS) - 13

American Society for Reconstructive Microsurgery (ASRMS) - 1 American Society of Breast Surgeons (ASBS) - 1

American Society of Cataract and Refractive Surgery American Society of Colon and Rectal Surgeons (ASCRS) - 1

American Society of General Surgeons (ASGS) - 1 American Soc of Maxillofacial Surgeons (ASMS) - 1 Amer Soc of Ophthalmic Plastic & Reconstructive Surg (ASOPRS) - 1 American Society of Plastic Surgeons (ASPS) - 2 American Society of Retina Specialists (ASRS) - 1

Eye and Contact Lens Association, ECLA (ECLA) - 1 International Coll of Surgeons-US Section (ICS-US) - 1 Society for Vascular Surgery (SVS) - 1 Society of Amer Gastrointestinal Endoscopic Surgeons (SAGES) - 2

Society of Laparoendoscopic Surgeons (SLR) - 2

Society of Thoracic Surgeons (STS) - 2

American Society of Transplant Surgeons (ASTS) - 1

TERRITORIES - 2

Guam - 1 Virgin Islands - 1

TEXAS - 25

Former Presidents (Dickey, Rohack) - 2 Delegates - 19 Medical Student Regional Delegate - 1 American College of Allergy, Asthma and Immunology

(ACAAI) - 1 International Society of Hair Restoration Surgery (ISHRS)

THORACIC MEDICINE - 2 American Thoracic Society (ATS) - 2

National Medical Association (NMA) - 1

UROLOGY - 5 American Assoc of Clinical Urologists (AACU) - 1 American Urological Association (AUA) - 4 Trustee (Underwood) - 1 Delegates -2 Resident and Fellow Section Delegate - 1

Former Board Chair (Flaherty) - 1 Delegates - 5

WISCONSIN - 8

Undersea & Hyperbaric Medical Society (UHMS) - 1 **OFFICIAL OBSERVERS - 28** Accreditation Association for Ambulatory Health Care

Resident and Fellow Section Delegate - 1

Alliance for Continuing Education in the Health Professions Alliance for Regenerative Medicine Ambulatory Surgery Center Association American Academy of Physician Assistants American Association of Medical Assistants American Board of Medical Specialties

American Dental Association

American Health Quality Association American Hospital Association American Nurses Association American Podiatric Medical Association American Public Health Association Association of periOperative Registered Nurses Association of State and Territorial Health Officials

Commission on Graduates of Foreign Nursing Schools Council of Medical Specialty Societies Educational Commission for Foreign Medical Graduates Federation of State Medical Boards Federation of State Physician Health Programs Medical Group Management Association Medical Professional Liability Association

National Indian Health Board Society for Academic Continuing Medical Education US Pharmacopeia

National Commission on Correctional Health Care

National Council of State Boards of Nursing

National Association of County and City Health Officials

TELLERS - 8

HOUSE OF DELEGATES - MANCHESTER GRAND HYATT, SAN DIEGO (I-19)

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MANCHESTER GRAND HYATT SAN DIEGO 1 Market Place

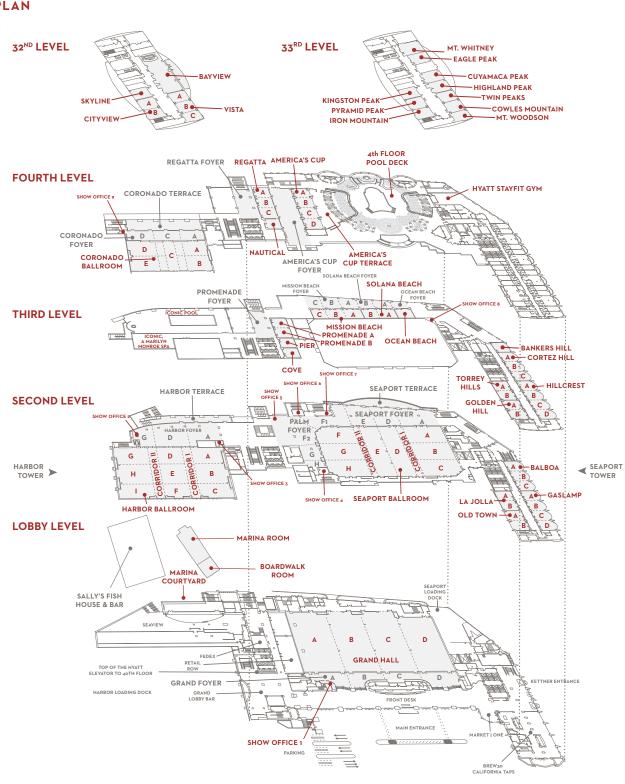
- San Diego, CA 92101, USA +1 619 232 1234 TELEPHONE
- +1 619 358 6720 FAX

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FLOOR PLAN

All Floors



Reference Committee Assignments Sunday, November 17

8:30am - Noon	Room
Reference Committee on Amendments to Constitution & Bylaws Reference Committee B (legislation) Reference Committee C (medical education) Reference Committee F (AMA governance and finance) Reference Committee J (medical service, medical practice, insurance) Reference Committee K (science and public health)	Grand Hall C Harbor Ballroom G-I Harbor Ballroom A-C Seaport Ballroom Harbor Ballroom D-F Grand Hall D

2019 INTERIM MEETING OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Official Call to the Officers and Members of the American Medical Association to attend the Interim Meeting of the House of Delegates in San Diego, California, November 16-19, 2019.

The House of Delegates will convene at 2 p.m. on November 16, at the Manchester Grand Hyatt, San Diego.

STATE ASSOCIATION REPRESENTATION IN THE HOUSE OF DELEGATES

Alabama 4	Guam 1	Massachusetts 13	New York 20	Tennessee 5
Alaska 1	Hawaii 2	Michigan 13	North Carolina 6	Texas 19
Arizona 5	Idaho 1	Minnesota 5	North Dakota 1	Utah 2
Arkansas 3	Illinois 12	Mississippi 3	Ohio 12	Vermont 1
California 23	Indiana 5	Missouri 5	Oklahoma 4	Virgin Islands 1
Colorado 5	Iowa 3	Montana 1	Oregon 2	Virginia 8
Connecticut 4	Kansas 3	Nebraska 2	Pennsylvania 14	Washington 4
Delaware 1	Kentucky 5	Nevada 2	Puerto Rico 2	West Virginia 2
District of Columbia 2	Louisiana 5	New Hampshire 1	Rhode Island 2	Wisconsin 5
Florida 14	Maine 2	New Jersey 8	South Carolina 5	Wyoming 1
Georgia 5	Maryland 5	New Mexico 2	South Dakota 1	

SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES

AMDA – The Society of Post-Acute and Long-Term Care	American Institute of Ultrasound in Medicine 2
Medicine 2	American Medical Group Association 4
American Academy of Child and Adolescent Psychiatry 2	American Psychiatric Association 8
American Academy of Dermatology 4	American Roentgen Ray Society 3
American Academy of Family Physicians 16	American Society for Clinical Pathology 3
American Academy of Neurology 4	American Society for Dermatologic Surgery 2
American Academy of Ophthalmology 4	American Society for Gastrointestinal Endoscopy 2
American Academy of Orthopaedic Surgeons 5	American Society for Reproductive Medicine 2
American Academy of Otolaryngology - Head and Neck	American Society of Addiction Medicine 2
Surgery 3	American Society of Anesthesiologists 7
American Academy of Pediatrics 5	American Society of Cataract and Refractive Surgery 2
American Academy of Physical Med. & Rehabilitation 2	American Society of Clinical Oncology 3
American Academy of Sleep Medicine 2	American Society of Echocardiography 2
American Association for Geriatric Psychiatry 2	American Society of Hematology 2
American Association of Clinical Endocrinologists 2	American Society of Plastic Surgeons 2
American Association of Gynecologic Laparoscopists 2	American Thoracic Society 2
American Association of Neurological Surgeons 2	American Urological Association 2
American College of Cardiology 6	College of American Pathologists 3
American College of Chest Physicians (CHEST) 3	Infectious Diseases Society of America 2
American College of Emergency Physicians 7	North American Spine Society 2
American College of Gastroenterology 2	Radiological Society of North America 3
American College of Obstetricians and Gynecologists 13	Society of American Gastrointestinal Endoscopic Surgeons 2
American College of Physicians 23	Society of Critical Care Medicine 2
American College of Radiology 7	Society of Hospital Medicine 2
American College of Rheumatology 2	Society of Laparoendoscopic Surgeons 2
American College of Surgeons 13	Society of Thoracic Surgeons 2
American Gastroenterological Association 2	The Endocrine Society 2
American Geriatrics Society 2	United States and Canadian Academy of Pathology 2
•	, 2,

Remaining eligible national medical specialty societies (70) are entitled to one delegate each.

The Academic Physicians Section, Integrated Physician Practice Section, International Medical Graduates Section, Medical Student Section, Minority Affairs Section, Organized Medical Staff Section, Resident and Fellow Section, Senior Physicians Section, Women Physicians Section, Young Physicians Section, Army, Navy, Air Force, Public Health Service, Department of Veterans Affairs, Professional Interest Medical Associations, AMWA, AOA and NMA are entitled to one delegate each.

State Medical Associations	283
National Medical Specialty Societies	281
Professional Interest Medical Associations	2
Other National Societies (AMWA, AOA, NMA)	3
Medical Student Regional Delegates	28
Resident and Fellow Delegate Representatives	28
Sections	10
Services	5
Total Delegates	640

Registration facilities will be maintained at the Manchester Grand Hyatt – Palm / Seaport Foyers $(2^{nd} \text{ level} - \text{Seaport Tower})$.

Patrice A. Harris, MD President Bruce A. Scott, MD Speaker, House of Delegates Bobby Mukkamala, MD Secretary

2019-2020

OFFICIALS OF THE ASSOCIATION

BOARD OF TRUSTEES (OFFICERS)

President - Patrice A. Harris	Atlanta, Georgia
President-Elect - Susan R. Bailey	Fort Worth, Texas
Immediate Past President - Barbara L. McAneny	Albuquerque, New Mexico
Secretary - S. Bobby Mukkamala	Flint, Michigan
Speaker, House of Delegates - Bruce A. Scott	
Vice Speaker, House of Delegates - Lisa Bohman Egbert	Kettering, Ohio
Grayson W. Armstrong (2021)	Roston Massachusetts
Willarda V. Edwards (2020)	
Jesse M. Ehrenfeld (2022), Chair.	
Scott Ferguson (2022)	
Sandra Adamson Fryhofer (2022)	
Gerald E. Harmon (2021)	
William E. Kobler (2020)	
Russell W.H. Kridel (2022), Chair-Elect	
William A. McDade (2020)	
Mario E. Motta (2022)	Salem, Massachusetts
Jack S. Resneck, Jr. (2022)	San Rafael, California
Sarah Mae Smith (2020)	Anaheim, California
Michael Suk (2023)	
Willie Underwood, III (2023)	Buffalo, New York
Kevin W. Williams (2020)	Nashville, Tennessee

COUNCILS OF THE AMA

COUNCIL ON CONSTITUTION AND BYLAWS

Patricia L. Austin, Alamo, California, Chair (2022); Madelyn E. Butler, Tampa, Florida, Vice Chair (2022); Ariel M. Anderson, New York, New York (Resident) (2021); Mark N. Bair, Highland, Utah (2023); Jerome C. Cohen, Loch Sheldrake, New York (2021); Pino D. Colone, West Bloomfield, Michigan (2020); Pauline P. Huynh, Baltimore, Maryland (Student) (2020); Kevin C. Reilly, Sr., Elizabethtown, Kentucky (2022). Ex Officio, without vote: Bruce A. Scott, Louisville, Kentucky; Lisa Bohman Egbert, Kettering, Ohio. Secretary: Janice Robertson, Chicago, Illinois.

COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Kathryn L. Moseley, Canton, Michigan, Chair (2020); Monique A. Spillman, Dallas, Texas, Vice Chair (2021); Rebecca W. Brendel, Boston, Massachusetts (2026); Kimberly A. Chernoby, Indianapolis, Indiana (Resident) (2021); David Fleming, Columbia, Missouri (2024); Jeremy A. Lazarus, Greenwood Village, Colorado (2025); Michael J. Rigby, Madison, Wisconsin (Student) ((2021); Alexander M. Rosenau, Allentown, Pennsylvania (2022); Peter A. Schwartz, Reading, Pennsylvania (2023). Secretary: Elliott Crigger, Chicago, Illinois.

COUNCIL ON LEGISLATION

David T. Tayloe, Jr., Goldsboro, North Carolina, Chair (2020); Marilyn J. Heine, Dresher, Pennsylvania, Vice Chair (2020); David H. Aizuss, Encino, California (2020); Vijaya L. Appareddy, Chattanooga, Tennessee (2020); Hans C. Arora, Cleveland Heights, Ohio (Resident) (2020); Maryanne C. Bombaugh, Falmouth, Massachusetts (2020); Mary S. Carpenter, Winner, South Dakota (2020); Gary W. Floyd, Keller, Texas (2020); Linda B. Ford, Bellevue, Nebraska (AMPAC Observer) (2020); Beth Irish, Bend, Oregon (Alliance Liaison) (2020); Tripti C. Kataria, Chicago, Illinois (2020); Ajeet Singh, Boston, Massachusetts (Student) (2020); Heather Ann Smith, Newport, Rhode Island (2020); Marta J. Van Beek, Iowa City, Iowa (2020). Secretary: George Cox, Washington, District of Columbia.

COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

James A. Goodyear, Lansdale, Pennsylvania, Chair (2021); Shannon P. Pryor, Washington, DC, Vice Chair (2020); Michelle Berger, Austin, Texas (2022); Edmond B. Cabbabe, St. Louis, Missouri (2021); Clarence P. Chou, Milwaukee, Wisconsin (2020); Rebecca A. Haines, Temple Texas (Student) (2020); Jan M. Kief, Highlands Ranch, Colorado (2023); G. Sealy Massingill, Fort Worth, Texas (2023); Benjamin D. Meyer, Milwaukee, Wisconsin (Resident) (2022); Gary D. Thal, Chicago, Illinois (2021). Secretary: Susan Close, Chicago, Illinois.

COUNCIL ON MEDICAL EDUCATION

Jacqueline A. Bello, New York, New York, Chair (2021); Liana Puscas, Durham, North Carolina, Chair-Elect (2021); Kelly J. Caverzagie, Omaha, Nebraska (2023); Sharon P. Douglas, Madison, Mississippi (2023); Robert B. Goldberg, New York, New York (2021); Cynthia A. Jumper, Lubbock, Texas (2020); Shannon M. Kilgore, Palo Alto, California (2023); Rafa Rahman, Centreville, Virginia (Student) (2020); Niranjan V. Rao, New Brunswick, New Jersey (2022); Luke V. Selby, Denver, Colorado (Resident) (2020); Krystal L. Tomei, Lyndhurst, Ohio (2021); John P. Williams, Gibsonia, Pennsylvania (2023). Secretary: Tanya Lopez, Chicago, Illinois.

COUNCIL ON MEDICAL SERVICE

W. Alan Harmon, Jacksonville, Florida, Chair (2020); Lynda M. Young, Worcester, Massachusetts, Chair-Elect (2021); Nonie S. Arora, Novi, Michigan (Student) (2020); A. Patrice Burgess, Boise, Idaho (2023); Betty S. Chu, West Bloomfield, Michigan (2022); Alice Coombs, Richmond, Virginia (2023); Meena Davuluri, New York, New York (Resident) (2020); Stephen K. Epstein, Needham, Massachusetts (2022); Lynn L. C. Jeffers, Oxnard, California (2020); Asa C. Lockhart, Tyler, Texas (2022); Thomas J. Madejski, Albion, New York (2023); Sheila Rege, Kennewick, Washington (2022).

Secretary: Val Carpenter, Chicago, Illinois.

COUNCIL ON SCIENCE AND PUBLIC HEALTH

Michael M. Miller, Oconomowoc, Wisconsin, Chair (2022); Kira A. Geraci-Ciardullo, Harrison, New York, Chair-Elect (2022); Ali Bokhari, Brooklyn, New York (Student) (2020); John T. Carlo, Dallas, Texas (2021); Noel N. Deep, Antigo, Wisconsin (2023); Alexander Ding, Belmont, California (2020); Laura E. Halpin, Playa Del Rey, California (Resident) (2022); Mary E. LaPlante, Broadview Heights, Ohio (2021); Tamaan K. Osbourne-Roberts, Denver, Colorado (2023); Padmini D. Ranasinghe, Baltimore, Maryland (2022); Corliss A. Varnum, Oswego, New York (2023); David J. Welsh, Batesville, Indiana (2020). Secretary: Andrea Garcia, Chicago, Illinois.

AMERICAN MEDICAL ASSOCIATION POLITICAL ACTION COMMITTEE

Lyle S. Thorstenson, Nacogdoches, Texas, Chair; Stephen A. Imbeau, Florence, South Carolina, Secretary; Miriam J. R. Bareman, Grand Rapids, Michigan (Student); Brooke M. Buckley, Annapolis, Maryland; Paul J. Carniol, Summit, New Jersey; Linda B. Ford, Bellevue, Nebraska; Benjamin Z. Galper, McLean, Virginia; Dev A. GnanaDev, Colton, California; James L. Milam, Libertyville, Illinois; L. Elizabeth Peterson, Spokane, Washington.

Executive Director and Treasurer: Kevin Walker, Washington, District of Columbia.

MEMBERS OF THE HOUSE OF DELEGATES - NOVEMBER 2019

The following is a list of delegates and alternate delegates to the House of Delegates as reported to the Executive Vice President

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Delegate(s)

Jorge Alsip, Daphne AL Steven P. Furr, Jackson AL B Jerry Harrison, Haleyville AL George C. Smith, Jr., Lineville AL

Alternate Delegate(s)

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Regional Medical Student Delegate(s)

Hannah M Ficarino, Mobile AL

Alaska State Medical Association

Delegate(s)

Alex Malter, Juneau AK

Alternate Delegate(s)

Mary Ann Foland, Anchorage AK

Arizona Medical Association

Delegate(s)

Daniel P. Aspery, Phoenix AZ Veronica K. Dowling, Lakeside AZ Gary R. Figge, Tucson AZ Thomas H. Hicks, Tucson AZ M Zuhdi Jasser, Phoenix AZ

Alternate Delegate(s)

Timothy Fagan, Tucson AZ Ross F. Goldberg, Phoenix AZ Michael Hamant, Tucson AZ Marc Leib, Phoenix AZ Elise Molnar, Phoenix AZ

Resident and Fellow Sectional Alternate Delegate(s)

John Trickett, Jr., Phoenix AZ

Regional Medical Student Delegate(s)

Adam Roussas, Tucson AZ

Regional Medical Student Alternate Delegate(s)

Maddy Banerjee, Tucson AZ

Arizona Medical Association

Regional Medical Student Alternate Delegate(s)

Akshara Malla, Phoenix AZ

Arkansas Medical Society

Delegate(s)

Omar Atiq, Little Rock AR Eugene Shelby, Hot Springs AR Alan Wilson, Crossett AR

Alternate Delegate(s)

Amy Cahill, Pine Bluff AR Stephen Magie, Conway AR

California Medical Association

Delegate(s)

David H. Aizuss. Encino CA Barbara J. Arnold. Sacramento CA Patricia L. Austin, Alamo CA Edward Bentley, Santa Barbara CA Peter N. Bretan, Jr., Novato CA J Brennan Cassidy, Newport Beach CA Luther Cobb, Eureka CA Alexander Ding, Belmont CA Kyle P. Edmonds, San Diego CA Dev A. GnanaDev, Redlands CA James T. Hay, Del Mar CA Robert Hertzka, Rancho Santa Fe CA James G. Hinsdale, San Jose CA Vito Imbasciani, Los Angeles CA Joshua Lesko, Roanoke VA Arthur N. Lurvey, Los Angeles CA Ramin Manshadi, Stockton CA Robert J. Margolin, San Francisco CA Theodore Mazer, San Diego CA Albert Ray, San Diego CA Neil Rens, Menlo Park CA Tatiana W. Spirtos, Redwood City CA James J. Strebig, Irvine CA

Alternate Delegate(s)

Dirk Stephen Baumann, Burlingame CA Jeffrey Brackett, Ventura CA

California Medical Association

Alternate Delegate(s)

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James Cotter, Fairfield CA

Melanie Crane, Riverside CA

Suparna Dutta, Oakland CA

George Fouras, Los Angeles CA

Samuel Huang, Los Angeles CA

Alexandra Iacob, Loma Linda CA

Dayna Isaacs, El Dorado Hills CA

Scott Richard Karlan, West Hollywood CA

Nikan Khatibi, Laguna Niguel CA

Mark H. Kogan, San Pablo CA

Mankit Leung, San Francisco CA

Sandra Mendez, Sacramento CA

Chang Na, Bakersfield CA

Richard Pan, Sacramento CA

Mihir Parikh, La Jolla CA

Ryan J. Ribeira, Mountain View CA

Sion Roy, Torrance CA

Joseph E. Scherger, San Diego CA

Holly Yang, San Diego CA

Paul Yost, Seal Beach CA

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Jacob Burns, Sacramento CA

Hunter Pattison, Sacramento CA

Resident and Fellow Sectional Alternate Delegate(s)

Sophia Yang, San Jose CA

Regional Medical Student Delegate(s)

Drayton Harvey, Los Angeles CA

Colorado Medical Society

Delegate(s)

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A. "Lee" Morgan, Denver CO

Tamaan Osbourne-Roberts, Denver CO

Lynn Parry, Littleton CO

Brigitta J. Robinson, Centennial CO

Alternate Delegate(s)

Carolynn Francavilla, Lakewood CO

Rachelle M. Klammer, Denver CO

Katie Lozano, Centennial CO

David Markenson, Cherry Hill Village CO

Michael Volz, Englewood CO

Colorado Medical Society

Regional Medical Student Delegate(s)

Halea K Meese, Denver CO

Regional Medical Student Alternate Delegate(s)

Iris Burgard, Denver CO

Connecticut State Medical Society

Delegate(s)

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Katherine L. Harvey, Torrington CT

Alfred Herzog, Hartford CT

Theodore Zanker, Cheshire CT

Alternate Delegate(s)

Kathleen A. LaVorgna, Norwalk CT

Bollepalli Subbarao, Middletown CT

Stacy Taylor, New Hartford CT

Steven C. Thornquist, Bethany CT

Regional Medical Student Delegate(s)

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Allie Clement, Farmington CT

Kate Topalis, Simsbury CT

Regional Medical Student Alternate Delegate(s)

Amy Steele, New Haven CT

Medical Society of Delaware

Delegate(s)

Janice Tildon-Burton, Wilmington DE

Alternate Delegate(s)

Stephanie Howe Guarino, Wilmington DE

Medical Society of the District of Columbia

Delegate(s)

Joseph E. Gutierrez, McLean VA

Peter E. Lavine, Washington DC

Alternate Delegate(s)

J Desiree Pineda, Washington DC

Raymond K. Tu, Washington DC

Regional Medical Student Delegate(s)

Damani Mcintosh Clarke, Washington DC

Florida Medical Association

Delegate(s)

Christienne P. Alexander, Tallahassee FL

Florida Medical Association

Delegate(s)

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David Becker, Safety Harbor FL

Madelyn E. Butler, Tampa FL

Mark Dobbertien, Orange Park FL

Ronald Frederic Giffler, Fort Lauderdale FL

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Douglas Murphy, Ocala FL

Ralph Jacinto Nobo, Jr., Bartow FL

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Michael Zimmer, St Petersburg FL

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James Booker, Winter Haven FL

Andrew Cooke, Orlando FL

Lisa Cosgrove, Merritt Island FL

Aaron Elkin, Miami FL

James Nathan Goldenberg, Atlantis FL

Raphael C. Haciski, Naples FL

Ryan Hall, Lake Mary FL

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Karen Harris, Gainesville FL

Rebecca Lynn Johnson, Tampa FL

Arthur E. Palamara, Hollywood FL

Alan B. Pillersdorf, Lake Worth FL

Sergio B. Seoane, Lakeland FL

James St George, Ponte Verdra FL

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Amber Clark, Trussville AL

Romela Petrosyan, Greenville SC

Regional Medical Student Delegate(s)

Charlotte K George, Tallahassee FL

Tanya Singh, Orlando FL

Regional Medical Student Alternate Delegate(s)

Ian Motie. Tallahassee FL

Medical Association of Georgia

Delegate(s)

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S William Clark, III, Waycross GA

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Maya A. Babu 2013-2017 Robert R. McMillan 2002-2008 Timothy E. Baldwin 1987-1989 Sandeep "Sunny" Mistry 2000-2001 David O. Barbe 2009-2016 Alan R. Nelson 1980-1988 Regina M. Benjamin 1995-1998 John C. Nelson 1994-2003 Scott L. Bernstein 1991-1992 Nancy H. Nielsen 2005-2007 Stefano M. Bertozzi 1986-1988 Albert J. Osbahr, III 2011-2019 David J. Brailer 1985-1986 Donald J. Palmisano 1996-2002 Lonnie R. Bristow 1985-1994 Rebecca J. Patchin 1998-1989 Duane M. Cady 1999-2007 Rebecca J. Patchin 2003-2011 Peter Carmel 2002-2010 Stephen R. Permut 2010-2018 Alice A. Chenault 1984-1985 Pamela Petersen-Crair 1996-1998 Yank D. Coble 1994-2001 Dina Marie Pitta 2015-2016 David S. Cockrum 1993-1994 William G. Plested, III 1998-2005 MaryAnn Contogiannis 1989-1993 Stephen Pool 1995-1996 Malini Daniel
Timothy E. Baldwin 1987-1989 Sandeep "Sunny" Mistry 2000-2001 David O. Barbe 2009-2016 Alan R. Nelson 1980-1988 Regina M. Benjamin 1995-1998 John C. Nelson 1994-2003 Scott L. Bernstein 1991-1992 Nancy H. Nielsen 2005-2007 Stefano M. Bertozzi 1986-1988 Albert J. Osbahr, III 2011-2019 David J. Brailer 1985-1986 Donald J. Palmisano 1996-2002 Lonnie R. Bristow 1985-1994 Rebecca J. Patchin 1988-1989 Duane M. Cady 1999-2007 Rebecca J. Patchin 2003-2011 Peter Carmel 2002-2010 Stephen R. Permut 2010-2018 Alice A. Chenault 1984-1985 Pamela Petersen-Crair 1996-1998 Yank D. Coble 1994-2001 Dina Marie Pitta 2015-2016 David S. Cockrum 1993-1994 William G. Plested, III 1998-2005 MaryAnn Contogiannis 1989-1993 Stephen Pool 1995-1996 Malini Daniel 2012-2013 Liana Puscas 1999-2001 Christopher M. DeRienzo
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Julie K. Goonewardene 2012-2016 Raymond Scalettar 1985-1994
Andrew W. Gurman 2007-2015 Bruce A. Scott 1998-2002
Alan C. Hartford 1989-1990 Carl A. Sirio 2010-2018
William A. Hazel, Jr. 2004-2009 Randolph D. Smoak, Jr. 1992-1999
Cyril M. Hetsko 2003-2011 Steven J. Stack 2006-2014
Joseph M. Heyman 2002-2010 Michael Suk 1994-1995
J. Edward Hill 1996-2004 Andrew M. Thomas 1997-1999
Ardis D. Hoven 2005-2012 Jeffrey A. Towson 1998-1999
William E. Jacott 1989-1998 Georgia A. Tuttle 2011-2019
Hillary D. Johnson 2001-2002 Jordan M. VanLare 2011-2012
Matthew D. Kagan 1999-2000 Robert M. Wah 2005-2013
Christopher K. Kay 2008-2012 Peter Y. Watson 2001-2003
Edward L. Langston 2003-2011 Monica C. Wehby 2011-2013
Matthew C. Lawyer 2004-2005 Meredith C. Williams 2010-2011
Jeremy A. Lazarus 2005-2011 Cecil B. Wilson 2002-2009
W. J. Lewis 1979-1984 Percy Wootton 1991-1996
Audrey J. Ludwig 1990-1991

SPECIALTY AND SERVICE SOCIETY REPRESENTATIVES

(The following are not members of the House of Delegates, but are representatives of the following societies which are represented in the SSS.)

American Academy of Emergency Medicine	Joseph Wood, MD, JD
American Association of Endocrine Surgeons	Steven De Jong, MD
American Association of Hip and Knee Surgeons	
American College of Correctional Physicians	Charles Lee, MD
American College of Medical Toxicology	Charles McKay, MD
American Contact Dermatitis Society	
American Epilepsy Society	
American Society for Laser Medicine and Surgery	
American Society of Nuclear Cardiology	Saurabh Malhotra, MD
American Society of Regional Anesthesia and Pain Medicine	Edward Mariano, MD
Americas Hernia Society	John Fischer, MD
Association of Academic Physiatrists	Prakash Jayabalan, MD, PhD
Association of Professors of Dermatology	Christopher R. Shea, MD
Korean American Medical Association	John Yun, MD
Outpatient Endovascular and Interventional Society	Eric Dippel, MD
Society of Cardiovascular Computed Tomography	
Society of Gynecologic Oncologists	

REFERENCE COMMITTEES OF THE HOUSE OF DELEGATES (I-19)

Reference Committee on Amendments to Constitution and Bylaws

David T. Walsworth, MD, Michigan, Chair

Joel T. Bundy, MD, Virginia*

Michael Hanak, MD, American Academy of Family Physicians

Priya Sushvet Kantesaria, New Jersey*, Regional Medical Student

Lee S. Perrin, MD, Massachusetts

Jennifer Piel, MD, American Academy of Psychiatry and the Law*

Joseph Sanfrancesco, MD, College of American Pathologists*

Reference Committee B (Legislation)

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Abby Solom, Minnesota, Regional Medical Student

Daniel M. Young, MD, New York*

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Anesthesiologists

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Reference Committee J (Advocacy Related to Medical Service, Medical Practice, Insurance and Related Topics)

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Christopher Garofalo, MD, Massachusetts*

Halea K. Meese, Colorado, Regional Medical Student

Josephine Nguyen, MD, Illinois, Women Physicians Section

Erin Shriver, MD, American Society of Ophthalmic Plastic and Reconstructive Surgery*

Linda Villarreal, MD, Texas

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Ankush Kumar Bansal, MD, Florida

Joanna T. Bisgrove, MD, American Academy of Family Physicians

Patricia A. Kolowich, MD, Michigan*

Damani Mcintosh Clarke, District of Columbia, Regional Medical Student

Thomas Vidic, MD, Indiana*

Sophia Yang, MD, California*, Sectional Resident

Committee on Rules and Credentials

Cheryl Gibson-Fountain, MD, American College of Obstetricians and Gynecologists, Chair

Thomas M. Anderson, Jr., MD, Illinois

Mark N. Bair, MD, Utah

Jerome C. Cohen, MD, New York

Gary A. Delaney, MD, South Carolina

Kyle P. Edmonds, MD, California

Amit Ghose, MD, Michigan*

Chief Teller

Jone Geimer-Flanders, MD, Hawaii

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

2019 Interim Meeting Notes on Orders of Business

FIRST SESSION, Saturday, November 16, 2:00 – 6:00 pm

SECOND SESSION, Sunday, November 17, 8:00 – 8:30 am

THIRD SESSION, Monday, November 18, 2:00 - 6:00 pm

FOURTH SESSION, Tuesday, November 19, 8:30 am - noon

BOT Report(s)

- 01 Legalization of the Deferred Action for Legal Childhood Arrival (DALCA): Minimal
- 02 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings: Modest
- 03 Restriction on IMG Moonlighting: Minimal
- 04 Involvement of Women in AMA Leadership, Recognition and Research Opportunities: Informational report
- 05 Restrictive Covenants of Large Health Care Systems: Informational report
- 06 Physician Health Policy Opportunity: Modest
- 07 2019 AMA Advocacy Efforts: Informational report
- 08 Implementing AMA Climate Change Principles Through JAMA Paper Consumption Reduction and Green Health Care Leadership: None
- 09 Opioid Mitigation: Minimal
- 11 Re-establishment of National Guideline Clearinghouse: Informational report
- 12 Distracted Driver Education and Advocacy: Informational report
- 13 Hospital Closures and Physician Credentialing: Informational report
- 14 Redefining AMA's Position on ACA and Healthcare Reform: Informational report

CC&B Report(s)

- 01 Parity in our House of Delegates: Minimal
- 02 Bylaw Consistency--Certification Authority for Societies represented in our AMA House of Delegates and Advance Certification for those Societies: Minimal
- 03 AMA Delegate Apportionment: Minimal

CEJA Report(s)

- 01 Competence, Self-Assessment and Self-Awareness: Minimal
- 02 Amendment to E-1.2.2., "Disruptive Behavior by Patients": Minimal

CLRPD Report(s)

01 Academic Physicians Section Five-Year Review: Minimal

CME Report(s)

- 01 For-Profit Medical Schools or Colleges: Informational Report
- 02 Healthcare Finance in the Medical School Curriculum: Minimal
- 03 Standardization of Medical Licensing Time Limits Across States: Minimal
- 04 Board Certification Changes Impact Access to Addiction Medicine Specialists: Minimal
- 05 The Transition from Undergraduate Medical Education to Graduate Medical Education: Informational Report
- 06 Veterans Health Administration Funding of Graduate Medical Education: Minimal

CMS Report(s)

- 01 Established Patient Relationships and Telemedicine: Minimal
- 02 Addressing Financial Incentives to Shop for Lower-Cost Health Care: Minimal
- 03 Improving Risk Adjustment in Alternative Payment Models: Minimal
- 04 Mechanisms to Address High and Escalating Pharmaceutical Prices: Minimal

CSAPH Report(s)

- 01 Mandatory Reporting of Diseases and Conditions: Minimal
- 02 Real-World Data and Real-World Evidence in Medical Product Decision Making: \$50,000
- 03 Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals: Minimal

HOD Comm on Compensation of the Officers

01* Report of the HOD Committee on Compensation of the Officers: Est. annual cost of \$49,950 based on data reported for July 1, 2018 through June 30, 2019. This cost represents the impact of the Governance Honorarium increase, the Per Diem increase, and the Telephonic Per Diem increase.

Report of the Speakers

01* Speakers' Report: Task Force on Election Reform: Informational Report

Resolution(s)

- 001 Support for the Use of Psychiatric Advance Directives: Minimal
- 002 Endorsing the Creation of a Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) Research IRB Training: Modest
- 003 Accurate Collection of Preferred Language and Disaggregated Race and Ethnicity to Characterize Health Disparities: Minimal
- 004 Improving Inclusiveness of Transgender Patients Within Electronic Medical Record Systems: Minimal
- 005 Removing Sex Designation from the Public Portion of the Birth Certificate: Minimal
- 006 Transparency Improving Informed Consent for Reproductive Health Services: Minimal
- 007 Addressing the Racial Pay Gap in Medicine: Minimal
- 009 Data for Specialty Society Five-Year Review: Minimal
- 010 Ban Conversion Therapy of LGBTQ Youth: Modest
- 011 End Child Marriage: Modest
- 201 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities: Minimal
- 202 Support for Veterans Courts: Minimal
- 203 Support Expansion of Good Samaritan Laws: Minimal
- 204 AMA Position on Payment Provisions in Health Insurance Policies: Modest
- 205 Co-Pay Accumulators: Modest
- 206 Improvement of Healthcare Access in Underserved Areas by Retaining and Incentivizing IMG Physicians: Minimal
- 207 Pharmaceutical Advertising in Electronic Health Record Systems: Modest
- 208 Net Neutrality and Public Health: Modest
- 209 Federal Government Regulation and Promoting Patient Access to Kidney Transplantation: Modest
- 210 Federal Government Regulation and Promoting Renal Transplantation: Modest
- 211 Effects of Net Neutrality on Public Health: Minimal
- 212 Centers for Medicare and Medicaid Services Open Payments Program: Modest
- 213 Data Completeness and the House of Medicine: Modest
- 214 AMA Should Provide a Summary of its Advocacy Efforts on Surprise Medical Bills: Modest
- 215* Board Certification of Physician Assistants: Minimal
- 216* Legislation to Facilitate Corrections-to-Community Healthcare Continuity via Medicaid: Minimal
- 217* Promoting Salary Transparency Among Veterans Health Administration Employed Physicians: Modest
- 218* Private Payers and Office Visit Policies: Modest
- 219* QPP and the Immediate Availability of Results in CEHRTs: Modest

Resolution(s)

- 301 Engaging Stakeholders for Establishment of a Two-Interval, or Pass/Fail, Grading System of Non-Clinical Curriculum in U.S. Medical Schools: Minimal
- 302 Strengthening Standards for LGBTQ Medical Education: Minimal
- 303 Investigation of Existing Application Barriers for Osteopathic Medical Students Applying for Away Rotations: Modest
- 304 Issues with the Match, The National Residency Matching Program (NRMP): Modest
- 305 Ensuring Access to Safe and Quality Care for our Veterans: Minimal
- 306 Financial Burden of USMLE Step 2 CS on Medical Students: Modest
- 307 Implementation of Financial Education Curriculum for Medical Students and Physicians in Training: Modest
- 308 Study Expediting Entry of Qualified IMG Physicians to US Medical Practice: Modest
- 801 Reimbursement for Post-Exposure Protocol for Needlestick Injuries: Modest
- 802 Ensuring Fair Pricing of Drugs Developed with the United States Government: Minimal
- 803 Encourage Federal Efforts to Expand Access to Scheduled Dialysis for Undocumented People: Minimal
- 804 Protecting Seniors from Medicare Advantage Plans: Modest
- 805 Fair Medication Pricing for Patients in United States: Advocating for a Global Pricing Standard: Modest
- 806 Support for Housing Modification Policies: Minimal
- 807 Addressing the Need for Low Vision Aid Devices: Minimal
- 808 Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs: Modest
- 809 AMA Principles of Medicaid Reform: Modest
- 810 Hospital Medical Staff Policy: Minimal
- 811 Require Payers to Share Prior Authorization Cost Burden: Minimal
- 812* Autopsy Standards as Condition of Participation: Modest
- 813* Public Reporting of PBM Rebates: Modest
- 814* PBM Value-Based Framework for Formulary Design: Modest
- 815* Step Therapy: Modest
- 901 Health Impact of Per- and Polyfluoroalkyl Substances (PFAS) Contamination in Drinking Water: Minimal
- 902 Amending H-490.913, Smoke-Free Environments and Workplaces, and H-409.907, Tobacco Smoke Exposure of Children in Multi-Unit Housing, to Include E-Cigarettes: Minima
- 903 Encouraging the Development of Multi-Language, Culturally Informed Mobile Health Applications: Minimal
- 904 Amendment to AMA Policy H-150.949, "Healthy Food Options in Hospitals": Minimal
- 905 Sunscreen Dispensers in Public Spaces as a Public Health Measure: Minimal
- 906 Ensuring the Best In-School Care for Children with Sickle Cell Disease: Minimal
- 907 Increasing Access to Gang-Related Laser Tattoo Removal in Prison and Community Settings: Minimal
- 908 Request for Benzodiazepine-Specific Prescribing Guidelines for Physicians: Minimal
- 909 Decreasing the Use of Oximetry Monitors for the Prevention of Sudden Infant Death Syndrome: Minimal
- 910 Ban on Electronic Nicotine Delivery System (ENDS) Products: Modest
- 911 Basic Courses in Nutrition: Minimal
- 912 Improving Emergency Response Planning for Infectious Disease Outbreaks: Minimal
- 913 Public Health Impacts and Unintended Consequences of Legalization and Decriminalization of Cannabis for Medicinal and Recreational Use: Modest
- 914 Nicotine Replacement Therapy for Minors: Modest
- 915 Preventing Death and Disability Due to Particulate Matter Produced by Automobiles: Minimal
- 916 Sale of Tobacco in Retail Pharmacies: Minimal
- 917 Supporting Research into the Therapeutic Potential of Psychedelics: Minimal

Resolution(s)

- 918 Banning Flavors, Including Menthol and Mint, in Combustible and Electronic Cigarettes and Other Nicotine Products: Minimal
- 919 Raising Awareness of the Health Impact of Cannabis: Modest
- 920 Maintaining Public Focus on Leading Causes of Nicotine-Related Death: Minimal
- 921 Vaping in New York State and Nationally: Minimal
- 922 Understanding the Effects of PFAS on Human Health: Minimal
- 923 Support Availability of Public Transit System: Minimal
- 924 Update Scheduled Medication Classification: Minimal
- 925* Suspending Sales of Vaping Products/Electronic Cigarettes Until FDA Review: Minimal
- 927* Climate Change: Minimal
- 928* CBD Oil and Supplement Use in Treatment: Minimal
- 929* Regulating Marketing and Distribution of Tobacco Products and Vaping-Related Products: Minimal

Resolutions not for consideration

- 008 Improving the Health and Safety of Consensual Sex Workers: Minimal
- 012* Study of Forced Organ Harvesting by China: Modest
- 601 Amending AMA Policy G-630.140, "Lodging, Meeting Venues, and Social Functions": Minimal
- 926* School Resource Officer Qualifications and Training: Minimal

Minimal - less than \$1,000 Modest - between \$1,000 - \$5,000 Moderate - between \$5,000 - \$10,000

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CC&B Report(s)

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- 02 Bylaw Consistency--Certification Authority for Societies represented in our AMA House of Delegates and Advance Certification for those Societies
- 03 AMA Delegate Apportionment

CEJA Report(s)

- 01 Competence, Self-Assessment and Self-Awareness
- 02 Amendment to E-1.2.2., "Disruptive Behavior by Patients"

Resolution(s)

- 001 Support for the Use of Psychiatric Advance Directives
- 002 Endorsing the Creation of a Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) Research IRB Training
- 003 Accurate Collection of Preferred Language and Disaggregated Race and Ethnicity to Characterize Health Disparities
- 004 Improving Inclusiveness of Transgender Patients Within Electronic Medical Record Systems
- 005 Removing Sex Designation from the Public Portion of the Birth Certificate
- 006 Transparency Improving Informed Consent for Reproductive Health Services
- 007 Addressing the Racial Pay Gap in Medicine
- 009 Data for Specialty Society Five-Year Review
- 010 Ban Conversion Therapy of LGBTQ Youth
- 011 End Child Marriage

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 1-I-19

Subject: Parity in our AMA House of Delegates

Presented by: Patricia L. Austin, MD, Chair

Reference Committee on Amendments to Constitution and Bylaws Referred to:

1 At the 2019 Annual Meeting, the House referred CCB Report 1, "Clarification to the Bylaws: 2 Delegate Representation, Registration and Credentialing," back to the Council for report back. 3 CCB Report 1-A-19 recommended a series of changes to the AMA Bylaws. To make consideration 4 and action easier for the House, the Council has broken its recommendations for bylaw amendments into distinct reports, each of which deals with a specific aspect of the Bylaws. This 5 6 report focuses on parity between constituent societies and the national medical specialty societies.

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The House of Delegates places great emphasis on the need for parity between the constituent societies and the national medical specialty societies. Bylaw 2.10.5 states that the current president of a constituent association may be certified as an additional alternate delegate at the discretion of each constituent association. The Council notes that there is no corresponding bylaw whereby a national medical specialty society or a professional interest medical association (PIMA) has that same privilege. The Council has proposed an equivalent bylaw that would accord the same opportunity. The Council also believes these additional alternate delegate positions may potentially minimize vacant delegate seats for these entities.

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24 25 Because of concern about potentially swelling the size of the House, the Council looked at the registration and credentialing lists from the 2019 Annual Meeting of the House of Delegates. The Council found that there were 9 national medical specialty societies/PIMAs that did not credential a full complement of delegates, and 78 specialty societies/PIMAs that had anywhere from a single alternate delegate vacancy to multiple alternate vacancies. To gain perspective about the frequency by which constituent societies credential a president as an alternate delegate, the Council discovered that at A-19 while 14 constituent societies credentialed a state medical society president as an alternate delegate, 6 of those 14 individuals ultimately were no-shows. The Council concluded that most national medical specialty societies/PIMA are unlikely to credential a president as an alternate delegate, but it believes the option to do so should be provided to them.

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RECOMMENDATIONS

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30 The Council on Constitution and Bylaws recommends: 1) that the following amendments to the AMA Bylaws be adopted; and 2) that the remainder of this report be filed. Adoption requires the 31 affirmative vote of two-thirds of the members of the House of Delegates present and voting. 32

1	2.10	Registi	ration and Seating of Delegates.
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5		2.10.5	Constituent Association President. The current president of a constituent
6			association may also be certified as an additional alternate delegate at the
7			discretion of each constituent association.
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9		2.10.6	National Medical Specialty Society or Professional Interest Medical
10			Association President. The current president of a national medical specialty
11			society or a professional interest medical association may also be certified as an
12			additional alternate delegate at the discretion of each national medical specialty
13			society or professional interest medical association.
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15	(Modi:	fy Bylaw	s)

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 2-I-19

Subject: Bylaw Consistency--Certification Authority for Societies represented in our AMA

House of Delegates and Advance Certification for those Societies

Presented by: Patricia L. Austin, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

At the 2019 Annual Meeting, the House referred CCB Report 1, Clarification to the Bylaws:
Delegate Representation, Registration and Credentialing to the Council for report back. CCB
Report 1-A-19 recommended a series of changes to the AMA Bylaws. To make consideration and action easier for the House, the Council has separated its recommendations for bylaw amendments into distinct reports, each of which focuses on a specific revision to the Bylaws.

This report focuses on the delegate certification authority of the various Federation entities represented in our House of Delegates as well as on the thirty-day requirement for advance certification. The proposed changes aim for consistent language applicable to all represented societies and groups.

BACKGROUND

A delegate certification process is essential in a democratic organization to ensure that only those entitled to vote may do so, and that each delegate votes only once. Existing AMA bylaw provisions use different terminology to identify the key individual(s) responsible for certifying the delegates of each entity represented in our AMA House of Delegates. For constituent associations and the national medical specialty societies, the bylaws accord certification responsibility to the president or secretary. The bylaws for the AMA Sections, military services and the professional interest medical associations put the responsibility for certification on the president, secretary or other authorized individual. With respect to the medical student regional delegates and the delegates from the Resident and Fellow Section, the bylaws designate the section chair as the authorized individual for purposes of credentialing. In addition, another bylaw allows the RFS chair to delegate the task; however, there is no such provision for the MSS chair to delegate authority for credentialing.

 The Council has proposed amendments to several bylaw provisions to make the certification authority more consistent across the different entities represented in our House of Delegates. The Council also notes, that while a president is generally recognized as the representative of an organization, not every organization has the position of President. Furthermore, certain duties and responsibilities may be delegated. With regard to the certification authority, it is typically the executive director or other staff person who confirms the entity's representatives to the House of Delegates.

With regard to the timing of the certification, existing provisions of our AMA Bylaws currently state that certification must occur at least 30 days prior to the Annual or Interim Meeting of the House of Delegates. The Office of the House of Delegates Affairs works diligently with the

1 Federation to manage the process to ensure that all certifications are received 30 days prior to the 2 meeting. The names of the credentialed delegates and alternate delegates become part of the Official Call, which is disseminated to all House of Delegates representatives in advance of the 3 4 meeting, included in the House of Delegates Handbook, incorporated into the AMA Pictorial 5 Directory, and used as a starting point for the final list published in the meeting proceedings. In 6 proposing to modify Bylaw 2.6.1, the Council is paralleling language that exists elsewhere for the 7 constituent societies and the national medical specialty societies. Also, the bylaw change will not 8 change current practice with respect to professional interest medical associations, the sections or 9 the federal services.

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The Council stresses that the 30-day advance certification requirement does not preclude late or onsite certification and applies equitably to all. When credentialed individuals find themselves unable to attend the meeting or have an emergency that precludes their participation, existing bylaws appropriately provide for those situations. Bylaw 2.10.3, Lack of Credentials, permits a delegate or alternate delegate to be seated/credentialed onsite provided proper identification is established and so certified to the AMA. Furthermore, Bylaw 2.10.4 provides for a "substitute delegate" when a delegate or alternate delegate is unable to attend a meeting. Bylaw 2.10.4.1 provides for "a temporary substitute delegate" when a delegate is not able to remain in attendance for the entire meeting. The Council also has proposed editorial amendments to these bylaws for consistency, accuracy and simplicity.

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RECOMMENDATIONS

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The Council on Constitution and Bylaws recommends: 1) that the following amendments to the AMA Bylaws be adopted; and 2) that the remainder of this report be filed. Adoption requires the affirmative vote of two-thirds of the members of the House of Delegates present and voting.

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Certification. The president or secretary of each constituent association, or the president's designee, shall certify to the AMA the delegates and alternate delegates from their respective associations. Certification must occur at least 30 days prior to the Annual or Interim Meeting of the House of Delegates.

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2.2.4 **Certification.** The president or secretary of each specialty society, or the president's designee, shall certify to the AMA the delegates and alternate delegates from their respective societies. Certification must occur at least 30 days prior to the Annual or Interim Meeting of the House of Delegates.

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2.3.4 **Certification.** The Chair of the Medical Student Section Governing Council, or the Chair's designee, shall certify to the AMA the delegates and alternate delegates for from each Medical Student Region. Certification of delegates and alternate delegates must occur at least 30 days prior to the Annual Meeting of the House of Delegates.

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1 2 3		2.4.4	Certification. The Chair of the Resident and Fellow Section Governing Council, or his or her the Chair's designee, shall certify to the AMA the delegates and alternate delegates for the Resident and Fellow Section. Certification of delegates
4			and alternate delegates must occur at least 30 days prior to the Annual Meeting of
5			the House of Delegates.
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7	2.6	0.41	
8 9	2.6		Delegates. Each of the following is entitled to a delegate: AMA Sections; the
10			ons General of the United States Army, United States Navy, United States Air Force, nited States Public Health Service; the Chief Medical Director of the Department of
11			ns Affairs; the National Medical Association; the American Medical Women's
12			ation; the American Osteopathic Association; and professional interest medical
13			ations granted representation in the House of Delegates.
14		associ	mons granted representation in the frouse of Belegates.
15		2.6.1	Certification. The president, secretary or other authorized individual of each entity
16			shall certify to the AMA their respective delegate and alternate delegate.
17			Certification must occur 30 days prior to the Annual or Interim Meeting.
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19	2.10	Regist	ration and Seating of Delegates.
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23		2.10.2	Credentials. A delegate or alternate delegate may only be seated if there is Before
24			being seated at any meeting of the House of Delegates, each delegate or alternate
25			delegate shall deposit with the Committee on Rules and Credentials a certificate
26			certification on file signed by the president, secretary, or other authorized
27			individual of the delegate's or alternate delegate's organization stating that the
28			delegate or alternate delegate has been properly selected to serve in the House of
29			Delegates.
30		2 10 2	Table & Condenda la Addition to the second delicate manifest and addition the
31 32		2.10.3	Lack of Credentials. A delegate or alternate delegate may be seated without the
33			certificate defined in Bylaw 2.10.2 provided proper identification as the delegate or alternate delegate selected by the respective organization entity is established, and
34			so certified to the AMA.
35			so certified to the AlviA.
36		2 10 4	Substitute. When a delegate or alternate delegate is unable to attend a meeting of
37		2.10.4	the House of Delegates, the appropriate authorities president, the president's
38			designee or other authorized individual of the organization entity may appoint a
39			substitute delegate or <u>substitute</u> alternate delegate, who on presenting proper
40			eredentials shall be eligible to serve as such delegate or alternate delegate in the
41			House of Delegates at that meeting.
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43			2.10.4.1 Temporary Substitute Delegate. A delegate whose credentials have
44			been accepted by the Committee on Rules and Credentials and whose
45			name has been placed on the roll of the House of Delegates shall
46			remain a delegate until final adjournment of that meeting of the House
47			of Delegates. However, if the delegate is not able to remain in
48			attendance, that place of that delegate may be taken during the period of
49			absence by an alternate delegate, or a substitute alternate delegate
50			selected in accordance with Bylaw 2.10.4 if an alternate delegate is not
51			available. The person who takes the place of the delegate must comply

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1	with the formal recredentialing procedures established by the
2	Committee on Rules and Credentials for such purpose have certification
3	on file and shall be known as a temporary substitute delegate. Such
4	temporary substitute delegate shall have all of the rights and privileges
5	of a delegate while serving as a temporary substitute delegate, including
6	the right to vote in the House of Delegates and to vote in any election
7	conducted by the House of Delegates. The temporary substitute
8	delegate shall not be eligible for nomination or election as Speaker or
9	Vice Speaker of the House of Delegates.
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13	2.10.67 Representation. No delegate or alternate delegate may be registered credentialed
14	or seated at any meeting to represent more than one organization in the House of
15	Delegates.
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17	(Modify Bylaws)

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 3-I-19

Subject: AMA Delegation Apportionment

Presented by: Patricia L. Austin, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

At the 2018 Interim Meeting, Policy G-600.016, "Data Used to Apportion Delegates," was 1 2 adopted. Among its recommendations were that "pending members" be added to the number of 3 active AMA members in the December 31 count for the purposes of AMA delegate allocations to 4 national medical specialty and state medical societies for the following year." At the 2019 Annual 5 Meeting, Policy G-600.016 subsequently was amended to read as follows: "Pending members" will 6 be added to the number of active AMA members in the December 31 count for the purposes of 7 AMA delegation allocations to state medical societies for the following year and this total will be 8 used to determine the number of national medical specialty delegates to maintain parity." The body 9 of the report defines "pending members" as individuals who at the time they apply for membership 10 are not current in their dues and who pay dues for the following calendar year. Board of Trustees Report 12-A-19, which proposed the adopted modification," also called for a report to the House at 11 the 2022 Annual Meeting on the impact of Policy G-600.016 and recommendations regarding 12 continuation of this policy. The Council on Constitution and Bylaws was directed to prepare a 13 14 report with bylaw amendments for the 2019 Interim Meeting to allow the implementation of Policy G-600.016. 15

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The Council on Constitution and Bylaws presents the requested amendments to the AMA Bylaws. It also will include a definition of "pending members" in the glossary to the Bylaws.

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RECOMMENDATIONS

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1. That the following amendment to the AMA Bylaws be adopted. Adoption requires the

The Council on Constitution and Bylaws recommends the following:

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2.1 Constituent Associations. Each recognized constituent association granted representation in the House of Delegates is entitled to delegate representation based on the number of seats allocated to it by apportionment, and such additional delegate seats as may be provided under Bylaw 2.1.1.2. Only one constituent association from each U.S. state, commonwealth, territory, or possession shall be granted representation in the House of Delegates.

affirmative vote of two-thirds of the members of the House of Delegates present and voting.

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2.1.1 Apportionment. The apportionment of delegates from each constituent association is one delegate for each 1,000, or fraction thereof, active constituent and active direct members of the AMA within the jurisdiction of each constituent association, as recorded by the AMA as of December 31 of each year.

1		2.1.1.1 The December 31 count will include pending members for purposes of
2		apportionment; however, pending members shall not be recounted the
3		following year absent membership renewal. This Bylaw will sunset as of
4		the close of business of the 2022 Interim Meeting unless the House of
5		Delegates acts to retain it.
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7		[Subsequent bylaw provisions shall be renumbered] (Modify Bylaws)
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9	2.	That Policy G-600.016(2) be amended by addition to read as follows:
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11		"Pending members" (defined as individuals who at the time they apply for membership are not
12		current in their dues and who pay dues for the following calendar year) will be added to the
13		number of active AMA members in the December 31 count for the purposes of AMA delegate
14		allocations to state medical societies for the following year and this total will be used to
15		determine the number of national medical specialty delegates to maintain parity. (Modify
16		Current HOD Policy)
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18	3.	That the remainder of this report be filed.

Fiscal Note: Less than \$500

AMA Policy

G-600.016, Data Used to Apportion Delegates

- 1. Our AMA shall issue an annual, mid-year report on or around June 30 to inform each state medical society and each national medical specialty society that is in the process of its 5-year review of its current AMA membership count.
- 2. "Pending members" will be added to the number of active AMA members in the December 31 count for the purposes of AMA delegate allocations to state medical societies for the following year and this total will be used to determine the number of national medical specialty delegates to maintain parity.
- 3. Our AMA will track "pending members" from a given year who are counted towards delegate allocation for the following year and these members will not be counted again for delegate allocation unless they renew their membership before the end of the following year.
- 4. Our AMA Board of Trustees will issue a report to the House of Delegates at the 2022 Annual Meeting on the impact of Policy G-600.016 and recommendations regarding continuation of this policy.

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (1-I-19)

Competence, Self-Assessment and Self-Awareness (Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient's well-being.

To fulfill their ethical responsibility of competence, physicians at all stages in their professional lives should cultivate and exercise skills of self-awareness and active self-observation; take advantage of tools for self-assessment that are appropriate to their practice settings and patient populations; and be attentive to environmental and other factors that may compromise their ability to bring their best skills to the care of individual patients. As a profession, medicine should provide meaningful opportunity for physicians to hone their ability to be self-reflective.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-19

Subject: Competence, Self-Assessment and Self-Awareness

Presented by: Kathryn L. Moseley, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

The expectation that physicians will provide competent care is central to medicine. This expectation shaped the founding mission of the American Medical Association (AMA) and runs throughout the AMA *Code of Medical Ethics* [1-4]. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society [5]. The profession promises that practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses [6-9].

Yet despite the centrality of competence to professionalism, the *Code* has not hitherto examined what the commitment to competence means as an ethical responsibility for individual physicians in day-to-day practice. This report by the Council on Ethical and Judicial Affairs (CEJA) explores this topic to develop ethics guidance for physicians.

DEFINING COMPETENCE

 A caveat is in order. Various bodies in medicine undertake point-in-time, cross-sectional assessments of physicians' technical knowledge and skills. However, this report is not concerned with matters of technical proficiency assessed by medical schools and residency programs, specialty boards (for purposes of certification), or hospital and other health care organizations (e.g., for privileging and credentialing). Such matters lie outside the Council's purview.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole. For purposes of this analysis, competence is understood as "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served" and as "developmental, impermanent, and context dependent" [10].

Moreover, the Council is keenly aware that technical proficiency evolves over time—what is expected of physicians just entering practice is not exactly the same as what is expected of mid-career physicians or physicians who are changing or re-entering practice or transitioning out of

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^{*} Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

active practice to other roles. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues.

The concept that informs this report differs as well from the narrower definition of competence as the knowledge and skills an individual has to do a job. Rather, this report explores a broader notion of competence that encompasses deeper aspects of wisdom, judgment and practice that enable physicians to assure patients, the public, and the profession that they provide safe, high quality care moment to moment over the course of a professional lifetime.

FROM SELF-ASSESSMENT TO "INFORMED" SELF-ASSESSMENT

Health care institutions and the medical profession as a whole take responsibility to regulate physicians through credentialing and privileging, routinely testing knowledge (maintenance of certification, requirements for continuing education, etc.) and, when needed, taking disciplinary action against physicians who fail to meet expectations for competent, professional practice. However, the better part of the responsibility to maintain competence rests with physicians' "individual capacity, as clinicians, to self-assess [their] strengths, deficiencies, and learning needs to maintain a level of competence commensurate with [their] clinical roles" [11].

Self-assessment has thus become integral to many appraisal systems [5, 10, 12-16]. Yet clinicians and trainees tend to assess their peers' performance more accurately than they do their own—for example, those who perform in the bottom quartile tend to over-estimate their abilities, while those in the top quartile tend to under-estimate themselves [5,12,13,17].

Self-assessment involves an interplay of factors that can be complicated by personal characteristics (e.g., gender, ethnicity, or cultural background); by lack of insight or ability to be self-observant in the moment; and by external factors, such as the purpose of self-assessment [12,18]. The published literature also indicates that interventions intended to enhance self-assessment may seek different goals—improving the accuracy of self-assessors' perceptions of their learning needs, promoting appropriate change in learning activities, or improving clinical practice or patient outcomes [12].

Thus self-assessment tools alone are not sufficient measures of physicians' ability to provide safe, high quality care. Feedback from third parties is essential [19]. However, physicians can be hesitant to seek feedback for fear of looking incompetent or exposing possible deficiencies or out of concern that soliciting feedback could adversely affect their relationships with those whom they approach [20]. They may also question the accuracy and credibility of the assessment process and the data it generates [21]. And they are not sure how to use information that is not congruent with their self-appraisals [20].

To be effective, feedback must be valued by those being assessed as well as by those offering assessment [14]. When there is tension between the stated goals of assessment and the implicit culture of the health care organization or institution, assessment programs can too readily devolve into an activity undertaken primarily to satisfy administrators that rarely improves patient care [20]. Feedback mechanisms should be appropriate to the skills being assessed—multi-source reviews ("360° reviews"), for example, are generally better suited to providing feedback on communication and interpersonal skills than on technical knowledge or skills—and easy for evaluators to understand and use [14]. High quality feedback will come from multiple sources; be specific and focus on key elements of the ability being assessed; address behaviors rather than personality or personal characteristics; and "provide both positive comments to reinforce good behavior and constructive comments with action items to address deficiencies" [22]. Beyond such formal

mechanisms, physicians should welcome and seek out informal input from colleagues. They should be willing to offer timely comments to colleagues as well.

One study among physicians and trainees found that participants interpreted and responded to multiple types of information, such as cognitive and affective data, from both formal and informal sources [23]. Participants described "critically reflecting 'in action,' that is, during an activity or throughout the day":

I think we do a lot of it without thinking of it as reflection. We do it every day when we look at a patient's chart. You look back and see the last visit, "What did I do, or should I have done something different?" I mean that's reflection, but yet I wouldn't have thought of that as self-assessment or self-reflection, but we do it dozens of times a day [23].

EXPERTISE & EXPERT JUDGMENT

On this broad understanding of competence, physicians' thought processes are as important as their knowledge base or technical skills. Thus, understanding competence requires understanding something of the nature of expertise and processes of expert reasoning, themselves topics of ongoing exploration [24,25,26,27].

Expert judgment is the ability "to respond effectively in the moment to the limits of [one's] automatic resources and to transition appropriately to a greater reliance on effortful processes when needed" [24], a practice described as "slowing down." Knowing when to slow down and be reflective has been demonstrated to improve diagnostic accuracy and other outcomes [26]. To respond to the unexpected events that often arise in a clinical situation, the physician must "vigilantly monitor relevant environmental cues" and use these as signals to slow down, to transition into a more effortful state [25]. This can happen, for example, when a surgeon confronts an unexpected tumor or anatomical anomaly during a procedure. "Slowing down when you should" serves as a critical marker for intraoperative surgical judgment [24].

Influences on Clinical Reasoning

Physicians' skills of clinical reasoning develop through education, training, and experiences. Every physician arrives at a diagnosis and treatment plan for an individual in ways that may align with or differ from the analytical and investigative processes of their colleagues in innumerable ways. Nonetheless, all physicians are susceptible to certain common pitfalls in reasoning, notably relying unduly on heuristics and habits of perception, and succumbing to overconfidence.

Physicians use time-saving cognitive short cuts (heuristics) to help identify and categorize relevant information. But such short cuts can also mislead physicians to miscategorize information based on seeming similarity or to place too much weight "on examples of things that come to mind easily [28]. Other common cognitive missteps can derail clinical reasoning as well, including misperceiving a coincidental relationship as a causal one, or the tendency to remember information transferred at the beginning or end of an exchange but not information transferred in the middle [28,29,30].

Like every other person, physicians can also find themselves prone to conscious or unconscious habits of perception or biases. They may allow unquestioned assumptions based on a patient's race or ethnicity, gender, socioeconomic status, or health behavior, for example, to shape how they perceive the patient and how they engage with, evaluate, and treat the individual [31]. Physicians may fall victim to the tendency to seek out information that confirms established expectations or

dismiss contradicting information that does not fit into predetermined beliefs [28]. These often inadvertent thought processes can result in a physician pursuing an incorrect line of questioning or testing that then leads to a misdiagnosis or the wrong treatment.

So too, despite their extensive training, physicians, like all people, are often poor at identifying the gaps in their knowledge [28,30]. They may consider their skills to be excellent, when, in fact, their peers have identified areas for improvement [30]. Overconfidence in one's abilities can lead to suboptimal care for a patient, be it through mismanaging resources, failing to consider the advice of others, or not acknowledging one's limits [28,30].

 Physicians should be aware of the information they do and do not have and they acknowledge that many factors can and will influence their judgment. They should keep in mind the likelihood of diseases and conditions and take the time to distinguish information that is truly essential to sound clinical judgment from the wealth of possibly relevant information available about a patient. They should consider reasons their decisions may be wrong and seek alternatives, as well as seek to disprove rather than confirm their hypotheses [28]. And they should be sensitive to the ways in which assumptions may color their reasoning and not allow expectations to govern their interactions with patients.

Shortcomings can be an opportunity for growth in medicine, as in any other field. By becoming aware of areas in which their skills are not at their strongest and seeking additional education or consulting with colleagues, physicians can enhance their practice and best serve their patients.

FROM INFORMED SELF-ASSESSMENT TO SELF-AWARENESS

Recognizing that many factors affect clinical reasoning and that self-assessment as traditionally conceived has significant shortcomings, several scholars have argued that a different understanding of self-assessment is needed, along with a different conceptualization of its role in a self-regulating profession [32]. Self-assessment, it is suggested, is a mechanism for identifying both one's weaknesses and one's strengths. One should be aware of one's weaknesses in order to self-limit practice in areas in which one has limited competence, to help set appropriate learning goals, and to identify areas that "should be accepted as forever outside one's scope of competent practice" [32]. Knowing one's strengths, meanwhile, allows a physician both to "act with appropriate confidence" and to "set appropriately challenging learning goals" that push the boundaries of the physician's knowledge [32].

If self-assessment is to fulfill these functions, physicians need to reflect on past performance to evaluate not only their general abilities but also specific completed performances. At the same time, they must use self-assessment predictively to assess how likely they are to be able to manage new challenges and new situations. More important, physicians should understand self-assessment as an ongoing process of monitoring tasks during performance [3]. The ability to monitor oneself in the moment is critical to physicians' ethical responsibility to practice safely, at the top of their expertise but not beyond it.

Self-awareness, in the form of attentive self-observation, alerts physicians when they need to direct additional cognitive resources to the immediate task. For example, among surgeons, knowing when to "slow down" during a procedure is critical to competent professional performance, whether that means actually stopping the procedure, withdrawing attention from the surrounding environment to focus more intently on the task at hand, or removing distractions from the operating environment [25].

Physicians should also be sensitive to the ways that interruptions and distractions, which are common in health care settings, can affect competence in the moment [34,35], by disrupting memory processes, particularly the "prospective memory"—i.e., "a memory performance in which a person must recall an intention or plan in the future without an agent telling them to do so"—important for resuming interrupted tasks [35,36]. Systems-level interventions have been shown to help reduce the number or type of interruptions and distractions and mitigate their impact on medical errors [37].

A key aspect of competence is demonstrating situation-specific awareness in the moment of being at the boundaries of one's knowledge and responding accordingly [33]. Slowing down, looking things up, consulting a colleague, or deferring from taking on a case can all be appropriate responses when physicians' self-awareness tells them they are at the limits of their abilities. The capacity for ongoing, attentive self-observation, for "mindful" practice, is an essential marker of competence broadly understood:

Safe practice in a health professional's day-to-day performance requires an awareness of when one lacks the specific knowledge or skill to make a good decision regarding a particular patient This decision making in context is importantly different from being able to accurately rate one's own strengths and weaknesses in an acontextual manner. . . . Safe practice requires that self-assessment be conceptualized as repeatedly enacted, situationally relevant assessments of self-efficacy and ongoing 'reflection-in-practice,' addressing emergent problems and continuously monitoring one's ability to effectively solve the current problem [32].

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills [32]. Self-aware physicians are also alert to how external stressors—the death of a loved one or other family crisis, or the reorganization of their practice, for example—may be affecting their ability to provide care appropriately at a given time. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient's well-being.

Physicians' ability to be sufficiently self-aware to practice safely can be compromised by illness, of course. In some circumstances, self-awareness may be impaired to the point that individuals are not aware of, or deny, their own health status and the adverse effects it can or is having on their practice. In such circumstances, individuals must rely on others—their personal physician, colleagues, family, social acquaintances, or even patients—to help them recognize and address the situation. Physicians have a responsibility to one another and to patients to promote health within the physician community, a responsibility that extends to intervening when a colleague's ability to practice safely is compromised [E-9.3.2]. Physicians who are unable to recognize that they are impaired due to cognitive disability or other illness are not necessarily blameworthy or unethical, unless they decline to address their condition and modify their practice once others have drawn attention to their inability to continue practicing medicine safely.

MAINTAINING COMPETENCE ACROSS A PRACTICE LIFETIME

For physicians, the ideal is not simply to be "good" practitioners, but to excel throughout their professional careers. This ideal holds not just over the course of a sustained clinical practice, but equally when physicians re-enter practice after a hiatus, transition from active patient care to roles as educators or administrators, or take on other functions in health care. Self-assessment and self-awareness are central to achieving that goal.

A variety of strategies is available to physicians to support effective self-assessment and help them cultivate the kind of self-awareness that enables them to "know when to slow down" in day-to-day practice. One such strategy might be to create a portfolio of materials for reflection in the form of written descriptions, audio or video recording, or photos of encounters with patients that can provide evidence of learning, achievement and accomplishment [16] or of opportunities to improve practice. A strength of portfolios as a tool for assessing one's practice is that, unlike standardized examinations, they are drawn from one's actual work and require self-reflection [15].

As noted above, to be effective, self-assessment must be joined with input from others. Well-designed multi-source feedback can be useful in this regard, particularly for providing information about interpersonal behaviors [14]. Research has shown that a four-domain tool with a simple response that elicits feedback about how well one maintains trust and professional relationships with patients, one's communication and teamwork skills, and accessibility offers a valid, reliable tool that can have practical value in helping to correct poor behavior and, just as important, consolidate good behavior [14]. Informal arrangements among colleagues to provide thoughtful feedback will not have the rigor of a validated tool but can accomplish similar ends.

Reflective practice, that is, the habit of using critical reflection to learn from experience, is essential to developing and maintaining competence across a physician's practice lifetime [38]. It enables physicians to "integrate personal beliefs, attitudes, and values in the context of professional culture," and to bridge new and existing knowledge. Studies suggest that reflective thinking can be assessed, and that it can be developed, but also that the habit can be lost over time with increasing years in practice [38].

"Mindful practice"—being fully present in everyday experience and aware of one's own mental processes (including those that cloud decision making) [39]—sustains the attitudes and skills that are central to self-awareness. Medical training, with its fatigue, dogmatism, and emphasis on behavior over consciousness, erects barriers to mindful practice, while an individual's unexamined negative emotions, failure of imagination, and literal-mindedness can do likewise. Physicians can cultivate mindfulness in myriad ways; e.g., through meditation, keeping a journal, reviewing videos of encounters with patients, or seeking insight from critical incident reports [39].

"Exemplary physicians," one scholar notes, "seem to have a capacity for self-critical reflection that pervades all aspects of practice, including being present with the patient, solving problems, eliciting and transmitting information, making evidence-based decisions, performing technical skills, and defining their own values" [39].

RECOMMENDATION

 Based on the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

 The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted by society. To this end, medical schools, residency and fellowship programs, specialty boards, and other health care organizations regularly assess physicians' technical knowledge and skills.

However, as an ethical responsibility competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should

1 2	know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues. Physicians at all stages of their professional lives need to be able to
3	recognize when they are and when they are not able to provide appropriate care for the patient
4	in front of them or the patients in their practice as a whole.
5	in front of them of the patients in their practice as a whole.
6	To fulfill the ethical responsibility of competence, individual physicians and physicians in
7	training should strive to:
8	daming should surve to.
9	(a) Cultivate continuous self-awareness and self-observation.
.0	(w) continuous son an areas and son sees and
1	(b) Recognize that different points of transition in professional life can make different
2	demands on competence.
3	•
4	(c) Take advantage of well-designed tools for self-assessment appropriate to their practice
.5	settings and patient populations.
.6	
.7	(d) Seek feedback from peers and others.
.8	
.9	(e) Be attentive to environmental and other factors that may compromise their ability to bring
20	appropriate skills to the care of individual patients and act in the patient's best interest.
21	(f) Maintain their own health, in collaboration with a personal physician, in keeping with
22 23 24	ethics guidance on physician health and wellness.
.5 24	ethics guidance on physician hearth and wenness.
25	(g) Intervene in a timely, appropriate, and compassionate manner when a colleague's ability to
26	practice safely is compromised by impairment, in keeping with ethics guidance on
27	physician responsibilities to impaired colleagues.
28	ryg
29	Medicine as a profession should continue to refine mechanisms for assessing knowledge and
80	skill and should develop meaningful opportunities for physicians and physicians in training to
31	hone their ability to be self-reflective and attentive in the moment.

(New HOD/CEJA Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-19

Subject: Amendment to E-1.2.2, "Disruptive Behavior by Patients"

Presented by: Kathryn L. Moseley, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Policy D-65.991, "Discrimination against Physicians by Patients," directs the American Medical Association (AMA) to study "(1) the prevalence, reasons for, and impact of physician, resident/fellow and medical student reassignment based upon patients' requests; (2) hospitals' and other health care systems' policies or procedures for handling patient bias; and (3) the legal, ethical, and practical implications of accommodating or refusing such reassignment requests."

The following analysis by the Council on Ethical and Judicial Affairs (CEJA) examines ethics concerns in this area and offers guidance for physicians when they encounter patients who refuse or demand care based on the physician's perceived personal, rather than professional, characteristics.

REASONS MATTER: DISTINGUISHING PREFERENCE FROM PREJUDICE

 It is not known just how often patients discriminate against or sexually harass physicians (and other health care personnel) as data are not systematically collected or publicly reported. However, a growing number of studies and an expanding body of anecdotal reports suggest that such behavior is pervasive in health U.S. care [e.g., 1–7]. In the words of one analyst discrimination by patients is medicine's "open secret" [4].

A survey conducted jointly by Medscape and WebMD in 2017 found that 59% of respondents overall heard an offensive remark from a patient about the physician's personal characteristic, including comments about the physician's weight and political views in addition to comments about age, ethnicity or national origin, gender, race, and sexual orientation [8]. Emergency physicians were significantly more likely to report having experienced bias (83%) than primary care physicians (62%) or specialists (59%). Among respondents, more African American (70%), Asian (69%), and Hispanic (63%) physicians reported hearing biased comments compared to white physicians (55%). The same survey found that male and female physicians experience bias differently, notably in terms of the physician characteristics targeted. For example, female respondents reported experiencing bias more often on the basis of their gender or age than male physicians (41% versus 6% and 36% versus 23%, respectively), while male physicians experienced bias based on their ethnicity or religion somewhat more often than their female colleagues (24% versus 20% and 15% versus 8%, respectively).

^{*}Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

A variety of factors can drive patient behavior that is disrespectful, derogatory, or prejudiced, including mental illness or incapacity or individual life experience, as well as personal beliefs and bias. Different drivers carry different implications for whether, or to what degree, patients can reasonably be held responsible for their problematic behavior. It would not be appropriate to hold patients responsible or blameworthy for statements or actions that are not the product of rational thought in the moment [9]. Thus, physicians' first response to problematic behavior should to explore the reasons underlying the behavior so that they can identify, appreciate, and address potentially treatable conditions. Behavior that outright threatens the safety of health care personnel or other patients calls for prompt action to de-escalate the situation or remove the threat [e.g., 10, 11].

Lingering systemic racism and health disparities in the United States shape the experience of both patients and health care professionals, especially those from nondominant communities [1, 3, 12]. Against this background, patients' reasons for refusing care by a specific physician or requesting a different physician cover a "spectrum of justifiability" [13].

Requests not to be treated by a specific physician may reflect fears or concerns about care that are rooted in systemic discrimination against members of the patient's community or traumatic experiences in a patient's personal history [4, 9, 13]. Requests *for* a physician concordant in ethnicity, religion, or gender may reflect cultural preferences or traditions, for example, a Muslim woman's preference to receive care from a female physician. Such requests may also reflect patients' experience, or reasonable expectation, that they will be better understood by a physician "like them." Evidence suggests that at least for some patients, racial/ethnic or cultural concordance between patient and physician supports more effective communication, enhances satisfaction, and may have clinical benefit [4]. In these situations, it is appropriate to respect patient concerns and preferences, when doing so is clinically feasible.

Requests for an alternative physician based solely on prejudice against personal characteristics of the physician, however, are not justifiable and need not—perhaps should not—be accommodated [4, 9, 13]. Requests based on a physician's (actual or perceived) race/ethnicity, national origin, creed, gender identity, sexual orientation, disability, or other personal characteristic are ethically objectionable.

For physicians and health care institutions faced with patients' strongly held views about who should provide care, then, a central task is distinguishing when a patient's stated preference rests on ethically acceptable reasons and when it reflects unacceptable bias or prejudice. When, that is, will accommodation serve important patient interests and when will it reinforce problematic stereotypes and, in effect if not intent, condone bigotry [2, 9]?

PROTECTING INTERESTS, MINIMIZING HARMS

Patient refusals of care or demands for alternative caregivers challenge physicians, and the institutions in which they work, to protect both the interests of patients and those of physicians. In such situations, physicians' professional obligations to promote patient well-being, respect patients as moral agents and autonomous decision makers, and fulfill the duty to treat without discrimination come into tension in potentially novel ways. Nor do these responsibilities align with physicians' own interests in upholding professional autonomy and themselves being free from discrimination. There are potential harms to both parties whether the physician/institution accommodates bigoted requests and removes the caregiver or requires patient and physician to engage one another in a troubled relationship.

 Physicians' fiduciary obligations are fundamental. Physicians are expected to promote patients' interest and well-being without regard to individuals' personal characteristics or behavior, up to and including providing care to individuals whose behavior may be morally repugnant [13, 14]. But whether continuing to provide care or allowing oneself to be withdrawn from a case better fulfills that fiduciary obligation is only intelligible in the individual case. So too are interpretations of how a physician is to respect the autonomy of a patient who asserts moral agency in the form of prejudice, and what the duty to care entails when the recipient behaves in a way that, arguably, is not morally worthy or acceptable. Reaching sound determinations in these matters cannot be done by rote; instead, as one commentator observed, doing so calls for "nuanced ethical judgment" [13].

1 2

The American Medical Association *Code of Medical Ethics* enjoins physicians to provide "competent medical care, with compassion and respect for human dignity and rights" [15]. It also acknowledges that, except in emergencies, physicians shall be "free to choose whom to serve" [16].

The Code further delineates the conditions under which a physician may decline to accept a new patient (or provide a specific service to an existing patient [17]. These include when the care requested is outside the physician's competence or scope of practice; when the physician lacks the resources to provide safe, competent, respectful care for the individual; and when meeting this patient's medically needs seriously compromises the physician's ability to provide the care needed by other patients. Importantly, guidance acknowledges that, except in emergencies, a physician may decline to provide care when the patient "is abusive or threatens the physician, staff, or other patients" [17]. At the same time, the *Code* provides that physicians may terminate a relationship with a patient who "uses derogatory language or acts in a prejudicial manner *only if the patient will not modify the behavior*," in which case the physician should arrange to transfer the patient's care [emphasis added] [18].

One approach to determining the ethically appropriate response to prejudiced behavior by patients is to explore the harms—to patients, to physicians and other health care professionals, and to health care institutions and even the wider community—that can result from different possible responses. Who, that is, is harmed by a given response, and in what way?

 Thwarting the requests of seemingly bigoted patients for alternative caregivers exposes patients to possible delays in care and poorer health outcomes, should they choose to leave the facility (with or without assistance from the institution). If they do not, or cannot leave, patients are subjected to the experience of receiving medical care from a physician against whom they are biased. Distinguishing between a preference for a different physician and a demand for one is important in thinking about the nature and degree of harm the patient may experience. A preference is "an expression of an inclination that may be gratified or not"; a demand is "more of an ultimatum, in which failure to meet its indicia may be met not only with disappointment but also anger and resentment" [9]. Further, it is important to determine why the patient is making the request/demand, which may have a clinical source, such as delirium, dementia, or psychosis [4, 13], that is outside the patient's control, as opposed to being a stance the patient has voluntarily adopted. And as noted previously, requests/demands may also reflect life experiences that color a patient's response to caregivers for which accommodation may be appropriate.

For physicians and other caregivers, acceding to bigoted demands can send powerful, but unintended and potentially hurtful messages—that minority or female physicians are "not as good" as white male physicians or that patient satisfaction scores are more important to the institution than promoting a safe and ethical working environment [1, 19]. Accommodating bigotry can make institutions complicit in discrimination [19], in the process tacitly condoning or reinforcing an

institutional culture that routinely subjects minority physicians to "barrages of microaggressions and biases" or expects them to serve as "race/ethnicity ambassadors" [1].

Institutions that fail to support staff in the face of prejudice convey that complying with patient demands "is more important than respecting the dignity of both their staff members and the majority of patients, who do not hold such repugnant views (or at least do not openly act on them)" [9]. Institutions, some argue, "have a duty to present a moral face to their community by refusing to honor bigoted or prejudicial requests or demands as a matter of course, up to and including declining to care for such patients (except in emergency situations)" [9, cp. 20].

Regardless of how their institutions respond, for many minority health care professionals, interactions with prejudiced patients are painful and degrading and contributed to moral distress and burnout [4]. *Requiring* physicians to provide care when a patient has openly expressed bias is not ethically tenable. As one physician described his own experience of ultimately declining to work with a particular patient, "After years of feeling that my race was a nonissue, I was subjected to the same kind of hurtful name-calling that I faced in childhood. Even as self-loathing for not having thicker skin began to creep in, I decided that, on this occasion, my feelings would count" [21]. Absent unique situations, institutions should allow physicians to control the decision about whether they will continue to provide care [19]. Some have argued that institutions have a responsibility to monitor such encounters and their effects on an ongoing basis "with the goal of supporting staff and improving the handling of these situations" [4].

Whether patient prejudice against physicians adversely affects quality of care has not been well studied. One experimental study among family practice physicians in the Netherlands concluded that "disruptive behaviours displayed by patients seem to induce doctors to make diagnostic errors" [22]. A companion study attributed this to the fact that the "mental resources" devoted to dealing with patient behavior interfered with "adequate processing of clinical findings" [23]. Evidence does indicate that physician "burnout" can adversely affect patient outcomes [e.g., 24–26]. To the extent that being the target of patient prejudice contributes to the emotional exhaustion, sense of depersonalization, and sense of low personal accomplishment characteristic of burnout, it is reasonable to expect biased behavior to be associated with lower quality of care, particularly if targeted physicians feel they do not have the support of their colleagues or institutions when bias occurs [1, 21, 27, 28].

LAW AND POLICY

Legally, at the federal level how a health care institution responds to prejudiced behavior by patients falls within the scope of the *Emergency Medical Treatment and Active Labor Act* (EMTALA) and by anti-discrimination law in Title VII of the *Civil Rights Act of 1965* (CRA). When patients make requests based on the physician's race, hospitals are in the position of having to meet EMTALA requirements while respecting physicians' employment rights [4]. Hospitals can "inform patients of their right to seek care elsewhere and their responsibility to refrain from hateful speech," but their ability "to remove physicians in response to race-based requests is circumscribed" [4]. Although physicians have not sued under CRA [4], in a case that ultimately settled, an African-American nurse in Michigan sued her employer when she was barred from caring for a white baby at the request of the child's father, a white supremacist [29].

At present, relatively few institutions have formal policy or procedures for dealing with incidents of patient prejudice, although an increasing number broadly enjoin patients to behave in a respectful manner under policies delineating patient rights and responsibilities and indicate that misconduct will not be tolerated [e.g., 30, 31]. Two notable exceptions are Toronto's University

Health Network (UHN) and Mayo Clinic, both of which explicitly seek to balance the interests of patients and health care personnel.

UHN's *Caregiver Preference Guidelines* focus on three key questions: whether the preference for an alternative caregiver appears to discriminate against the health care professional on the basis of race, ancestry or other characteristic as provided in the *Ontario Human Rights Code*; whether the request is clinically feasible and/or indicated to a reasonable degree; and whether the caregiver wishes to excuse themselves from caring for the patient [27]. Mayo's recently adopted policy directs staff to step in when they observe behavior that is not in keeping with Mayo Clinic values; address the behavior with the patient, focusing the conversation on Mayo's published values; explain the institution's expectations and set boundaries with the individual; and report the incident to supervisors and document it via a patient misconduct form [27].

RECOMMENDATION

In light of the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that Policy D-65.991, "Discrimination against Physicians by Patients," be rescinded; Opinion 1.2.2, "Disruptive Behavior by Patients," be amended by addition and deletion as follows; and the remainder of this report be filed:

The relationship between patients and physicians is based on trust and should serve to promote patients' well-being while respecting their the dignity and rights of both patients and physicians.

Disrespectful, or derogatory, or prejudiced, language or conduct, or prejudiced requests for accommodation of personal preferences on the part of either physicians or patients can undermine trust and compromise the integrity of the patient-physician relationship. It can make members of targeted groups reluctant to seek or provide care, and create an environment that strains relationships among patients, physicians, and the health care team.

Trust can be established and maintained only when there is mutual respect. Therefore, in their interactions with patients, physicians should:

(a) Recognize that disrespectful, derogatory, or prejudiced language or conduct can cause psychological harm to those they target who are targeted.

(b) Always treat patients with compassion and respect.

(c) Explore the reasons for which a patient behaves in disrespectful, derogatory, or prejudiced ways. Physicians should identify, appreciate, and address potentially treatable clinical conditions or personal experiences that influence patient behavior. Regardless of cause, when a patient's behavior threatens the safety of health care personnel or other patients, steps should be taken to de-escalate or remove the threat.

(d) <u>In general, decline to accommodate patient requests for an alternative physician when the</u> request is solely the product of prejudice against the physician's personal characteristics.

(e) Consider accommodating a patient's request for an alternative physician when the request derives from the patient's adverse personal experience, doing so would promote effective care, and another appropriately qualified physician is available to provide the needed care.

1	(f) In emergency situations, patients who persist in opposing treatment from the physician
2	assigned may be helped to seek care from other sources. When transfer is not feasible,
3	patients should be informed that care will be provided by appropriately qualified staff
4	independent of the patient's expressed preference.
5	(as)Tampingto the noticest absolution relationship with a noticest subspace dancestom language
6 7	(eg) Terminate the patient-physician relationship with a patient who uses derogatory language
	or acts in a prejudiced manner whose volitional behavior is disrespectful, derogatory, or
8	<u>prejudiced</u> only if the patient will not modify the conduct. In such cases, the physician
9	should arrange to transfer the patient's care when that is feasible.
10	Dhysicians, compaidly those in landaushin roles, should an asymptotic institutions with which
l 1 l 2	Physicians, especially those in leadership roles, should encourage the institutions with which they are affiliated to:
13	they are anniated to.
14	(h) Be mindful of the messages the institution conveys within and outside its walls by how it
15	responds to prejudiced behavior by patients.
16	responds to prejudiced behavior by patients.
17	(i) Promote a safe and respectful working environment and formally set clear expectations fo
18	how disrespectful, derogatory, or prejudiced behavior by patients will be managed.
19	now disrespectivit, derogatory, or prejudiced behavior by patients will be managed.
20	(j) Clearly and openly support physicians, trainees, and facility personnel who experience
	prejudiced behavior and discrimination by patients.
22	prejudiced benavior and discrimination by patients.
23	(k) Collect data regarding incidents of discrimination by patients and their effects on
23	physicians and facility personnel on an ongoing basis and seek to improve how incidents
25	are addressed to better meet the needs of patients, physicians, other facility personnel, and
26	the community.
21 22 23 24 25 26 27	the community.
28	(Modify HOD/CEJA Policy)
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Fiscal Note: Less than \$500

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Resolution: 001

(I-19)

Introduced by: Medical Student Section

Subject: Support for the Use of Psychiatric Advance Directives

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Nearly 10 million US adults live with serious mental illness, defined as a mental illness that "result[s] in serious functional impairment" and "interferes with one or more major life activities" 1-2; and

Whereas, A survey of 213 patients who previously received coercive psychiatric treatment found that they would like to engage in advance planning to determine their preferences for future care during psychiatric crises³; and

Whereas, A psychiatric advance directive is a legal document written by a competent individual with a mental illness, specifying their treatment preferences and/or granting their medical power of attorney to a surrogate during a future psychiatric crisis that impairs the individual's capacity⁴⁻⁶; and

Whereas, A psychiatric advance directive differs from generic advance directives due to the unique nature of psychiatric illness and treatment⁵⁻⁷; and

Whereas, While most states enable psychiatric advance directive creation under broader advance directive statues, only 25 states have legislation pertaining specifically to the use of psychiatric advance directives⁴⁻⁶; and

Whereas, In Nevada and New Hampshire, while a patient may designate an agent to make healthcare decisions for them should they become incompetent, they may only specify in writing advance instructions on non-psychiatric life-sustaining care⁴⁻⁶; and

Whereas, The Patient Self-Determination Act of 1990 states that Medicare and Medicaid patients should be advised on opportunities to specify treatment preferences prior to the loss of decision-making capacity when possible⁸; and

Whereas, The Centers for Medicare & Medicaid Services Inpatient Psychiatric Facility Quality Reporting Program Manual specifies that a "patient should be allowed the opportunity to appoint a surrogate decision maker or complete non-psychiatric and psychiatric advance directives"; and

Whereas, The use of psychiatric advance directives can help improve patient autonomy, treatment adherence, and the physician-patient relationship and reduce the need for coercive interventions such as involuntary commitment, seclusion, restraints, police transport, and involuntary medications¹⁰⁻¹²; and

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Whereas, In the first 6 months following psychiatric advance directive completion, 6.5 percent of 1 2 patients experienced a coherence crisis intervention compared to 19.7 percent of non-3 completers¹⁰: and

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Whereas, Patients with serious mental illness who participated in a facilitated psychiatric advance directive completion session were 1.57 times more likely to experience an increase in working alliance between themselves and clinicians after 1 month compared to patients who did not experience the session¹¹; and

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Whereas, Psychiatric advance directive completers were 7.8 times more likely to be adherent to their psychiatric mediation after 1 year compared to non-completers¹²; and

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Whereas, In the largest study of psychiatric advance directive usage to date, in over 1,000 patients with mental illness, only 7 percent of respondents had completed a psychiatric AD or designated a surrogate for future psychiatric crises, while 68 percent of respondents expressed interest in completing one¹³; and

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Whereas, A survey of over 400 psychiatrists and psychologists showed that only 37 percent of respondents demonstrated sufficient legal knowledge regarding psychiatric advance directives¹⁴; and

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Whereas, The use of facilitated psychiatric advance directive, an intervention in which a psychiatric advance directive is completed by a patient with the assistance of a trained individual, can reduce most barriers to psychiatric advance directive completion 10,15; and

Whereas, Low usage of psychiatric advance directive has led several states and organizations to take steps to increase awareness and utilization of psychiatric advance directives, such as establishing psychiatric advance directive completion clinics¹⁶⁻¹⁹; and

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Whereas, Existing AMA policy "encourage[es] the use of advance directives and health care powers of attorney" (H-140.845, Encouraging the Use of Advance Directives and Health Care Powers of Attorney), "educating physicians about advance care planning" (H-85.956, Educating Physicians About Advance Care Planning), and "promotes awareness and understanding of" advance care planning in the unique situation of pregnancy (H-85.952, Advance Directives During Pregnancy); and

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Whereas, Similar to pregnant women, individuals with serious mental illness constitute a special population with unique considerations that warrants additional attention in the area of advance directive usage³⁻⁶; therefore be it

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RESOLVED, That our American Medical Association support efforts to increase awareness and appropriate utilization of psychiatric advance directives. (New HOD Policy)

Fiscal note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Encouraging the Use of Advance Directives and Health Care Powers of Attorney H-140.845

Our AMA will: (1) encourage health care providers to discuss with and educate young adults about the establishment of advance directives and the appointment of health care proxies; (2) encourage nursing homes to discuss with resident patients or their health care surrogates/decision maker as appropriate, a care plan including advance directives, and to have on file such care plans including advance directives; and that when a nursing home resident patient's advance directive is on file with the nursing home, that advance directive shall accompany the resident patient upon transfer to another facility; (3) encourage all physicians and their families to complete a Durable Power of Attorney for Health Care (DPAHC) and an Advance Directive (AD); (4) encourage all medical schools to educate medical students and residents about the importance of having a DPAHC/AD before becoming severely ill and encourage them to fill out their own DPAHC/AD; (5) along with other state and specialty societies, work with any state that has technical problems with their DPAHC/AD to correct those problems; (6) encourage every state medical association and their member physicians to make information about Living Wills and health care powers of attorney continuously available in patient reception areas; (7) (a) communicate with key health insurance organizations, both private and public, and their institutional members to include information regarding advance directives and related forms and (b) recommend to state Departments of Motor Vehicles the distribution of information about advance directives to individuals obtaining or renewing a driver's license: (8) work with Congress and the Department of Health and Human Services to (a) make it a national public health priority to educate the public as to the importance of having a DPAHC/AD and to

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encourage patients to work with their physicians to complete a DPAHC/AD and (b) to develop incentives to individuals who prepare advance directives consistent with our current AMA policies and legislative priorities on advance directives; (9) work with the Centers for Medicare and Medicaid Services to use the Medicare enrollment process as an opportunity for patients to receive information about advance health care directives; (10) continue to seek other strategies to help physicians encourage all their patients to complete their DPAHC/AD; and (11) advocate for the implementation of secure electronic advance health care directives. Citation: CCB/CLRPD Rep. 3, A-14; Reaffirmed: BOT Rep. 9, I-15; Reaffirmed: Res. 517, A-16; Reaffirmed: BOT Rep. 05, I-16; Reaffirmed in lieu of: Res. 121, A-17

Educating Physicians About Advance Care Planning H-85.956

Our AMA: (1) will continue efforts to better educate physicians in the skills necessary to increase the prevalence and quality of meaningful advance care planning, including the use of advance directives, and to improve recognition of and adherence to a patient's advance care decisions; (2) supports development of materials to educate physicians about the requirements and implications of the Patient Self-Determination Act, and supports the development of materials (including, but not necessarily limited to, fact sheets and/or brochures) which physicians can use to educate their patients about advance directives and requirements of the Patient Self-Determination Act; (3) encourages residency training programs, regardless of or in addition to current specialty specific ACGME requirements, to promote and develop a high level of knowledge of and ethical standards for the use of such documents as living wills, durable powers of attorney for health care, and ordering DNR status, which should include medical, legal, and ethical principles guiding such physician decisions. This knowledge should include aspects of medical case management in which decisions are made to limit the duration and intensity of treatment; (4) will work with medical schools, graduate medical education programs and other interested groups to increase the awareness and the creation of personal advance directives for all medical students and physicians; and (5) encourages development of a model educational module for the teaching of advance directives and advance care planning.

Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 307, A-14; Reaffirmed: BOT Rep. 05, I-16; Reaffirmed in lieu of: Res. 121, A-17

Advance Directives During Pregnancy H-85.952

- 1. Our AMA vigorously affirms the patient-physician relationship as the appropriate locus of decision making and the independence and integrity of that relationship.
- 2. Our AMA will promote awareness and understanding of the ethical responsibilities of physicians with respect to advance care planning, the use of advance directives, and surrogate decision making, regardless of gender or pregnancy status, set out in the Code of Medical Ethics.
- 3. Our AMA recognizes that there may be extenuating circumstances which may benefit from institutional ethics committee review, or review by another body where appropriate.
- 4. The Council on Ethical and Judicial Affairs will consider examining the issue of advance directives in pregnancy through an informational report.

Citation: (BOT Rep. 9, I-15)

Maintaining Mental Health Services by States H-345.975Our AMA:

- 1. supports maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers, and other state-supported psychiatric services;
- 2. supports state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment, to avoid repeated psychiatric hospitalizations and repeated interactions with the law, primarily as a result of untreated mental conditions;
- 3. supports increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness;
- 4. supports enforcement of the Mental Health Parity Act at the federal and state level; and
- 5. will take these resolves into consideration when developing policy on essential benefit services. Citation: (Res. 116, A-12; Reaffirmation A-15)

E-5.1 Advance Care Planning

The process of advance care planning is widely recognized as a way to support patient self-determination, facilitate decision making, and promote better care at the end of life. Although often

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thought of primarily for terminally ill patients or those with chronic medical conditions, advance care planning is valuable for everyone, regardless of age or current health status. Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions. Importantly, these discussions also give individuals the opportunity to identify who they would want to make decisions for them should they not have decision-making capacity.

Proactively discussing with patients what they would or would not want if recovery from illness or injury is improbable also gives physicians opportunity to address patients' concerns and expectations and clarify misunderstandings individuals may have about specific medical conditions or interventions. Encouraging patients to share their views with their families or other intimates and record them in advance directives, and to name a surrogate decision maker, helps to ensure that patients' own values, goals, and preferences will inform care decisions even when they cannot speak for themselves.

Physicians must recognize, however that patients and families approach decision making in many different ways, informed by culture, faith traditions, and life experience, and should be sensitive to each patient's individual situations and preferences when broaching discussion of planning for care at the end of life.

Physicians should routinely engage their patients in advance care planning in keeping with the following auidelines:

- (a) Regularly encourage all patients, regardless of age or health status, to:
- (i) think about their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness or injury, including any preferences they may have about specific medical interventions (such as pain management, medically administered nutrition and hydration, mechanical ventilation, use of antibiotics, dialysis, or cardiopulmonary resuscitation);
- (ii) identify someone they would want to have make decisions on their behalf if they did not have decision-making capacity;
- (iii) make their views known to their designated surrogate and to (other) family members or intimates.
- (b) Be prepared to answer questions about advance care planning, to help patients formulate their views, and to help them articulate their preferences for care (including their wishes regarding time-limited trials of interventions and surrogate decision maker). Physicians should also be prepared to refer patients to additional resources for further information and guidance if appropriate.
- (c) Explain how advance directives, as written articulations of patients' preferences, are used as tools to help guide treatment decisions in collaboration with patients themselves when they have decision-making capacity, or with surrogates when they do not, and explain the surrogate's responsibilities in decision making. Involve the patient's surrogate in this conversation whenever possible.
- (d) Incorporate notes from the advance care planning discussion into the medical record. Patient values, preferences for treatment, and designation of surrogate decision maker should be included in the notes to be used as guidance when the patient is unable to express his or her own decisions. If the patient has an advance directive document or written designation of proxy, include a copy (or note the existence of the directive) in the medical record and encourage the patient to give a copy to his or her surrogate and others to help ensure it will be available when needed.
- (e) Periodically review with the patient his or her goals, preferences, and chosen decision maker, which often change over time or with changes in health status. Update the patient's medical records accordingly when preferences have changed to ensure that these continue to reflect the individual's current wishes. If applicable, assist the patient with updating his or her advance directive or designation of proxy forms. Involve the patient's surrogate in these reviews whenever possible.

Issued: 2016

E-5.2 Advance Directives

Respect for autonomy and fidelity to the patient are widely acknowledged as core values in the professional ethics of medicine. For patients who lack decision-making capacity, these values are fulfilled through third-party decision making and the use of advance directives. Advance directives also support continuity of care for patients when they transition across care settings, physicians, or health care teams.

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Advance directives, whether oral or written, advisory or a formal statutory document, are tools that give patients of all ages and health status the opportunity to express their values, goals for care, and treatment preferences to guide future decisions about health care. Advance directives also allow patients to identify whom they want to make decisions on their behalf when they cannot do so themselves. They enable physicians and surrogates to make good-faith efforts to respect the patient's goals and implement the patient's preferences when the patient does not have decision-making capacity.

An advance directive never takes precedence over the contemporaneous wishes of a patient who has decision-making capacity.

In emergency situations when a patient is not able to participate in treatment decisions and there is no surrogate or advance directive available to guide decisions, physicians should provide medically appropriate interventions when urgently needed to meet the patient's immediate clinical needs. Interventions may be withdrawn at a later time in keeping with the patient's preferences when they become known and in accordance with ethics guidance for withdrawing treatment.

Before initiating or continuing treatment, including, but not limited to, life-sustaining interventions, the physician should:

- (a) Assess the patient's decision-making capacity in the current clinical circumstances.
- (b) Ascertain whether the patient has an advance directive and if so, whether it accurately reflects his/her current values and preferences. Determine whether the patient's current clinical circumstances meet relevant thresholds set out in the directive.
- (c) Ascertain whether the patient has named a health care proxy (e.g., orally or through a formal legal document). If the patient has not, ask who the patient would want to have make decisions should he or she become unable to do so.
- (d) Document the conversation, including the patient's goals for care, and specific preferences regarding interventions and surrogate decision maker, in the medical record; incorporate any written directives (as available) into the medical record to ensure they are accessible to the health care team.
- (e) When treatment decisions must be made by the patient's surrogate, help the surrogate understand how to carry out the patient's wishes in keeping with the advance directive (when available), including whether the directive applies in the patient's current clinical circumstances and what medically appropriate interventions are available to achieve the patient's goals for care. When conflicts arise between the advance directive and the wishes of the patient's surrogate, the attending physician should seek assistance from an ethics committee or other appropriate institutional resource.
- (f) When a patient who lacks decision-making capacity has no advance directive and there is no surrogate available and willing to make treatment decisions on the patient's behalf, or no surrogate can be identified, the attending physician should seek assistance from an ethics committee or other appropriate resource in ascertaining the patient's best interest.
- (g) Document physician orders to implement treatment decisions in the medical record, including both orders for specific, ongoing interventions (e.g., palliative interventions) and orders to forgo specific interventions (e.g., orders not to attempt resuscitation, not to intubate, not to provide antibiotics or dialysis).

Issued: 2016

Resolution: 002 (I-19)

Introduced by: Medical Student Section

Subject: Endorsing the Creation of a Lesbian, Gay, Bisexual, Transgender, and Queer

(LGBTQ) Research IRB Training

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, In 2016, the National Institute of Minority Health and Health Disparities, a division of the National Institutes of Health (NIH), designated sexual and gender minorities a health disparity population for research purposes¹; and

Whereas, The NIH established in 2015 a Sexual and Gender Minority (SGM) Research Office and provides funding earmarked for SGM-specific medical research^{2,3}; and

Whereas, Pursuant to existing AMA policy H-160.991, our AMA believes in "educating physicians on the current state of research in and knowledge of LGBTQ Health"; and

Whereas, The need for further research within LGBTQ communities is well established, especially for vulnerable populations such as LGBTQ-identified youth and older adults⁴; and

Whereas, Novel peer-reviewed recommendations for ethical research with transgender populations and best-practices for research processes such as sexual orientation and gender identity (SOGI) data have been documented ^{4, 5, 6, 7}; and

Whereas, Because of the patchwork legal protection afforded to LGBTQ populations, disclosure of research participant SGM status through collection of SOGI data or LGBTQ research affiliation can negatively impact participants' livelihood^{8, 9}; and

Whereas, Prominent LGBTQ health organizations, such as Fenway Institute, GLMA: Health Professionals Advancing LGBTQ Health Equality, World Professional Association for Transgender Health, and the William's Institute have not produced a standardized training module on how to protect SOGI data and LGBTQ patient identity in research processes^{10, 11}; therefore be it

RESOLVED, That our American Medical Association work with appropriate stakeholders to support the creation of model training for Institutional Review Boards to use and/or modify for their unique institutional needs as it relates to research collecting data on Lesbian, Gay, Bisexual, Transgender and Queer populations. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 08/28/19

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RELEVANT AMA POLICY

Health Care Needs of Lesbian, Gay, Bisexual and Transgender Populations H-160.991

- 1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
- 2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.
- 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
- 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.

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Citation: CSA Rep. C, I-81; Reaffirmed: CLRPD Rep. F, I-91; CSA Rep. 8 - I-94; Appended: Res. 506, A-00; Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18; Reaffirmed: CSAPH Rep. 01, I-18

Support of Human Rights and Freedom H-65.965

Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.

Citation: CCB/CLRPD Rep. 3, A-14; Reaffirmed in lieu of: Res. 001, I-16; Reaffirmation: A-17

Resolution: 003

(I-19)

Introduced by: Medical Student Section

Subject: Accurate Collection of Preferred Language and Disaggregated Race and

Ethnicity to Characterize Health Disparities

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, The Office of the National Coordinator for Health Information Technology (ONC) is the principal federal entity coordinating the electronic exchange of health information¹; and

Whereas, The U.S. Census collects data based on racial self-identification as White, Black or African American, American Indian or Alaska Native, Asian, and Native Hawaiian or Other Pacific Islander²; and

Whereas, In addition to health disparities between racial and ethnic groups, health disparities also exist within U.S. Census-defined racial and ethnic groups^{3,4}; and

Whereas, Disaggregating racial and ethnic data is defined for the purpose of this resolution as subdividing U.S. Census-defined racial or ethnic (i.e. Hispanic and non-Hispanic) designations into ethnic subgroups (i.e. by splitting "Asian" into Vietnamese, Chinese, Japanese, Laotian, Burmese, Pakistani, Indian, etc.)⁴; and

Whereas, A series of systematic literature reviews reported to the Robert Wood Johnson Foundation identified that within-group disparities were more accurately accounted for by research methodologies that used disaggregated racial and ethnic data among American Indian/Alaska Native (AIAN); Asian American, Native Hawaiian, and Pacific Islander (AANHPI); Latinx; non-Hispanic White Americans; and Black/African American populations⁴; and

Whereas, Despite being classified as White by the U.S. Census and other registries, several population-level disparities exist between Arab Americans and other White ethnic groups⁵; and

Whereas, Health behaviors, such as dietary practices, vary within Asian and Latino subgroups and thus require different interventions and may lead to different health outcomes 6.7; and

Whereas, Accurate preferred language data can help identify "hot-spot" geographic areas with a high density of morbidity and could facilitate addressing social determinants of health⁸; and

Whereas, A 2017 randomized controlled trial and retrospective study at an inner-city pain clinic demonstrated improved adherence to treatment and attendance at scheduled appointments after an intervention was deployed that utilized accurate preferred language data 9.10; and

Whereas, Race, ethnicity, and language (REL) and other socio-demographic data could be used to identify targeted interventions for high-risk patients or areas for quality improvement and

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Whereas, Despite recognition that such data can improve care, reliable collection of REL is 1 2 uncommon, even in settings that treat large minority and immigrant populations^{8,11–13}; and

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Whereas, Several successful systems-level interventions with evidence of improved screening for accurate REL data have been published to date 12.14; and

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Whereas, Existing guidelines for electronic health record (EHR) collection of REL data have led to inaccuracies that could reduce the effectiveness of interventions based on this data¹³; and

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Whereas, Our AMA has supported reducing racial and ethnic disparities in health care by studying health system opportunities and barriers to eliminating disparities (D-350.995); and

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Whereas, Our AMA has advocated for precision in racial, ethnic, and religious designations in medical records, but has not done so for preferred language (H-315.996); and

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Whereas. Our AMA has supported the collection of disaggregated racial data, but current policy lacks actionable language to engage stakeholders (H-350.954); therefore be it

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RESOLVED, That our American Medical Association amend Policy H-315.996 by addition to read as follows:

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Accuracy in Racial, Ethnic, Lingual, and Religious Designations in Medical Records, H-315.996

The AMA advocates precision in racial, ethnic, preferred language, and religious designations in medical records, with information obtained from the patient, always respecting the personal privacy of the patient (Modify Current HOD Policy); and be it further

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RESOLVED. That our AMA encourage the Office of the National Coordinator for Health Information Technology (ONC) to expand their data collection requirements, such that electronic health record (EHR) vendors include options for disaggregated coding of race and ethnicity. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY:

Disaggregation of Demographic Data Within Ethnic Groups H-350.954

- 1. Our AMA supports the disaggregation of demographic data regarding: (a) Asian-Americans and Pacific Islanders in order to reveal the within-group disparities that exist in health outcomes and representation in medicine; and (b) ethnic groups in order to reveal the within-group disparities that exist in health outcomes and representation in medicine.
- 2. Our AMA: (a) will advocate for restoration of webpages on the Asian American and Pacific Islander (AAPI) initiative (similar to those from prior administrations) that specifically address disaggregation of health outcomes related to AAPI data; (b) supports the disaggregation of data regarding AAPIs in order to reveal the AAPI ethnic subgroup disparities that exist in health outcomes; (c) supports the disaggregation of data regarding AAPIs in order to reveal the AAPI ethnic subgroup disparities that exist in representation in medicine, including but not limited to leadership positions in academic medicine; and (d) will report back at the 2020 Annual Meeting on the issue of disaggregation of data regarding AAPIs (and other ethnic subgroups) with regards to the ethnic subgroup disparities that exist in health outcomes and representation in medicine, including leadership positions in academic medicine.

Citation: Res. 001, I-17; Appended: Res. 403, A-19

National Health Information Technology D-478.995

- 1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care.
- 2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care; and (D) advocates for continued research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems.
- 3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop, with physician input, minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs.
- 4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery.
- 5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process.
- 6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability.
- 7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability.

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8. Our AMA will advocate for appropriate, effective, and less burdensome documentation requirements in the use of electronic health records.

9. Our AMA will urge EHR vendors to adopt social determinants of health templates, created with input from our AMA, medical specialty societies, and other stakeholders with expertise in social determinants of health metrics and development, without adding further cost or documentation burden for physicians. Citation: Res. 730, I-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation A-10; Reaffirmed: BOT Rep. 16, A-11; Modified: BOT Rep. 16, A-11; Modified: BOT Rep. 17, A-12; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed: BOT Rep. 24, A-13; Reaffirmed in lieu of Res. 724, A-13; Appended: Res. 720, A-13; Appended: Sub. Res. 721, A-13; Reaffirmed: CMS Rep. 4, I-13; Reaffirmation I-13; Appended: BOT Rep. 18, A-14; Appended: BOT Rep. 20, A-14; Reaffirmation A-14; Reaffirmed: BOT Rep. 17, A-15; Reaffirmed in lieu of Res. 208, A-15; Reaffirmed in lieu of Res. 223, A-15; Reaffirmed: BOT Rep. 07, I-16; Reaffirmed: BOT Rep. 05, I-16; Appended: Res. 227, A-17; Reaffirmed in lieu of: Res. 243, A-17; Modified: BOT Rep. 39, A-18; Reaffirmed: BOT Rep. 45, A-18; Reaffirmed: BOT Rep. 19, A-18; Reaffirmation: A-19;

Hospital Surveys and Health Care Disparities H-450.924

- 1. Our AMA supports that the goal of hospital quality program assessments should be to identify areas to improve patient outcomes and quality of patient care.
- 2. Our AMA recognizes the importance of cultural competency to patient experience and treatment plan adherence and encourage the implementation of cultural competency practices across health care settings.
- 3. Our AMA supports that hospital quality program assessments should account for social risk factors so that they do not have the unintended effect of financially penalizing safety net hospitals and exacerbating health care disparities.
- 4. Our AMA will continue to advocate for better risk models that account for social risk factors in hospital quality program assessments.
- 5. Our AMA will continue to work with CMS and other stakeholders, including representatives of Americas Essential Hospitals, to address issues related to hospital quality program assessments.
- 6. Our AMA opposes hospital quality program assessments that have the effect of financially penalizing physicians, including those practicing in safety net hospitals.

Citation: CMS Rep. 02, I-17; Reaffirmed: CMS Rep. 10, A-19

Sharing Demographic Medicare Data with Other Public Entities by CMS H-330.934

The AMA supports continued provision of aggregate anonymous demographic information to state and local health agencies where its use will promote community health and improve utilization of health care dollars, as long as adequate safeguards to protect individual privacy are preserved.

Citation: Sub. Res. 810, I-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed: CMS Rep. 01, A-16

Accuracy in Racial, Ethnic and Religious Designations in Medical Records H-315.996

The AMA advocates precision in racial, ethnic and religious designations in medical records, with information obtained from the patient, always respecting the personal privacy of the patient. Citation: (Res. 4, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CSA Rep. 8, A-05; Modified: CSAPH Rep. 1, A-15)

Race and Ethnicity as Variables in Medical Research H-460.924

Our AMA policy is that: (1) race and ethnicity are valuable research variables when used and interpreted appropriately;

- (2) health data be collected on patients, by race and ethnicity, in hospitals, managed care organizations, independent practice associations, and other large insurance organizations;
- (3) physicians recognize that race and ethnicity are conceptually distinct;
- (4) our AMA supports research into the use of methodologies that allow for multiple racial and ethnic self-designations by research participants;
- (5) our AMA encourages investigators to recognize the limitations of all current methods for classifying race and ethnic groups in all medical studies by stating explicitly how race and/or ethnic taxonomies were developed or selected;
- (6) our AMA encourages appropriate organizations to apply the results from studies of race-ethnicity and health to the planning and evaluation of health services; and

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(7) our AMA continues to monitor developments in the field of racial and ethnic classification so that it can assist physicians in interpreting these findings and their implications for health care for patients. Citation: CSA Rep. 11, A-98; Appended: Res. 509, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

Reducing Racial and Ethnic Disparities in Health Care D-350.995

Our AMA's initiative on reducing racial and ethnic disparities in health care will include the following recommendations:

- (1) Studying health system opportunities and barriers to eliminating racial and ethnic disparities in health care.
- (2) Working with public health and other appropriate agencies to increase medical student, resident physician, and practicing physician awareness of racial and ethnic disparities in health care and the role of professionalism and professional obligations in efforts to reduce health care disparities.
- (3) Promoting diversity within the profession by encouraging publication of successful outreach programs that increase minority applicants to medical schools, and take appropriate action to support such programs, for example, by expanding the "Doctors Back to School" program into secondary schools in minority communities.

Citation: BOT Rep. 4, A-03; Reaffirmation A-11; Reaffirmation: A-16; Reaffirmed: CMS Rep. 10, A-19

Racial and Ethnic Disparities in Health Care H-350.974

- 1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.
- 2. The AMA emphasizes three approaches that it believes should be given high priority:
- A. Greater access the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.
- B. Greater awareness racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.
- C. Practice parameters the racial disparities in access to treatment indicate that inappropriate considerations may enter the decision-making process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities.
- 3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.
- 4.Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations. Citation: CLRPD Rep. 3, I-98; Appended and Reaffirmed: CSA Rep.1, I-02; Reaffirmed: BOT Rep. 4, A-03; Reaffirmed in lieu of Res. 106, A-12; Appended: Res. 952, I-17; Reaffirmed: CMS Rep. 10, A-19

Resolution: 004

(I-19)

Introduced by: Medical Student Section

Subject: Improving Inclusiveness of Transgender Patients Within Electronic Medical

Record Systems

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Approximately 1.4 million individuals in the United States identify as transgender 1; and

Whereas, 39% of transgender individuals reported experiencing serious psychological distress and 40% reported having attempted suicide in their lifetime ³; and

Whereas, 33% of transgender individuals in a survey identified having at least one negative experience with their healthcare provider in the last year ³; and

Whereas, 28% of transgender individuals reported postponing needed medical care due to fear of discrimination, which contributes to the significant health disparities they experience ⁴; and

Whereas, A majority of transgender men prefer self-sampling, self-collecting vaginal or cervical samples at home, to screen for cervical cancer versus provider-administered Pap smear 5; and

Whereas, Only 49.5% of transgender men have had a Pap smear screening within the past 3 years and 31.9% of transgender men have never had Pap smear screening 5; and

Whereas, Individuals in a study who classified their gender expression as "female" and sex as male were significantly more likely to have routine Pap testing compared with individuals who identified as "transgender," suggesting a discrepancy in Pap smears provided to cisgender women versus transgender individuals⁶; and

Whereas, Transgender individuals may often require specific screenings and considerations, particularly if they have past or current usage of hormone therapy, such as monitoring for diabetes mellitus in transgender women, as they have an increased risk for development of diabetes mellitus while on estrogen therapy 7; and

Whereas, In a transgender woman with an intact prostate, it is recommended to regularly screen for prostate cancer 7; and

Whereas, The World Professional Association for Transgender Health (WPATH) states that sexspecific organ procedures and diagnoses relating to organs such as the penis, testes, vagina, prostate, uterus, etc., should be un-coupled, so that "(as an example) a prostatic ultrasound may be ordered on a patient registered as female, or a cervical pap smear ordered on a patient registered as male" ⁹; and

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Whereas, The US General Accountability Office's Health Information Technology (HIT) Policy
Committee recommended the inclusion of gender ID data in electronic medical records (EMR)
and recent research demonstrates current proposed Systematized Nomenclature in Medicine
(SNOMED) codes do not reflect these recommendations ^{9,10}; and

Whereas, The World Professional Association for Transgender Health (WPATH) executive committee in 2011 recommended demographic variables in EMR include assigned sex at birth, gender identity, and pronoun preference, but these practices remain uncommon in the United States ¹¹; and

Whereas, In a study to determine the extent to which patients' notes in EMR contained transgender-related terms, where ICD codes specific to transgender experience could be verified as a transgender experience could be verified as a transgender patient's using free text searches in the note, 89.3% of patients defined as transgender were identified with transgender-preferred terms^{12,14}; and

Whereas, It was found that diagnostic codes alone were not a significantly sensitive identifier or transgender charts, supporting the need for increased demographic and organ inventory data¹⁵; and

Whereas, Pap smears may be traumatic for transgender patients, and EMR indicating transgender identity and related history can allow the physician and healthcare team to properly care for the individual during a pap smear ⁷; and

Whereas, Research shows mis-gendering and misclassification are psychologically disruptive and are associated with negative affect, negative impact on mental health, and transgender-felt stigma ¹³; and

Whereas, The above data indicates that EMR can have a negative impact on the mental health of transgender individuals due to mis-gendering from EMR that is not fully inclusive of transgender patients; and

Whereas, Based on data stated above, discrepancies in EMR system may contribute to poor health outcomes in transgender individuals; and

Whereas, The World Professional Association for Transgender Health (WPATH) strongly recommends including "preferred name, gender identity, and pronoun preference, as identified by patients," to be included as demographic variables, along with providing a "means to maintain an inventory of a patient's medical transition history and current anatomy" ⁹; and

Whereas, Our AMA believes that the physician's recognition of patients' sexual orientations, sexual behaviors, and gender identities without judgement or bias optimizes patient care in health as well as in illness, and that this recognition is especially important in addressing the specific health care needs of people who are or may be LGBTQ (AMA Policy H.160.991); therefore be it

Page 3 of 4

RESOLVED, That our American Medical Association amend Policy H-315.967, "Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation," by addition and deletion to read as follows:

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Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation, H-315.967

Our AMA: (1) supports the voluntary inclusion of a patient's biological sex. current gender identity, sexual orientation, and preferred gender pronoun(s), preferred name, and an inventory of current anatomy in medical documentation and related forms, including in electronic health records, in a culturally-sensitive and voluntary manner and (2) will advocate for collection of patient data in medical documentation and in medical research studies, according to current best practices, that is inclusive of sexual orientation, gender identity, and other sexual and gender minority traits for the purposes of research into patient and population health; (3) will research the problems related to the handling of sex and gender within health information technology (HIT) products and how to best work with vendors so their HIT products treat patients equally and appropriately, regardless of sexual or gender identity; (4) will investigate the use of personal health records to reduce physician burden in maintaining accurate patient information instead of having to query each patient regarding sexual orientation and gender identity at each encounter; and (5) will advocate for the incorporation of recommended best practices into electronic health records and other HIT products at no additional cost to physicians. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY:

H-160.991 Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations

- 1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
- 2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.
- 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
- 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.

 Citation: CSA Rep. C. I-81: Reaffirmed: CLRPD Rep. F. I-91: CSA Rep. 8 I-94: Appended: Res. 506. A-00:

Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18; Reaffirmed: CSAPH Rep. 01, I-18

H-65.967 Conforming birth certificate policies to current medical standards for transgender patients

- 1. Our AMA supports every individual's right to determine their gender identity and sex designation on government documents and other forms of government identification.
- 2. Our AMA supports policies that allow for a sex designation or change of designation on all government IDs to reflect an individual's gender identity, as reported by the individual and without need for verification by a medical professional.
- 3. Our AMA supports policies that include an undesignated or nonbinary gender option for government records and forms of government-issued identification, which would be in addition to "male" and "female."
- 4. Our AMA supports efforts to ensure that the sex designation on an individual's government-issued documents and identification does not hinder access to medically appropriate care or other social services in accordance with that individual's needs.

Citation: Res. 4, A-13; Appended: BOT Rep. 26, A-14; Modified: Res. 003, A-19

H-315.967 Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation Our AMA: (1) supports the voluntary inclusion of a patient's biological sex, current gender identity, sexual orientation, and preferred gender pronoun(s) in medical documentation and related forms, including in electronic health records, in a culturally-sensitive and voluntary manner; (2) will advocate for collection of patient data in medical documentation and in medical research studies, according to current best practices, that is inclusive of sexual orientation, gender identity, and other sexual and gender minority traits for the purposes of research into patient and population health; (3) will research the problems related to the handling of sex and gender within health information technology (HIT) products and how to best work with vendors so their HIT products treat patients equally and appropriately, regardless of sexual or gender identity; (4) will investigate the use of personal health records to reduce physician burden in maintaining accurate patient information instead of having to query each patient regarding sexual orientation and gender identity at each encounter; and (5) will advocate for the incorporation of recommended best practices into electronic health records and other HIT products at no additional cost to physicians.

Citation: Res. 014, A-18

Resolution: 005

(I-19)

Introduced by: Medical Student Section

Subject: Removing Sex Designation from the Public Portion of the Birth Certificate

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Our AMA believes that the physician's nonjudgmental recognition of patients' gender identities enhances the ability to render optimal patient care (H-160.991) and opposes any efforts to deny an individual's right to determine their stated sex marker or gender identity (H-65.962); and

Whereas, The legal sex designated on the public "upper portion" of a birth certificate by a physician is typically based solely on an external evaluation and if sex cannot be determined it is left blank with no entry; sex is also not recorded on the private "lower portion" of the birth certificate where vital medical data is recorded and reported to public health officials¹⁻³; and

Whereas, The certificate of live birth draws on the information contained in the medical record but is solely a legal document and is not used for patient care^{3,4}; and

Whereas, Analysis of data from 1955-2000 found that up to 1.7% of births in countries including the US, Europe, and to a lesser extent Asia and Africa, deviate in some way from binary sex designation, and therefore are categorized incorrectly as male or female on their birth certificate⁵; and

Whereas, Only 9% of transgender people who want to change the sex designation on their birth certificate actually do so, and 32% of transgender people with an ID who wanted to change the sex did not do so due to cost⁶⁻⁸; and

Whereas, The National Transgender Discrimination Survey found only 24% of transgender people were able to correct the gender marker on their birth certificates, 18% were denied the correction, and 53% had not attempted correction⁸; and

Whereas, A national survey of transgender individuals showed 32% of transgender people were harassed, asked to leave an establishment, or assaulted due to presenting identification that did not match their gender presentation, and 13% were denied coverage for medical services considered to be gender-specific, including routine sexual or reproductive health screenings such as Pap smears, prostate exams, and mammograms^{7,8}; and

Whereas, The process of changing the sex designation on a birth certificate is complex and typically requires legal counsel, adding additional cost and a necessary education level that further disenfranchises the most vulnerable of transgender and intersex people⁸; and

Whereas, "Sexual and gender identity are characterized by fluidity and change," and individuals can and do identify as genders other than male, female, or other, and would not be aided by adding a third catch-all gender or sex category to the birth certificate⁹; and

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- 1 Whereas, The German Constitutional Court recently ruled gender markers may be omitted from
- 2 birth certificates in children who cannot be assigned to a binary male/female sex, and similar
- 3 legislation is being considered in Malta and California¹⁰; therefore be it

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- 5 RESOLVED, That our American Medical Association advocate for the removal of sex as a legal
- 6 designation on the public portion of the birth certificate and that it be visible for medical and
- 7 statistical use only. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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- 7. Grant et al 2011 "Injustice at every turn: A report of the transgender discrimination survey. National Center for Transgender Equality and National Gay and Lesbian Task Force.
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 https://www.bverfg.de/e/rs20171010_1bvr201916en.html

RELEVANT AMA POLICY:

Affirming the Medical Spectrum of Gender H-65.962

Our AMA opposes any efforts to deny an individual's right to determine their stated sex marker or gender identity.

Citation: Res. 005, I-18

Medical Spectrum of Gender D-295.312

Given the medical spectrum of gender identity and sex, Our AMA: (1) Will work with appropriate medical organizations and community based organizations to inform and educate the medical community and the public on the medical spectrum of gender identity; (2) Encourages members to educate state and federal policymakers and legislators on and advocate for policies addressing the medical spectrum of gender identity to ensure access to quality health care; (3) Affirms that an individual's genotypic sex, phenotypic sex, sexual orientation, gender and gender identity are not always aligned or indicative of the other, and that gender for many individuals may differ from the sex assigned at birth.

Citation: Res. 003, A-17; Modified: Res. 005, I-18

Conforming Birth Certificate Policies to Current Medical Standards for Transgender Patients H-65.967

1. Our AMA supports every individual's right to determine their gender identity and sex designation on government documents and other forms of government identification.2. Our AMA supports policies that allow for a sex designation or change of designation on all government IDs to reflect an individual's gender identity, as reported by the individual and without need for verification by a medical professional.3. Our AMA supports policies that include an undesignated or nonbinary gender option for government records and forms of government-issued identification, which would be in addition to "male" and "female."4. Our AMA supports efforts to ensure that the sex designation

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on an individual's government-issued documents and identification does not hinder access to medically appropriate care or other social services in accordance with that individual's needs. Citation: Res. 4, A-13; Appended: BOT Rep. 26, A-14; Modified: Res. 003, A-19

Accuracy, Importance, and Application of Data from the US Vital Statistics System H-85.961 Our AMA encourages physicians to provide complete and accurate information on prenatal care and hospital patient records of the mother and infant, as this information is the basis for the health and medical information on birth certificates.

Citation: (CSA Rep. 6, I-00; Reaffirmed: Sub. Res. 419, A-02; Modified: CSAPH Rep. 1, A-12)

Reducing Suicide Risk Among Lesbian, Gay, Bisexual, Transgender, and Questioning Youth Through Collaboration with Allied Organizations H-60.927

Our AMA will partner with public and private organizations dedicated to public health and public policy to reduce lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth suicide and improve health among LGBTQ youth.

Citation: (Res. 402, A-12)

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients: these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity. 2. Our AMA will collaborate with our partner organizations to educate physicians regarding; (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, gueer/guestioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisqender, heterosexual peers and may have unique complicating factors. 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues. 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.

Citation: CSA Rep. C, I-81; Reaffirmed: CLRPD Rep. F, I-91; CSA Rep. 8 - I-94; Appended: Res. 506, A-00; Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18; Reaffirmed: CSAPH Rep. 01, I-18

Support of Human Rights and Freedom H-65.965

Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual

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capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.

Citation: CCB/CLRPD Rep. 3, A-14; Reaffirmed in lieu of: Res. 001, I-16; Reaffirmation: A-17

Access to Basic Human Services for Transgender Individuals H-65.964

Our AMA: (1) opposes policies preventing transgender individuals from accessing basic human services and public facilities in line with one's gender identity, including, but not limited to, the use of restrooms; and (2) will advocate for the creation of policies that promote social equality and safe access to basic human services and public facilities for transgender individuals according to one's gender identity.

Citation: Res. 010, A-17

Appropriate Placement of Transgender Prisoners H-430.982

- 1. Our AMA supports the ability of transgender prisoners to be placed in facilities, if they so choose, that are reflective of their affirmed gender status, regardless of the prisoner's genitalia, chromosomal make-up, hormonal treatment, or non-, pre-, or post-operative status.
- 2. Our AMA supports that the facilities housing transgender prisoners shall not be a form of administrative segregation or solitary confinement.

Citation: BOT Rep. 24, A-18

Resolution: 006

(I-19)

Introduced by: Medical Student Section

Subject: Transparency Improving Informed Consent for Reproductive Health Services

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Federal regulations passed by Health and Human Services in 2018 and state laws allow organizations to refuse coverage and services for contraceptives and infertility care mandated in the Affordable Care Act^{1,2}; and

Whereas, Institutional obligations under those refusals impinge on a physician's ability to follow standard of care in consulting and providing reproductive health services³; and

Whereas, American College of Obstetricians and Gynecology (ACOG) guidelines state that physicians are obligated to inform patients of their prior personal moral commitments and refer patients to other providers in cases of moral or religious objection for management, medication, or surgical evacuation^{4,5}; and

Whereas, The American Medical Association advocates for transparency when best practice medical care may conflict with a physician's or their institution's commitments; which is not currently occurring according to a recent national survey of obstetricians and gynecologists showing that 35% of non-abortion providers would not provide a referral to a different institution for the service; and

Whereas, Reproductive healthcare access is vital to the health and well-being of both the mother and her child given that mis-timed pregnancies are associated with poor or delayed prenatal care, negative birth outcomes, Sexually Transmitted Infections (STIs) and cervical cancer of the mother^{8,9}; and

Whereas, Contraceptive care has applications beyond family planning: improving patient safety when given in conjunction with teratogenic medications, protecting women who have significant likelihood of mortality with pregnancy, or during teratogenic disease outbreaks like the 2016 Zika Virus ^{10, 11}; and

Whereas, Emergency contraception is widely utilized as 28.4% of women of reproductive age in the United States have used emergency contraceptives¹²; and

Whereas, Public expenditures on family planning services save seven dollars on future expenditures for each dollar spent on these measures by reducing the incidence of preterm and low birth weight births, STIs, infertility, and cervical cancer¹³; and

Whereas, Infertility services including In-Vitro Fertilization (IVF) and ova/sperm retrieval service availability varies significantly between states, insurance policies, and hospital systems¹⁴; and

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Whereas, Studies have shown patients are "in dire need of positive rights to information about and services to avoid the potential gap in care" which non-transparent clinical policies present, similar to the Medicare overhauls currently underway for price transparency¹⁵; therefore be it

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RESOLVED, That our American Medical Association work with relevant stakeholders to establish a list of Essential Reproductive Health Services (Directive to Take Action); and be it further

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- RESOLVED, That our AMA advocate for legislation requiring healthcare organizations to clearly publish online and in points of service which Essential Reproductive Health Services are
- available at the organization along with any restrictions on Essential Reproductive Health
- 12 Services at the institution, and include referral information to patients of other providers that
- 13 cover the services within the same coverage area. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Truth and Transparency in Pregnancy Counseling Centers H-420.954

1. Our AMA supports that any entity offering crisis pregnancy services disclose information on site, in its advertising, and before any services are provided concerning the medical services, contraception, termination of pregnancy or referral for such services, adoption options or referral for such services that it provides; and be it further

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2. Our AMA advocates that any entity providing medical or health services to pregnant women that markets medical or any clinical services abide by licensing requirements and have the appropriate qualified licensed personnel to do so and abide by federal health information privacy laws.

Citation: (Res. 7, I-11)

Access to Emergency Contraception D-75.997

1. Our AMA will: (a) intensify efforts to improve awareness and understanding about the availability of emergency contraception in the general public; and (b) support and monitor the application process of manufacturers filing for over-the-counter approval of emergency contraception pills with the Food and Drug Administration (FDA).

2. Our AMA: (a) will work in collaboration with other stakeholders (such as American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American College of Preventive Medicine) to communicate with the National Association of Chain Drug Stores and the National Community Pharmacists Association, and request that pharmacies utilize their web site or other means to signify whether they stock and dispense emergency contraception, and if not, where it can be obtained in their region, either with or without a prescription; and (b) urges that established emergency contraception regimens be approved for over-the-counter access to women of reproductive age, as recommended by the relevant medical specialty societies and the US Food and Drug Administration's own expert panel.

Reducing Unintended Pregnancy H-75.987

Our AMA: (1) urges health care professionals to provide care for women of reproductive age, to assist them in planning for pregnancy and support age-appropriate education in esteem building, decision-making and family life in an effort to introduce the concept of planning for childbearing in the educational process; (2) supports reducing unintended pregnancies as a national goal; and (3) supports the training of all primary care physicians and relevant allied health professionals in the area of preconception counseling, including the recognition of long-acting reversible contraceptives as efficacious and economical forms of contraception.

Citation: CMS Rep. 1, A-00; Appended: Res. 506, A-07; Reaffirmed: CMS Rep. 01, A-17;

AMA Principles for Physician Employment H-225.950

- 1. Addressing Conflicts of Interest
- a) A physician's paramount responsibility is to his or her patients. Additionally, given that an employed physician occupies a position of significant trust, he or she owes a duty of loyalty to his or her employer. This divided loyalty can create conflicts of interest, such as financial incentives to over- or under-treat patients, which employed physicians should strive to recognize and address.
- b) Employed physicians should be free to exercise their personal and professional judgement in voting, speaking and advocating on any manner regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment. Employed physicians should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. Employed physicians also should enjoy academic freedom to pursue clinical research and other academic pursuits within the ethical principles of the medical profession and the guidelines of the organization.
- c) In any situation where the economic or other interests of the employer are in conflict with patient welfare, patient welfare must take priority.
- d) Physicians should always make treatment and referral decisions based on the best interests of their patients. Employers and the physicians they employ must assure that agreements or understandings (explicit or implicit) restricting, discouraging, or encouraging particular treatment or referral options are disclosed to patients.
- (i) No physician should be required or coerced to perform or assist in any non-emergent procedure that would be contrary to his/her religious beliefs or moral convictions; and
- (ii) No physician should be discriminated against in employment, promotion, or the extension of staff or other privileges because he/she either performed or assisted in a lawful, non-emergent procedure, or refused to do so on the grounds that it violates his/her religious beliefs or moral convictions.
- e) Assuming a title or position that may remove a physician from direct patient-physician relationships--such as medical director, vice president for medical affairs, etc.--does not override professional ethical obligations. Physicians whose actions serve to override the individual patient care decisions of other physicians are themselves engaged in the practice of medicine and are subject to professional ethical obligations and may be legally responsible for such decisions. Physicians who hold administrative leadership positions should use whatever administrative and governance mechanisms exist within the organization to foster policies that enhance the quality of patient care and the patient care experience.

Refer to the AMA Code of Medical Ethics for further guidance on conflicts of interest.

- 2. Advocacy for Patients and the Profession
- a) Patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the health care system or setting in which physicians practice, or the methods by which they are compensated.

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b) Employed physicians should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.

3. Contracting

- a) Physicians should be free to enter into mutually satisfactory contractual arrangements, including employment, with hospitals, health care systems, medical groups, insurance plans, and other entities as permitted by law and in accordance with the ethical principles of the medical profession.
- b) Physicians should never be coerced into employment with hospitals, health care systems, medical groups, insurance plans, or any other entities. Employment agreements between physicians and their employers should be negotiated in good faith. Both parties are urged to obtain the advice of legal counsel experienced in physician employment matters when negotiating employment contracts.
- c) When a physician's compensation is related to the revenue he or she generates, or to similar factors, the employer should make clear to the physician the factors upon which compensation is based.
- d) Termination of an employment or contractual relationship between a physician and an entity employing that physician does not necessarily end the patient-physician relationship between the employed physician and persons under his/her care. When a physician's employment status is unilaterally terminated by an employer, the physician and his or her employer should notify the physician's patients that the physician will no longer be working with the employer and should provide them with the physician's new contact information. Patients should be given the choice to continue to be seen by the physician in his or her new practice setting or to be treated by another physician still working with the employer. Records for the physician's patients should be retained for as long as they are necessary for the care of the patients or for addressing legal issues faced by the physician; records should not be destroyed without notice to the former employee. Where physician possession of all medical records of his or her patients is not already required by state law, the employment agreement should specify that the physician is entitled to copies of patient charts and records upon a specific request in writing from any patient, or when such records are necessary for the physician's defense in malpractice actions, administrative investigations, or other proceedings against the physician.
- (e) Physician employment agreements should contain provisions to protect a physician's right to due process before termination for cause. When such cause relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff, the physician should be afforded full due process under the medical staff bylaws, and the agreement should not be terminated before the governing body has acted on the recommendation of the medical staff. Physician employment agreements should specify whether or not termination of employment is grounds for automatic termination of hospital medical staff membership or clinical privileges. When such cause is non-clinical or not otherwise a concern of the medical staff, the physician should be afforded whatever due process is outlined in the employer's human resources policies and procedures.
- (f) Physicians are encouraged to carefully consider the potential benefits and harms of entering into employment agreements containing without cause termination provisions. Employers should never terminate agreements without cause when the underlying reason for the termination relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff.
- (g) Physicians are discouraged from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment.
- (h) Physician employment agreements should contain dispute resolution provisions. If the parties desire an alternative to going to court, such as arbitration, the contract should specify the manner in which disputes will be resolved.

Refer to the AMA Annotated Model Physician-Hospital Employment Agreement and the AMA Annotated Model Physician-Group Practice Employment Agreement for further guidance on physician employment contracts.

- 4. Hospital Medical Staff Relations
- a) Employed physicians should be members of the organized medical staffs of the hospitals or health systems with which they have contractual or financial arrangements, should be subject to the bylaws of those medical staffs, and should conduct their professional activities according to the bylaws, standards, rules, and regulations and policies adopted by those medical staffs.
- b) Regardless of the employment status of its individual members, the organized medical staff remains responsible for the provision of quality care and must work collectively to improve patient care and outcomes.
- c) Employed physicians who are members of the organized medical staff should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter regarding medical staff matters and should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests.
- d) Employers should seek the input of the medical staff prior to the initiation, renewal, or termination of exclusive employment contracts.

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Refer to the AMA Conflict of Interest Guidelines for the Organized Medical Staff for further guidance on the relationship between employed physicians and the medical staff organization.

- 5. Peer Review and Performance Evaluations
- a) All physicians should promote and be subject to an effective program of peer review to monitor and evaluate the quality, appropriateness, medical necessity, and efficiency of the patient care services provided within their practice settings.
- b) Peer review should follow established procedures that are identical for all physicians practicing within a given health care organization, regardless of their employment status.
- c) Peer review of employed physicians should be conducted independently of and without interference from any human resources activities of the employer. Physicians--not lay administrators--should be ultimately responsible for all peer review of medical services provided by employed physicians.
- d) Employed physicians should be accorded due process protections, including a fair and objective hearing, in all peer review proceedings. The fundamental aspects of a fair hearing are a listing of specific charges, adequate notice of the right to a hearing, the opportunity to be present and to rebut evidence, and the opportunity to present a defense. Due process protections should extend to any disciplinary action sought by the employer that relates to the employed physician's independent exercise of medical judgment.
- e) Employers should provide employed physicians with regular performance evaluations, which should be presented in writing and accompanied by an oral discussion with the employed physician. Physicians should be informed before the beginning of the evaluation period of the general criteria to be considered in their performance evaluations, for example: quality of medical services provided, nature and frequency of patient complaints, employee productivity, employee contribution to the administrative/operational activities of the employer, etc.
- (f) Upon termination of employment with or without cause, an employed physician generally should not be required to resign his or her hospital medical staff membership or any of the clinical privileges held during the term of employment, unless an independent action of the medical staff calls for such action, and the physician has been afforded full due process under the medical staff bylaws. Automatic rescission of medical staff membership and/or clinical privileges following termination of an employment agreement is tolerable only if each of the following conditions is met:
- i. The agreement is for the provision of services on an exclusive basis; and
- ii. Prior to the termination of the exclusive contract, the medical staff holds a hearing, as defined by the medical staff and hospital, to permit interested parties to express their views on the matter, with the medical staff subsequently making a recommendation to the governing body as to whether the contract should be terminated, as outlined in AMA Policy H-225.985; and
- iii. The agreement explicitly states that medical staff membership and/or clinical privileges must be resigned upon termination of the agreement.

Refer to the AMA Principles for Incident-Based Peer Review and Disciplining at Health Care Organizations (AMA Policy H-375.965) for further guidance on peer review.

- 6. Payment Agreements
- a) Although they typically assign their billing privileges to their employers, employed physicians or their chosen representatives should be prospectively involved if the employer negotiates agreements for them for professional fees, capitation or global billing, or shared savings. Additionally, employed physicians should be informed about the actual payment amount allocated to the professional fee component of the total payment received by the contractual arrangement.
- b) Employed physicians have a responsibility to assure that bills issued for services they provide are accurate and should therefore retain the right to review billing claims as may be necessary to verify that such bills are correct. Employers should indemnify and defend, and save harmless, employed physicians with respect to any violation of law or regulation or breach of contract in connection with the employer's billing for physician services, which violation is not the fault of the employee.

Citation: BOT Rep. 6, I-12; Reaffirmed: CMS Rep. 6, I-13; Modified in lieu of Res. 2, I-13; Modified: Res. 737, A-14; Reaffirmed: BOT Rep. 21, A-16; Reaffirmed: CMS Rep. 05, A-17; Reaffirmed: CMS Rep. 07, A-19; Reaffirmed: CMS Rep. 11, A-19; Modified: BOT Rep. 13, A-19

Increasing Availability and Coverage for Immediate Postpartum Long-Acting Reversible Contraceptive Placement H-75.984

1. Our AMA: (a) recognizes the practice of immediate postpartum and post pregnancy long-acting reversible contraception placement to be a safe and cost effective way of reducing future unintended pregnancies; and (b) supports the coverage by Medicaid, Medicare, and private insurers for immediate postpartum long-acting reversible contraception devices and placement, and that these be billed separately from the obstetrical global fee.

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2. Our AMA encourages relevant specialty organizations to provide training for physicians regarding (a) patients who are eligible for immediate postpartum long-acting reversible contraception, and (b) immediate postpartum long-acting reversible contraception placement protocols and procedures.

Citation: Res. 101, A-16

Abortion H-5.995

Our AMA reaffirms that: (1) abortion is a medical procedure and should be performed only by a duly licensed physician and surgeon in conformance with standards of good medical practice and the Medical Practice Act of his state; and (2) no physician or other professional personnel shall be required to perform an act violative of good medical judgment. Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally held moral principles. In these circumstances, good medical practice requires only that the physician or other professional withdraw from the case, so long as the withdrawal is consistent with good medical practice. Citation: (Sub. Res. 43, A-73; Reaffirmed: I-86; Reaffirmed: Sunset Report, I-96; Reaffirmed by Sub. Res. 208, I-96; Reaffirmed by BOT Rep. 26, A-97; Reaffirmed: CMS Rep. 1, I-00; Reaffirmed: CEJA Rep. 6, A-10)

Policy on Abortion H-5.990

The issue of support of or opposition to abortion is a matter for members of the AMA to decide individually, based on personal values or beliefs. The AMA will take no action which may be construed as an attempt to alter or influence the personal views of individual physicians regarding abortion procedures.

Citation: Res. 158, A-90; Reaffirmed by Sub. Res. 208, I-96; Reaffirmed by BOT Rep. 26, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: Res. 1, A-09; Reaffirmed: CEJA Rep. 03, A-19

Increasing Transparency of Hospital Contracts for Clinical and Non-Clinical Services H-215.963

- 1. Our AMA encourage hospitals to publicly disclose the following parameters of their contracts for the delivery of clinical and non-clinical services:
- (a) The entity with which the hospital has contracted;
- (b) The ownership of the entity with which the hospital has contracted;
- (c) What services are being provided in accordance with the contract;
- (d) Which entity owners, if any, serve on any of the hospital's boards or its affiliates' boards; and
- (e) Whether the hospital requires exclusive physician referrals to hospital subsidiaries for services.
- 2. AMA policy is that the organized medical staffs have an opportunity to be involved in the selection of clinical and non-clinical service providers in hospitals with adherence to appropriate conflict of interest policies. Citation: BOT Rep. 2, A-09; Reaffirmed: CMS Rep. 01, A-19

Price Transparency D-155.987

- 1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible.
- 2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
- 3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide.
- 4. Our AMA will work with states to support and strengthen the development of all-payer claims databases.
- 5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients.
- 6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
- 7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments. Citation: CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed in lieu of: Res. 213, I-17; Reaffirmed: BOT Rep. 14, A-18; Reaffirmed in lieu of: Res. 112, A-19

Resolution: 007

(I-19)

Introduced by: Medical Student Section

Subject: Addressing the Racial Pay Gap in Medicine

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, The Civil Rights Act prohibits discrimination based on race, color, religion, sex, or national origin¹; and

Whereas, The racial wage gap persists across the labor market in the United States, meaning that people of color earn less than their white counterparts in the same professions, conducting the same work, with the same education and experience²; and

Whereas, The Bureau of Labor Statistics reports that in 1979 black men earned 80% of what white men earned, whereas in 2016 black men earned 70% of what white men earn, suggesting a worsening of the racial pay gap³; and

Whereas, The American College of Physicians has shown that after controlling for age, sex, race, hours worked, and state of residence, Black physicians made \$194,444 annually, compared to \$228,585 for White physicians – a difference of \$34,1414; and

Whereas, Black male physicians earn substantially less than white male physicians after adjustment for physician specialty practice characteristics, age, and hours worked; and black female physicians earn even less than their black male counterpart with adjustments accounting for characteristics of physician and practice⁵; and

Whereas, White female physicians made 19 percent and Black female physicians made 29 percent less than their white male counterparts after controlling for hours worked, years of practice, practice ownership status, board certification status, IMG status, type of degree, demographics of practice, and proportion of Medicare and Medicaid patients⁵; and

Whereas, Black male physicians are more likely to work in primary care and to treat Medicaid patients compared with white male physicians, adjustment for these and other practice characteristics, does not eliminate, or even significantly reduce, the estimated differences in earnings⁵; and

Whereas, A study of 128 academic medical centers found that Black or Hispanic faculty constituted only 5% of new academic hires and had significantly longer promotion timelines when compared to their white counterparts, after factors such as gender, tenure status, degree, and NIH award status were adjusted for. Underrepresented minority (URM) faculty were still less likely to be promoted at all levels⁶; therefore be it

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RESOLVED, That our American Medical Association support measures of racial pay awareness 1 2 and the specific challenges that minority physicians face in regards to equal pay financial 3

attainment (New HOD Policy); and be it further

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RESOLVED, That our AMA support efforts to increase the transparency and accountability of

physician earnings through establishing transparency measures, in which physicians can

access information including but not limited to the salaries and race of medical physicians. (New

8 **HOD Policy**)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

References:

1. Civil Rights Act of 1964, Pub.L. 88-352, 78 Stat. 241 (1964)

- Treadwell HM. Wages and Women in Health Care: The Race and Gender Gap. Am J Public Health. 2019;109(2):208-209. doi:10.2105/AJPH.2018.304866
- 3. Bureau of Labor Statistics https://www.bls.gov/opub/mlr/2017/beyond-bls/the-unexplainable-growing-black-white-wage-gap.htm
- 4. Grisham, Sarah. "Medscape Physician Compensation Report 2017. "Medscape. April 5, 2017. Accessed August 23, 2017. http://www.medscape.com/slideshow/compensation-2017-overview-6008547#1
- 5. Ly DP, Seabury SA, Jena AB. Differences in incomes of physicians in the United States by race and sex: observational study. BMJ. 2016;353:i2923.[Differences in incomes of physicians in the United States by race and sex: observational study https://www.bmj.com/content/353/bmj.i2923]
- 6. Nunez-smith M, Ciarleglio MM, Sandoval-schaefer T, et al. Institutional variation in the promotion of racial/ethnic minority faculty at US medical schools. Am J Public Health. 2012;102(5):852-8.

RELEVANT AMA POLICY

Increase the Representation of Minority and Economically Disadvantaged Populations in the Medical Profession H-350.979

- 1. Our AMA supports increasing the representation of minorities in the physician population by:
- (1) Supporting efforts to increase the applicant pool of qualified minority students by: (a) Encouraging state and local governments to make quality elementary and secondary education opportunities available to all: (b) Urging medical schools to strengthen or initiate programs that offer special premedical and precollegiate experiences to underrepresented minority students; (c) urging medical schools and other health training institutions to develop new and innovative measures to recruit underrepresented minority students, and (d) Supporting legislation that provides targeted financial aid to financially disadvantaged students at both the collegiate and medical school levels. (2). Encouraging all medical schools to reaffirm the goal of increasing representation of underrepresented minorities in their student bodies and faculties.
- (3) Urging medical school admission committees to consider minority representation as one factor in reaching their decisions.
- (4) Increasing the supply of minority health professionals.
- (5) Continuing its efforts to increase the proportion of minorities in medical schools and medical school faculty.
- (6) Facilitating communication between medical school admission committees and premedical counselors concerning the relative importance of requirements, including grade point average and Medical College Aptitude Test scores.
- (7) Continuing to urge for state legislation that will provide funds for medical education both directly to medical schools and indirectly through financial support to students.
- (8) Continuing to provide strong support for federal legislation that provides financial assistance for able students whose financial need is such that otherwise they would be unable to attend

Citation: CLRPD Rep. 3, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Reaffirmed: CME Rep. 01, A-18

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Revisions to AMA Policy on the Physician Workforce H-200.955 It is AMA policy that:

(1) any workforce planning efforts, done by the AMA or others, should utilize data on all aspects of the health care system, including projected demographics of both providers and patients, the number and roles of other health professionals in providing care, and practice environment changes. Planning should have as a goal appropriate physician numbers, specialty mix, and geographic distribution.

- (2) Our AMA encourages and collaborates in the collection of the data needed for workforce planning and in the conduct of national and regional research on physician supply and distribution. The AMA will independently and in collaboration with state and specialty societies, national medical organizations, and other public and private sector groups, compile and disseminate the results of the research.
- (3) The medical profession must be integrally involved in any workforce planning efforts sponsored by federal or state governments, or by the private sector.
- (4) In order to enhance access to care, our AMA collaborates with the public and private sectors to ensure an adequate supply of physicians in all specialties and to develop strategies to mitigate the current geographic maldistribution of physicians.
- (5) There is a need to enhance underrepresented minority representation in medical schools and in the physician workforce, as a means to ultimately improve access to care for minority and underserved groups.
- (6) There should be no decrease in the number of funded graduate medical education (GME) positions. Any increase in the number of funded GME positions, overall or in a given specialty, and in the number of US medical students should be based on a demonstrated regional or national need.
- (7) Our AMA will collect and disseminate information on market demands and workforce needs, so as to assist medical students and resident physicians in selecting a specialty and choosing a career.
- (8) Our AMA will encourage the Health Resources & Service Administration to collaborate with specialty societies to determine specific changes that would improve the agencys physician workforce projections process, to potentially include more detailed projection inputs, with the goal of producing more accurate and detailed projections including specialty and subspecialty workforces.
- (9) Our AMA will consider physician retraining during all its deliberations on physician workforce planning.

Citation: CME Rep. 2, I-03; Reaffirmation I-06; Reaffirmation I-07; Reaffirmed: CME Rep. 15, A-10; Reaffirmation: I-12; Reaffirmation A-13; Appended: Res. 324, A-17; Appended: CME Rep. 01, A-19

Resolution: 009

(1-19)

Introduced by: Jerry Halverson, MD; Shannon Kilgore, MD; Meridith Englander, MD;

Hugh Taylor, MD; Steven Chen, MD; Adam Rubin, MD; David Tayloe, MD;

Stuart Glassman, MD; Delegates

Subject: Data for Specialty Society Five-Year Review

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Policy G-600.020, "Admission of Specialty Organizations to our AMA House of Delegates," establishes the guidelines for evaluating specialty society applications and five-year review submissions; and

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> Whereas, The policy focuses on the physician membership of specialty societies and AMA policy defines physicians as those possessing the degree of Doctor of Medicine or Doctor of Osteopathy (Policies H-405.951, H-405.969 and D-405.991); and

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Whereas, Specialty organizations establish their own rules determining who within their membership will have full voting privileges and is eligible to hold office, allowing different organizations to report different categories of members to the AMA for the five-year review process thus impacting delegate apportionment under Bylaw 2.2 (G-600.027); and

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Whereas, The requirement that an "organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges, and are eligible to hold office" is not always clear as to who should be counted and leads to many inquiries, suggesting that societies are interpreting the requirement differently; and

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Whereas, Most of the confusion of who can be counted by the AMA is around who can hold office and what that means, and who can vote and what they can vote for/on; therefore be it

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RESOLVED, That American Medical Association policy G-600.020, "Admission of Specialty Organizations to our AMA House," item 6, be amended by addition and deletion to read as follows:

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The organization must have a voluntary membership and must report as members only those physician members who are current in payment of applicable dues, have full voting privileges, and eligible to serve on committees or the governing body hold office. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/01/19

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RELEVANT AMA POLICY

Admission of Specialty Organizations to our AMA House G-600.020

The following guidelines shall be utilized in evaluating specialty society applications for representation in our AMA House of Delegates (new specialty organization applications will be considered only at Annual Meetings of the House of Delegates):(1) The organization must not be in conflict with the Constitution and Bylaws of our AMA with regard to discrimination in membership; (2) The organization must: (a) represent a field of medicine that has recognized scientific validity; (b) not have board certification as its primary focus; and (c) not require membership in the specialty organization as a requisite for board certification; (3) The organization must meet one of the following criteria: (a) a specialty organization must demonstrate that it has 1,000 or more AMA members; or (b) a specialty organization must demonstrate that it has a minimum of 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or (c) a specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; (4) The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application; (5) Physicians should comprise the majority of the voting membership of the organization; (6) The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges, and are eligible to hold office; (7) The organization must be active within its field of medicine and hold at least one meeting of its members per year; (8) The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states; (9) The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization; (10) If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

CLRPD Rep. A, A-87CLRPD Rep. D, I-90CLRPD Rep. B, I-91Modified: CLRPD Rep. 2, I-97Modfied: CLRPD Rep. 3, A-00Consolidated: CLRPD Rep. 3, I-01Reaffirmed: CLRPD Rep. 2, A-05BOT Rep. 6, I-08Modified: CCB/CLRPD Rep. 3, A-12Modified: BOT Rep. 1, I-12

Definition and Use of the Term Physician H-405.951

Our AMA: 1. Affirms that the term physician be limited to those people who have a Doctor of Medicine, Doctor of Osteopathic Medicine, or a recognized equivalent physician degree and who would be eligible for an Accreditation Council for Graduate Medical Education (ACGME) residency. 2. Will, in conjunction with the Federation, aggressively advocate for the definition of physician to be limited as defined above: a. In any federal or state law or regulation including the Social Security Act or any other law or regulation that defines physician; b. To any federal and state legislature or agency including the Department of Health and Human Services, Federal Aviation Administration, the Department of Transportation, or any other federal or state agency that defines physician; and c. To any accrediting body or deeming authority including the Joint Commission, Health Facilities Accreditation Program, or any other potential body or authority that defines physician. 3. Urges all physicians to insist on being identified as a physician, to sign only those professional or medical documents identifying them as physicians, and to not let the term physician be used by any other organization or person involved in health care. 4. Ensure that all references to physicians by government, payers, and other health care entities involving contracts, advertising, agreements, published descriptions, and other communications at all times distinguish between physician, as defined above, and nonphysicians and to discontinue the use of the term provider. 5. Policy requires any individual who has direct patient contact and presents to the patient as a doctor, and who is not a physician, as defined above, must specifically and simultaneously declare themselves a non-physician and

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define the nature of their doctorate degree. 6. Will review and revise its own publications as necessary to conform with the House of Delegates' policies on physician identification and physician reference and will refrain from any definition of physicians as providers that is not otherwise covered by existing Journal of the American Medical Association (JAMA) Editorial Governance Plan, which protects the editorial independence of JAMA. 7. Actively supports the Scope of Practice Partnership in the Truth in Advertising campaign. Res. 214, A-19

Definition of a Physician H-405.969

1. The AMA affirms that a physician is an individual who has received a "Doctor of Medicine" or a "Doctor of Osteopathic Medicine" degree or an equivalent degree following successful completion of a prescribed course of study from a school of medicine or osteopathic medicine. 2. AMA policy requires anyone in a hospital environment who has direct contact with a patient who presents himself or herself to the patient as a "doctor," and who is not a "physician" according to the AMA definition above, must specifically and simultaneously declare themselves a "non-physician" and define the nature of their doctorate degree. 3. Our AMA actively supports the Scope of Practice Partnership in the Truth in Advertising campaign. CME Rep. 4-A-94, Reaffirmed by Sub. Res. 712, I-94, Reaffirmed and Modified: CME Rep. 2, A-04, Res. 846, I-08, Reaffirmed in lieu or Res. 235, A-09, Reaffirmed: Res. 821, I-09, Appended: BOT Rep. 9, I-09, Reaffirmed: BOT Rep. 9, I-11, Reaffirmation A-13, Reaffirmation A-15, Reaffirmed in lieu of: Res. 225, A-17, Reaffirmed: Res. 228, A-19.

Clarification of the Title "Doctor" in the Hospital Environment D-405.991

1. Our AMA Commissioners will, for the purpose of patient safety, request that The Joint Commission develop and implement standards for an identification system for all hospital facility staff who have direct contact with patients which would require that an identification badge be worn which indicates the individual's name and credentials as appropriate (i.e., MD, DO, RN, LPN, DC, DPM, DDS, etc), to differentiate between those who have achieved a Doctorate, and those with other types of credentials. 2. Our AMA Commissioners will, for the purpose of patient safety, request that The Joint Commission develop and implement new standards that require anyone in a hospital environment who has direct contact with a patient who presents himself or herself to the patient as a "doctor," and who is not a "physician" according to the AMA definition (H-405.969, ?that a physician is an individual who has received a "Doctor of Medicine" or a "Doctor of Osteopathic Medicine" degree or an equivalent degree following successful completion of a prescribed course of study from a school of medicine or osteopathic medicine?) must specifically and simultaneously declare themselves a "non-physician" and define the nature of their doctorate degree. 3. Our AMA will request the American Osteopathic Association (AOA) to (1) expand their standards to include proper identification of all medical staff and hospital personnel with their applicable credential (i.e., MD, DO, RN, LPN, DC, DPM, DDS, etc), and (2) Require anyone in a hospital environment who has direct contact with a patient presenting himself or herself to the patient as a "doctor", who is not a "Physician" according to the AMA definition (AMA Policy H-405.969 .. that a physician is an individual who has received a "Doctor of Medicine" or a "Doctor of Osteopathic Medicine" degree or an equivalent degree following successful completion of a prescribed course of study from a school of medicine or osteopathic medicine) must specifically and simultaneously declare themselves a "nonphysician" and define the nature of their doctorate degree.

Res. 846, I-08, Modified: BOT Rep. 9, I-09, Reaffirmed: Res. 218, A-12

National Medical Specialty Organizations. B-2.2

2.2 National Medical Specialty Societies. The number of delegates representing national medical specialty societies shall equal the number of delegates representing the constituent societies. Each national medical specialty society granted representation in the House of

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Delegates is entitled to delegate representation based on the number of seats allocated to it by apportionment, and such additional delegate seat as may be provided under Bylaw 2.2.2. The total number of delegates apportioned to national medical specialty societies under Bylaw 2.2.1 shall be adjusted to be equal to the total number of delegates apportioned to constituent societies under sections 2.1.1 and 2.1.1.1.1 using methods specified in AMA policy. 2.2.1 Apportionment. The apportionment of delegates from each specialty society represented in the AMA House of Delegates is one delegate for each 1,000, or fraction thereof, specialty society members as of December 31 of each year who have full voting privileges, are eligible to hold office in that society, are active members of the AMA and are members in good standing of both the specialty society and the AMA. The delegates eligible for seating in the House of Delegates by apportionment are in addition to the additional delegate and alternate delegate authorized for unified specialty societies meeting the requirements of **Bylaw** 2.2.2. 2.2.1.1 Effective Date. Such apportionment shall take effect on January 1 of the following year and shall remain effective for one year. 2.2.2 Additional Delegate. A specialty society that has adopted and implemented bylaw provisions requiring unified membership is entitled to one additional delegate. If during any calendar year the specialty society adopts bylaw provisions requiring unified membership, and such unified membership is to be fully implemented within the following calendar year, the specialty society shall be entitled to the additional delegate. The specialty society shall retain the additional delegate only if the membership information recorded by the AMA as of each subsequent December 31 confirms that all of the specialty society's members are members of the AMA. 2.2.3 Selection. Each specialty society shall select and adjust the number of delegates to conform with the number of seats authorized under this bylaw. 2.2.4 Certification. The president or secretary of each specialty society shall certify to the AMA the delegates and alternate delegates from their respective societies. Certification must occur at least 30 days prior to the Annual or Interim Meeting of the House of Delegates. 2.2.5 Term. Delegates from specialty societies shall be selected for 2-year terms, and shall assume office on the date set by the specialty society provided that such seats are authorized pursuant to these Bylaws. Specialty societies entitled to more than one delegate shall select them so that half the number, as near as may be, are selected each year. One-year terms may be provided but only to the extent and for such time as is necessary to accomplish this proportion. 2.2.6 Vacancies. The delegate selected to fill a vacancy shall assume office immediately after selection and serve for the remainder of that term.

Designation of Specialty Societies for Representation in the House of Delegates G-600.027

1. Specialty society delegate allocation in the House of Delegates will be determined so that the total number of national specialty society delegates shall be equal to the total number of delegates apportioned to constituent societies under section 2.1.1 (and subsections thereof) of AMA bylaws, and will be distributed based on the latest available membership data for each society, which is generally from the society's most recent five year review, but may be determined annually at the society's request. 2. Specialty society delegate allocation will be determined annually, based on the latest available membership data, using a two-step process: (a) First, the number of delegates per specialty society will be calculated as one delegate per 1,000 AMA members in that society, or fraction thereof. (i) At the time of this calculation, any specialty society that has applied for representation in the HOD, and has met SSS criteria for representation, will be apportioned delegates in anticipation of its formal acceptance to the HOD at the subsequent Annual Meeting. Should the society not be accepted, the delegate seat(s) apportioned to that society will remain vacant until the apportionment of delegates occurs the following year. (b) Second, the total number of specialty society delegates will be adjusted up or down to equal the number of delegates allocated to constituent societies. (i) Should the calculated total number of specialty society delegates be fewer than the total number of delegates allocated to constituent societies, additional delegates will be apportioned, one each,

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to those societies that are numerically closest to qualifying for an additional delegate, until the total number of national specialty society delegates equals the number of constituent society delegates. (ii) Should the calculated total number of specialty society delegates be greater than the number of delegates allocated to constituent societies, then the excess delegates will be removed, one each, from those societies numerically closest to losing a delegate, until the total number of national specialty society delegates equals the number of constituent society delegates. (iii) In the case of a tie, the previous year's data will be used as a tie breaker. In the case of an additional delegate being necessary, the society that was closest to gaining a delegate in the previous year will be awarded the delegate. In the case of a delegate reduction being necessary, the society that was next closest to losing a delegate in the previous year will lose a delegate. 3. Should a specialty society lose representation during a meeting of the HOD, the delegate seat(s) apportioned to that society will remain vacant until the apportionment of delegates occurs the following year.

BOT Rep. 06, I-16, Modified: CLRPD Rep. 01, A-17, Modified: Speakers Rep., I-17, Modified: Speakers Rep., A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 010

(I-19)

Introduced by: Michigan

Subject: Ban Conversion Therapy of LGBTQ Youth

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Conversion or reparative therapy is any individual or group therapy in inpatient or outpatient settings that attempts to change an individual's sexual orientation; and

Whereas, It is estimated that 350,000 adolescents have undergone conversion therapy, and that as many as 40,000 adolescents in the United States will undergo conversion therapy this year; and

Whereas, Behavioral therapists have practiced aversion therapy by submitting patients to physical harm such as electric shocks, nausea, vomiting, or paralysis, or encouraging the patient to self-harm when they become aroused by the same sex; and

Whereas, Individuals who have undergone conversion therapy have subsequently experienced adverse consequences including increased risk of suicide, poor self-esteem, depression and social withdrawal and were more likely to develop impotence and sexual dysfunction; and

Whereas, Lesbian, gay, bisexual, transgender and questioning (LGBTQ) youth are five times more likely to attempt suicide compared to heterosexual youth; and

 Whereas, The nation's leading professional medical, health, and mental health organizations do not support efforts to change young people's sexual orientation through therapy and have raised serious concerns about the potential harm from such efforts, according to a publication endorsed by the American Academy of Pediatrics, American Association of School Administrators, American Counseling Association, American Federation of Teachers, American Psychological Association, American School Counselor Association, American School Health Association, Interfaith Alliance Foundation, National Association of School Psychologists, National Association of Secondary School Principals, National Association of Social Workers, National Education Association, and School Social Work Association of America; and

Whereas, The original psychologist who published on the efficacy of conversion therapy has since rejected their own research as flawed and acknowledges the damage they have done to the LGBTQ community; and

 Whereas, The American Psychiatric Association has called upon lawmakers to "ban the harmful and discriminatory practice" of conversion therapy which the organization describes as "posing a significant risk of harm" in addition to lacking credible evidence to support its efficacy or safety; and

Whereas, The United Nations Human Rights Council, in an attempt to "prevent torture and ill-treatment" of LGBTQ persons, condemns the use of conversion therapy practices; and

Resolution: 010 (I-19) Page 2 of 3

Whereas, Legal scholars have successfully argued that conversion therapy bans are supported by constitutional law; and

3

Whereas, Eighteen states and the District of Columbia have passed laws prohibiting the use of conversion therapy practices by licensed health care practitioners on minors; and

5 6 7

Whereas, Our American Medical Association has policy (H-160.991) opposing "the use of "reparative" or "conversion" therapy for sexual orientation or gender identity;" therefore be it

8

RESOLVED, That our American Medical Association advocate for federal legislation to ban conversion therapy. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/03/19

Sources:

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- 10. American Psychiatric Association. APA reiterates strong opposition to conversion therapy. Published November 15, 2018.
- United Nations Human Rights Council. Discrimination and Violence Against Individuals Based on Their Sexual Orientation and Gender Identity: Report of the Office of the United Nations High Commissioner for Human Rights. A/HRC/29/23. https://undocs.org/A/HRC/29/23. Published May 4, 2015. Accessed February 27, 2019.
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- 13. Conversion Therapy Laws. Movement Advancement Project website. www.lgbtmap.org/equality-maps/conversion_therapy. Updated February 26, 2019. Accessed October 2, 2019.

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RELEVANT AMA POLICY

Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations H-160.991

- 1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
- 2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.
- 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
- 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.

Citation: CSA Rep. C, I-81; Reaffirmed: CLRPD Rep. F, I-91; CSA Rep. 8 - I-94; Appended: Res. 506, A-00; Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18; Reaffirmed: CSAPH Rep. 01, I-18;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 011

(I-19)

Introduced by: Michigan

Subject: End Child Marriage

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, With the adoption of the Convention on the Rights of the Child, the United Nations defined a child as any person younger than 18; this definition has since been used to establish quantifiable targets for international development including child marriage; and

Whereas, The United States Global Strategy to Empower Adolescent Girls, released in 2016 by the State Department, states that marriage before age 18 is a "human rights abuse" that produces devastating effect on a girl's life; and

Whereas, Between 2000 and 2010 more than 167,000 children across 38 states were married, mostly to men 18 or older while the remaining twelve states and the District of Columbia did not track this information; and

Whereas, Child marriage in the United States is associated with a 23 percent greater risk of disease onset, including heart attack, diabetes, cancer, and stroke; and

Whereas, Child marriage is associated with higher rates of sexually transmitted infections, early pregnancies, divorce, and intimate partner violence than women married at 21; and

Whereas, Mothers around the world who are under the age of 18 have a 35 percent to 55 percent higher risk of delivering a preterm or low-birthweight infant than mothers older than 19 years; and

Whereas, Child marriage in the United States has been associated with significantly increased risk of almost all psychiatric disorders; approximately 35 percent of women who were married as children presented with psychiatric disorders and 53 percent had a lifetime history of psychiatric illnesses; and

Whereas, The majority of marriages among immigrant children occur after their arrival to the United States with only a minority being wed outside of the country; and

Whereas, Statutory rape charges when young girls become pregnant may be avoided and have been motivation to encourage marriage between the offender and the girl; and

Whereas, Delaware was the first state in the United States to ban child marriage with no exception based on the consideration that children under 18 are unable to file for divorce or seek shelter at a domestic violence shelter if needed; therefore be it

Page 2 of 2

1 RESOLVED, That our American Medical Association oppose the practice of child marriage (New HOD Policy); and be it further

3

4 RESOLVED, That our AMA advocate for the passage of state and federal legislation to end the practice of child marriage. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/03/19

Sources:

- 1. Koski A, Heymann J. Child marriage in the united states: how common is the practice, and which children are at greatest risk? Perspectives on Sexual and Reproductive Health. 2018; 50(2):59-65.
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Reference Committee B

BOT Report(s)

- 01 Legalization of the Deferred Action for Legal Childhood Arrival (DALCA)
- 02 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings
- 03 Restriction on IMG Moonlighting
- 09 Opioid Mitigation

Resolution(s)

- 201 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities
- 202 Support for Veterans Courts
- 203 Support Expansion of Good Samaritan Laws
- 204 AMA Position on Payment Provisions in Health Insurance Policies
- 205 Co-Pay Accumulators
- 206 Improvement of Healthcare Access in Underserved Areas by Retaining and Incentivizing IMG Physicians
- 207 Pharmaceutical Advertising in Electronic Health Record Systems
- 208 Net Neutrality and Public Health
- 209 Federal Government Regulation and Promoting Patient Access to Kidney Transplantation
- 210 Federal Government Regulation and Promoting Renal Transplantation
- 211 Effects of Net Neutrality on Public Health
- 212 Centers for Medicare and Medicaid Services Open Payments Program
- 213 Data Completeness and the House of Medicine
- 214 AMA Should Provide a Summary of its Advocacy Efforts on Surprise Medical Bills
- 215* Board Certification of Physician Assistants
- 216* Legislation to Facilitate Corrections-to-Community Healthcare Continuity via Medicaid
- 217* Promoting Salary Transparency Among Veterans Health Administration Employed Physicians
- 218* Private Payers and Office Visit Policies
- 219* QPP and the Immediate Availability of Results in CEHRTs

REPORT OF THE BOARD OF TRUSTEES

B of T Report 1-I-19

Subject: Legalization of the Deferred Action for Legal Childhood Arrival (DALCA)

(Resolution 205-I-18)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

the U.S. and eventually obtain their own green cards.

Referred to: Reference Committee B

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INTRODUCTION

 At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 205-I-18, "Legalization of the Deferred Action for Legal Childhood Arrival (DALCA)" for study. Resolution 205-I-18 was introduced by the International Medical Graduates (IMG) Section. Resolution 205 asked that our AMA support legalization of DALCA; and that our AMA work with the appropriate agencies to allow DALCA children to start and finish medical school and/or residency training until these DALCA children have officially become legal.

BACKGROUND

DALCA is a new policy term not widely used by immigration attorneys or Members of Congress, and it is not a legally recognized term. The term was created to distinguish children of H-1B visa holders who legally entered the U.S. from Deferred Action for Childhood Arrivals (DACA) recipients. The term DACA applies only to children who were brought to the United States illegally and thus does not apply to children of H-1B visa holders, including International Medical Graduates (IMGs).

 Under current U.S. immigration law, the spouse and children of a H-1B visa holder can accompany the worker to the U.S. by obtaining an H-4 visa. Each family member must obtain his or her own H-4 visa. There are a number of extensions for H-1B holders once an I-140 application (i.e., petition for green card) is approved. For those on H-4 spousal visas, there are no limitations as long as the related H-1B visa is valid. Additionally, in 2015 the Obama Administration issued a final rule allowing those on H-4 spousal visas to work if their H-1B visa spouse is applying to become a lawful permanent resident (i.e., green card holder). According to the U.S. Citizenship and Immigration Services (USCIS), there have been close to 91,000 initially approved employment authorization applications for H-4 spousal visas. However, children lose their H-4 visa status once they turn 21. These children have only two choices: they can have their H-4 visa changed to an international student visa, also called the student F-1 visa, so they can attend college/university in the U.S., or they can return to their home country and then return to the U.S. after their H-1B visa physician parent obtains permanent residency. Once these children finish their education while on the F-1 visa, they would need to seek H-1B employment sponsors of their own so they can work in

DISCUSSION

The sponsors of Resolution 205 assert that many DALCA children are in medical school or have already graduated from U.S. medical schools, but are subject to deportation because they are considered illegal once they are over age 21. Many of the DALCA children have matched in residency programs but are unable to attend due to their lack of proper legal status.

It is well known that there is expected to be a <u>physician shortage</u> in the U.S. The projected shortage of between 46,900 and 121,900 physicians by 2032 includes both primary care (between 21,100 and 55,200) and specialty care (between 24,800 and 65,800). Among specialists, the data project a shortage of between 1,900 and 12,100 medical specialists, 14,300 and 23,400 surgical specialists, and 20,600 and 39,100 other specialists, such as pathologists, neurologists, radiologists, and psychiatrists, by 2032. Supporting permanent legal status for DALCA children could help in reducing the impact of the expected physician shortage and support the families of H-1B visa physicians.

 The AMA has extensive policy supporting DACA students as well as permanent residence status for physicians; however, there is no policy directly supporting children on H-4 visas that have aged out waiting for their physician-parent to receive their green card. The Board concludes that Resolution 205 is consistent with existing AMA policy and should be adopted by appropriately amending existing policy to incorporate the intent of the resolution.

RECCOMENDATION

The Board recommends that our AMA amend Policy D-255.979, "Permanent Residence Status for Physicians on H1-B Visas," by addition to read as follows, in lieu of Resolution 205-I-18 and that the remainder of the report be filed:

Our AMA will work with all relevant stakeholders to: 1) clear the backlog for conversion from H1-B visas for physicians to permanent resident status, and 2) allow the children of H-1B visa holders, who have aged out of the H-4 non-immigrant classification, to remain in the U.S. legally while their parents' green card applications are pending. (Modify Current HOD Policy)

Fiscal Note: Less than \$500

RELEVANT AMA POLICIES

Policy D-255.979, "Permanent Residence Status for Physicians on H1-B Visas"

Our AMA will work with all relevant stakeholders to clear the backlog for conversion from H1-B visas for physicians to permanent resident status.

Res. 229, A-18

Policy D-255.980, "Impact of Immigration Barriers on the Nation's Health"

1. Our AMA recognizes the valuable contributions and affirms our support of international medical students and international medical graduates and their participation in U.S. medical schools, residency and fellowship training programs and in the practice of medicine. 2. Our AMA will oppose laws and regulations that would broadly deny entry or re-entry to the United States of persons who currently have legal visas, including permanent resident status (green card) and student visas, based on their country of origin and/or religion. 3. Our AMA will oppose policies that would broadly deny issuance of legal visas to persons based on their country of origin and/or religion. 4. Our AMA will advocate for the immediate reinstatement of premium processing of H-1B visas for physicians and trainees to prevent any negative impact on patient care. 5. Our AMA will advocate for the timely processing of visas for all physicians, including residents, fellows, and

physicians in independent practice. 6. Our AMA will work with other stakeholders to study the current impact of immigration reform efforts on residency and fellowship programs, physician supply, and timely access of patients to health care throughout the U.S.

Alt. Res. 308, A-17 Modified: CME Rep. 01, A-18

Policy H-255.988, "AMA Principles on International Medical Graduates"

Our AMA supports: 1. Current U.S. visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada. 2. Current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE. 3. The AMA reaffirms its policy that the U.S. and Canada medical schools be accredited by a nongovernmental accrediting body. 4. Cooperation in the collection and analysis of information on medical schools in nations other than the U.S. and Canada. 5. Continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. An AMA member, who is an IMG, should be appointed regularly as one of the AMA's representatives to the ECFMG Board of Trustees. 6. Working with the Accreditation Council for Graduate Medical Education (ACGME) and the Federation of State Medical Boards (FSMB) to assure that institutions offering accredited residencies, residency program directors, and U.S. licensing authorities do not deviate from established standards when evaluating graduates of foreign medical schools. 7. In cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care. 8. The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs. 9. That special consideration be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure. 10. That accreditation standards enhance the quality of patient care and medical education and not be used for purposes of regulating physician manpower. 11. That AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. Medical school admissions officers and directors of residency programs should select applicants on the basis of merit, without considering status as an IMG or an ethnic name as a negative factor. 12. The requirement that all medical school graduates complete at least one year of graduate medical education in an accredited U.S. program in order to qualify for full and unrestricted licensure. 13. Publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities. 14. The participation of all physicians, including graduates of foreign as well as U.S. and Canadian medical schools, in organized medicine. The AMA offers encouragement and assistance to state, county, and specialty medical societies in fostering greater membership among IMGs and their participation in leadership positions at all levels of organized medicine, including AMA committees and councils and state boards of medicine, by providing guidelines and nonfinancial incentives, such as recognition for outstanding achievements by either individuals or organizations in promoting leadership among IMGs. 15. Support studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members. 16. AMA membership outreach to IMGs, to include a) using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians; b) publicizing its many relevant resources to all physicians, especially to nonmember IMGs; c) identifying and publicizing AMA resources to respond to inquiries from IMGs; and d) expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the U.S. that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools. 17. Recognition of the common aims and goals of all physicians, particularly those practicing in the U.S., and support for including all physicians who are permanent residents of the U.S. in the mainstream of American medicine. 18. Its leadership role to promote the international exchange of medical knowledge as well as cultural understanding between the U.S. and other nations. 19. Institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return. 20. Informing foreign national IMGs that the availability of training and practice opportunities in the U.S. is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the U.S., and that those IMGs who plan to return to their country of origin have the opportunity to obtain GME in the United States. 21. U.S. medical schools offering admission with

advanced standing, within the capabilities determined by each institution, to international medical students who satisfy the requirements of the institution for matriculation. 22. The Federation of State Medical Boards, its member boards, and the ECFMG in their willingness to adjust their administrative procedures in processing IMG applications so that original documents do not have to be recertified in home countries when physicians apply for licenses in a second state.

BOT Rep. Z, A-86 Reaffirmed: Res. 312, I-93 Modified: CME Rep. 2, A-03 Reaffirmation I-11 Reaffirmed: CME Rep. 1, I-13 Modified: BOT Rep. 25, A-15 Modified: CME Rep. 01, A-16 Appended: Res. 304, A-17 Modified: CME Rep. 01, I-17

Policy D-255.99, "Visa Complications for IMGs in GME"

1. Our AMA will: (A) work with the ECFMG to minimize delays in the visa process for International Medical Graduates applying for visas to enter the US for postgraduate medical training and/or medical practice; (B) promote regular communication between the Department of Homeland Security and AMA IMG representatives to address and discuss existing and evolving issues related to the immigration and registration process required for International Medical Graduates; and (C) work through the appropriate channels to assist residency program directors, as a group or individually, to establish effective contacts with the State Department and the Department of Homeland Security, in order to prioritize and expedite the necessary procedures for qualified residency applicants to reduce the uncertainty associated with considering a noncitizen or permanent resident IMG for a residency position. 2. Our AMA International Medical Graduates Section will continue to monitor any H-1B visa denials as they relate to IMGs? inability to complete accredited GME programs. 3. Our AMA will study, in collaboration with the Educational Commission on Foreign Medical Graduates and the Accreditation Council for Graduate Medical Education, the frequency of such J-1 Visa reentry denials and its impact on patient care and residency training. 4. Our AMA will, in collaboration with other stakeholders, advocate for unfettered travel for IMGs for the duration of their legal stay in the US in order to complete their residency or fellowship training to prevent disruption of patient care. Res. 844, I-03 Reaffirmation A-09 Reaffirmation I-10 Appended: CME Rep. 10, A-11 Appended: Res. 323, A-12

Policy D-350.986, "Evaluation of DACA-Eligible Medical Students, Residents and Physicians in Addressing Physician Shortages"

1. Our American Medical Association will study the issue of Deferred Action for Childhood Arrivals-eligible medical students, residents, and physicians and consider the opportunities for their participation in the physician profession and report its findings to the House of Delegates. 2. Our AMA will issue a statement in support of current US healthcare professionals, including those currently training as medical students or residents and fellows, who are Deferred Action for Childhood Arrivals recipients.

Res. 305, A-15 Appended: Late Res. 1001, I-16

REPORT OF THE BOARD OF TRUSTEES

B of T Report 2-I-19

Subject: Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings

(Resolution 202-I-18)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

Referred to: Reference Committee B

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INTRODUCTION

At the 2018 Interim Meeting, the House of Delegates referred Resolution 202-I-18, "Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings," introduced by the Pennsylvania Delegation, which asked:

That our American Medical Association study the implications of removing those administrative and/or legal barriers that hamper the ability of primary care physician practices to dispense methadone, as part of medication assisted treatment;

That our AMA study the implications of working with other Federation stakeholders to identify the appropriate educational tools that would support primary care practices in dispensing ongoing methadone for appropriate patients as part of medication-assisted treatment.

Testimony on Resolution 202 was generally supportive of having the AMA study the implications of removing barriers that hamper the ability of physician practices to dispense methadone, one of the three main drug classes commonly referred to as medication-assisted treatment (MAT). There also was testimony that the AMA does not need to study working with state and specialty societies regarding the issues raised in Resolution 202 but instead should work directly with the Federation on supporting greater access to methadone treatment for opioid use disorder, including removing stigma. There was some confusion about what educational resources may exist to further these goals—one of the areas which this report seeks to resolve.

DISCUSSION

Background

 As outlined in Board of Trustees Report 5-I-18, "Exclusive State Control of Methadone Clinics," the AMA has been a strong supporter of methadone maintenance treatment (MMT) as an evidence-based option to help treat patients with an opioid use disorder. MMT has been used for more than 40 years to help patients, having been approved in 1972 by the U.S. Food and Drug Administration (FDA) for treatment of heroin addiction. The health and safety of methadone has been studied extensively and ample evidence exists supporting its use to aid in mortality and crime reduction. ¹

There are 1,685 certified opioid treatment programs (OTPs) offering methadone in the United States.² According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the number of persons receiving methadone increased by 34 percent from 2006 (258,752) to 2016 (345,443). With respect to opioid-related mortality, deaths attributed to methadone increased rapidly from 1999 (784 deaths) to their peak in 2007 (5,518) and have steadily declined since. In the past five years, for example, methadone-related mortality has decreased from 3,493 (2015) to 3,078 (2019), according to the Centers for Disease Control and Prevention.⁴ It is beyond the scope of this report, however, to detail whether the methadone use in these deaths was for the treatment of pain, for opioid use disorder, related to illicit use or was a complicating polypharmacy factor. It is further beyond the scope of this report to try and ascertain how many of those persons were under the care of a physician or being treated in an OTP.

Administrative/legal requirements for dispensing methadone

SAMHSA has broad regulatory authority concerning MMT and OTPs. This includes the authority to certify an OTP, which is defined as "a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 USC 823(g)(1)."⁵

Regulations governing OTPs are generally contained in 42 CFR Part 8, which provides that the definition of "dispense" means "to deliver a controlled substance to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." Any medication dispensed at an OTP must be dispensed by a health care professional licensed to do so under state law as well as registered under applicable state and/or federal law. In most cases, methadone is dispensed on a daily basis to the patient at the OTP, and OTP staff must observe the patient taking the medication. Take-home use is permitted under federal regulations in certain situations—subject to considerable additional oversight, documentation and monitoring for appropriate use and preventing diversion.

Federal rules also provide that "methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse." 42 CFR Part 8 also requires that for each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents, in the patient's record, that 40 milligrams did not suppress opioid abstinence symptoms.

A study of primary care practices outside of an OTP providing MMT has been conducted. For the study to take place, prior approval from state and county officials and the Drug Enforcement Administration (DEA) and extensive additional documentation was required. In addition, significant controls were required, including a highly motivated group of physicians, patients who were stable for at least one year on MMT and multiple administrative requirements including regular and random toxicology screens, patient assessments, close affiliation with a cooperative OTP, close relationships with pharmacists, counselors and other staff as necessary. Notably, the primary care practice was required to have an ongoing relationship with the community OTP.

Patient selection and care coordination were two additional keys to the program's positive outcomes. Of the 684 patients in the community OTP, 30 qualified and agreed to the primary care provider program managing their ongoing care. Of these, 445 of 449 urinalysis tests were negative, and all random callback urinalysis tests were positive for methadone and negative for other drugs of abuse. For at least this one study and primary care practice, adding 30 patients with complex medical needs may not cause undue strain on the practice—and even likely adds many benefits. In

other words, experimental primary care models to provide MMT are possible, but whether this study can be a model for other practices is not clear.

Other studies also found that patients stable on long-term MMT have benefited from having their care provided in a primary care setting outside of an OTP.⁸ These studies also found that, in addition to low relapse and successful provision of additional primary care services (e.g., tobacco cessation, treatment for hypertension), there were increased services provided for treatment of infectious disease. Studies also found patient and physician satisfaction levels increased during the course of the study. In addition, physician education increased and there was a reduction in stigma.

 Thus, while federal law has strict controls that methadone only be dispensed from an OTP, there have been experimental programs—subject to prior federal approval—that have demonstrated benefits of having MMT provided in a primary care setting outside of a traditional OTP. These experimental programs, however, are highly structured and still must comply with state and federal rules (including who can dispense, take-home rules for stable patients, patient monitoring, strict record-keeping, etc.) governing the provision of MMT.

Educational resources to support the provision of MMT

The AMA has broadly supported efforts to enhance physicians' education with respect to many aspects of the nation's opioid epidemic, including broad support for all forms of MAT. The AMA has broadly supported legislative and regulatory efforts at the state and federal levels to expand access to MAT. AMA model state legislation calls for all payers to make all forms of MAT available without prior authorization and placed on a formulary's lowest cost-sharing tier. AMA advocacy has led to more than one dozen states removing prior authorization for MAT, including methadone, in the commercial and/or Medicaid markets in 2019.

 At the same time, a review of educational resources focused on methadone shows that the AMA opioid microsite (accessible here: www.end-opioid-epidemic.org) only has three titles focused on methadone education in its library of more than 400 resources. There are, however, several physician-led organizations that have considerable education and training resources on a wide variety of areas related to methadone, including induction, ongoing maintenance, stigma and more. This includes the Providers Clinical Support System (PCSS), which is led by the American Academy of Addiction Psychiatry (and of which the AMA is a steering committee member), American Society of Addiction Medicine, the *Journal of the American Medical Association* and other trusted organizations and resources.

While it is speculative to know whether the identification and promotion of these resources would lead to increased numbers of primary care physicians either determining to open their own OTP, providing services in an OTP or even pursuing office-based opioid treatment options that do not include MMT, the Board strongly supports additional educational efforts to, at the very least, reduce the stigma of MMT and increase general knowledge about MMT.

AMA POLICY

AMA policy supports MMT as an evidence-based treatment for opioid use disorder and supports having stable patients treated in a traditional office-based setting (Policy H-95.957, "Methadone Maintenance in Private Practice"). AMA policy also supports the types of investigational studies described above to further efforts to enable office-based physicians to use MMT "to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols" (Policy H-95.957, "Methadone

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1 Maintenance in Private Practice"). AMA policy also calls for broad support to expand MMT 2 services (Policy D-95.999, "Reduction of Medical and Public Health Consequences of Drug 3 Abuse: Update"). This includes broad support of OTPs (Policy H-95.921, "Exclusive State Control 4 of Methadone Clinics"). With respect to physician dispensing, the AMA "supports the physician's 5 right to dispense drugs and devices when it is in the best interest of the patient and consistent with 6 AMA's ethical guidelines" (Policy H-120.990, "Physician Dispensing").

7 8

RECOMMENDATIONS

9 10

The Board recommends that the following recommendations be adopted in lieu of Resolution 202-I-18, and that the remainder of the report be filed.

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13 That our American Medical Association (AMA) support further research into how primary care practices can implement MAT into their practices and disseminate such 14 research in coordination with primary care specialties; (New HOD Policy)

15 16

17 2. That our AMA support efforts to expand primary care services to patients receiving methadone maintenance therapy (MMT) for patients receiving care in an Opioid 18 19 Treatment Program or via office-based therapy; (New HOD Policy)

20

21 3. That the AMA Opioid Task Force increase its evidence-based educational resources 22 focused on MMT and publicize those resources to the Federation. (Directive to Take 23 Action)

Fiscal Note: \$2,500

REFERENCES

- ¹ See, for example, Kleber HD. Methadone Maintenance 4 Decades Later. JAMA. 2008;300(19):2303–2305. doi:10.1001/jama.2008.648. Available at https://jamanetwork.com/journals/jama/fullarticle/182898
- ² Opioid Treatment Program Directory. Substance Abuse and Mental Health Services Association. Available at https://dpt2.samhsa.gov/treatment/directory.aspx https://dpt2.samhsa.gov/treatment/directory.aspx; last reviewed July 17, 2019.
- ³ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2016 Data on Substance Abuse Treatment Facilities. Available at https://www.samhsa.gov/data/sites/default/files/2016 NSSATS.pdf
- ⁴ https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-type-of-opioid/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7DThe data points are from the predicted January 12-month total as reported by the National Vital Statistics System. Available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard
- ⁵ 42 CFR Part 8, available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=3&SID=7282616ac574225f795d5849935efc45&ty=HTML&h=L&n=pt42.1.8&r=PART#se42.1.8_12
- ⁶ 42 CFR Part 8.12(h)
- ⁷ See, for example Joseph O Merrill, MD, MPH, et al, "Methadone Medical Maintenance in Primary Care, An Implementation Evaluation." J Gen Intern Med. 2005 Apr; 20(4): 344–349.
- ⁸ See, for example, Fiellin DA, O'Connor PG, Chawarski M, Pakes JP, Pantalon MV, Schottenfeld RS. Methadone Maintenance in Primary Care: A Randomized Controlled Trial. JAMA. 2001;286(14):1724–1731. doi:10.1001/jama.286.14.1724
- ⁹ The resources that include "methadone" in the title on the microsite are from the American Society of Addiction Medicine and Providers Clinical Support System.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 3-I-19

Subject: Restriction on IMG Moonlighting

(Resolution 204-I-18)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

Referred to: Reference Committee B

INTRODUCTION

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 204-I-18, "Restriction on IMG Moonlighting." Resolution 204 was introduced by the Resident and Fellow Section.

Resolution 204 asks that our AMA advocate for changes to federal legislation allowing physicians with a J-1 visa in fellowship training programs the ability to moonlight.

This report provides a brief background on the J-1 visa program and discusses the issues that are raised when considering changes to federal legislation that would allow physicians with a J-1 visa in fellowship training programs the ability to moonlight.

BACKGROUND

The U.S. generally requires citizens of foreign countries to obtain a U.S. visa prior to entry. Based on the purpose of travel, an individual may receive one of two types of visas: immigrant and non-immigrant. Immigrant visas are issued to individuals who wish to live in the U.S. permanently, while non-immigrant visas are issued to individuals with permanent residence outside the U.S. who wish to be in the U.S. temporarily for tourism, business, temporary work, or other specified purposes.

 The Exchange Visitor (J) non-immigrant visa category is for individuals approved to participate in work- and study-based exchange visitor programs. The first step in pursuing an exchange visitor visa is to apply through a designated sponsoring organization in the U.S. Physicians may be sponsored for J-1 status by the Educational Commission for Foreign Medical Graduates (ECFMG) for participation in accredited clinical programs or directly associated fellowship programs. These sponsored physicians have J-1 "alien physician" status and pursue graduate medical education or training at a U.S. accredited school of medicine or scientific institution, or pursue programs involving observation, consultation, teaching, or research. The J-1 classification is explicitly reserved for educational and cultural exchange.

- J-1 status physicians are participants in the U.S. Department of State (DoS) Exchange Visitor
- Program. The primary goals of the Exchange Visitor Program are to allow participants the opportunity to engage broadly with Americans, share their culture, strengthen their English
- language abilities, and learn new skills or build skills that will help them in future careers.

According to the DoS, for Calendar Year 2018, there were 2,738 new J-1 physicians participating in the exchange program. For CY 2018 the top three "sending countries" for J-1 physicians were: Canada 689; India 489; and Pakistan 248. The top three "receiving U.S. states" for J-1 physicians were: New York 556; Michigan 182; and Texas 163.¹

DISCUSSION

A J-1 visa holder may only perform the curricular activity listed on his/her Form DS-2019, or as provided for in the regulations for the specific category for which entry was obtained and with the approval of the Sponsor's Responsible or Alternate Responsible Officer. As a result, J-1 physician participants are not currently permitted to engage in any work outside of their approved program of graduate medical education. If the proposed activity by the J-1 physician falls outside of the normal scope and/or is not a required component of the training program, then it is deemed to be "work outside of the approved training program" and not permitted for J-1 physicians.

In June 1999, the U.S. Information Agency issued a statement of policy on the Exchange Visitor Program. In the statement of policy, the agency specifically comments on the ability of J-1 physicians to moonlight, stating that, "...a foreign medical graduate is not authorized to 'moonlight' and is without work authorization to do so. A foreign medical graduate may receive compensation from the medical training facility for work activities that are an integral part of his or her residency program. The foreign medical graduate is not authorized to work at other medical facilities or emergency rooms at night or on weekends. Such outside employment is a violation of the foreign medical graduate's program status and would subject the foreign medical graduate to termination of his or her program."²

The Administration has further outlined its rationale on this issue in a formal Notice of Proposed Rulemaking (NPRM) and later a final rule which strengthens the program's oversight by requiring management reviews for Private Sector Program sponsors of, for instance, alien physicians. The final rule confirmed the policy prohibiting moonlighting as outlined in 22 U.S. Code of Federal Regulations (CFR) §62.16:

22 CFR (§62.16) – Employment

 (a) An exchange visitor may receive compensation from the sponsor or the sponsor's appropriate designee, such as the host organization, when employment activities are part of the exchange visitor's program.

(b) An exchange visitor who engages in unauthorized employment shall be deemed to be in violation of his or her program status and is subject to termination as a participant in an exchange visitor program.

 (c) The acceptance of employment by the accompanying spouse and dependents of an exchange visitor is governed by Department of Homeland Security regulations.

Currently, <u>42 CFR §415.208</u> provides substantial regulations for the services of moonlighting residents who are not foreign nationals. Again, the particular purpose of the J-1 program is to increase mutual understanding between the people of the U.S. and the people of other countries by means of educational and cultural exchanges. Thus, because J-1 physicians are foreign nationals participating in an educational/cultural exchange program offered by the DoS, they are not permitted to moonlight or receive additional compensation outside of the J-1 visa program.

DoS' final rule states that strict oversight of the exchange program is critical as an affirmative step "to protect the health, safety and welfare of foreign nationals." When problems occur, "the U.S.

Government is often held accountable by foreign governments for the treatment of their nationals,

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regardless of who is responsible." Any changes to program policy that may weaken protections could have "direct and substantial adverse effects on the foreign affairs of the U.S.."³

In accordance with the DoS policy, the AMA also has strong and lengthy policy outlining the rights of residents/fellows and limiting duty hours to ensure patient safety and an optimal learning environment for these physicians.

Those in support of Resolution 204 argue that moonlighting will improve access to care for underserved populations in certain areas around the U.S. facing a physician shortage. Allowing J-1 physicians to moonlight would provide these physicians with an increased opportunity to provide care to underserved populations while at the same time garner increased training and education during their time in the U.S. However, under the current program's purpose and restrictions, as set out by the Administration, this activity is not possible without significant changes to the J-1 program.⁴

Both the DoS and ECFMG ultimately desire that the J-1 visa program remain as a training/education program for which participants are paid. According to the DoS and ECFMG, if the alien physician program shifts to something other than a training/education program, then it will receive increased scrutiny (as is the case regarding the au pair and summer work travel programs) and could potentially be absorbed into the current immigration discussions between the U.S. Congress and the Administration. While the Board understands and appreciates the intent of the sponsors of Resolution 204, we conclude that the focus of the J-1 program should remain on the training and education of the physicians in the program and that our AMA should not pursue changes that could create a risk to those physicians and potentially the entire program.

RECOMMENDATION

The Board recommends that our American Medical Association not adopt Resolution 204-I-18, "Restriction on IMG Moonlighting," and that the remainder of the report be filed.

Fiscal Note: Less than \$500

¹ https://j1visa.state.gov/wp-content/uploads/2019/03/Alien-Physician-Flyer-2018-web.pdf

² https://www.govinfo.gov/content/pkg/FR-1999-06-30/pdf/99-16757.pdf, 64 Federal Register 34983

³ https://www.govinfo.gov/content/pkg/FR-2014-10-06/pdf/2014-23510.pdf, 79 Federal Register 60305

⁴ Id.

RELEVANT AMA POLICY

CME Report on Duty Hours, CME Report 5, A-14

Policy H-255.970, "Employment of Non-Certified IMGs"

Our AMA will: (1) oppose efforts to employ graduates of foreign medical schools who are neither certified by the Educational Commission for Foreign Medical Graduates, nor have met state criteria for full licensure; and (2) encourage states that have difficulty recruiting doctors to underserved areas to explore the expanded use of incentive programs such as the National Health Service Corps or J1 or other visa waiver programs. Citation: (Res. 309, A-03; Reaffirmed: CME Rep. 2, A-13)

Policy H-310.907, "AMA Duty Hours Policy"

Our AMA adopts the following Principles of Resident/Fellow Duty Hours, Patient Safety, and Quality of Physician Training: 1. Our AMA reaffirms support of the 2003 Accreditation Council for Graduate Medical Education (ACGME) duty hour standards. 2. Our AMA will continue to monitor the enforcement and impact of duty hour standards, in the context of the larger issues of patient safety and the optimal learning environment for residents. 3. Our AMA encourages publication and supports dissemination of studies in peer-reviewed publications and educational sessions about all aspects of duty hours, to include such topics as extended work shifts, handoffs, in-house call and at-home call, level of supervision by attending physicians, workload and growing service demands, moonlighting, protected sleep periods, sleep deprivation and fatigue, patient safety, medical error, continuity of care, resident well-being and burnout, development of professionalism, resident learning outcomes, and preparation for independent practice. 4. Our AMA endorses the study of innovative models of duty hour requirements and, pending the outcomes of ongoing and future research, should consider the evolution of specialty- and rotation-specific duty hours requirements that are evidence-based and will optimize patient safety and competency-based learning opportunities. 5. Our AMA encourages the ACGME to: a) Decrease the barriers to reporting of both duty hour violations and resident intimidation. b) Ensure that readily accessible, timely and accurate information about duty hours is not constrained by the cycle of ACGME survey visits. c) Use, where possible, recommendations from respective specialty societies and evidence-based approaches to any future revision or introduction of resident duty hour rules. d) Broadly disseminate aggregate data from the annual ACGME survey on the educational environment of resident physicians, encompassing all aspects of duty hours.6. Our AMA recognizes the ACGME for its work in ensuring an appropriate balance between resident education and patient safety, and encourages the ACGME to continue to: a) Offer incentives to programs/institutions to ensure compliance with duty hour standards. b) Ensure that site visits include meetings with peer-selected or randomly selected residents and that residents who are not interviewed during site visits have the opportunity to provide information directly to the site visitor. c) Collect data on at-home call from both program directors and resident/fellow physicians; release these aggregate data annually; and develop standards to ensure that appropriate education and supervision are maintained, whether the setting is in-house or at-home. d) Ensure that resident/fellow physicians receive education on sleep deprivation and fatigue. 7. Our AMA supports the following statements related to duty hours: a) Resident physician total duty hours must not exceed 80 hours per week, averaged over a four-week period (Note: Total duty hours' includes providing direct patient care or supervised patient care that contributes to meeting educational goals; participating in formal educational activities; providing administrative and patient care services of limited or no educational value; and time needed to transfer the care of patients). b) Scheduled on-call assignments should not exceed 24 hours. Residents may remain on-duty for an additional 4 hours to complete the transfer of care, patient follow-up, and education; however, residents may not be assigned new patients, cross-coverage of other providers' patients, or continuity clinic during that time. c) Time spent in the hospital by residents on at-home call must count towards the 80-hour maximum weekly hour limit, and on-call frequency must not exceed every third night averaged over four weeks. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one-day-in-seven free of duty, when averaged over four weeks. d) At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident. e) Residents are permitted to return to the hospital while on at-home call to care for new or established patients. Each episode of this type of care, while it must be included in the 80-hour weekly maximum, will not initiate a new "off-duty period." f) Given the different education and patient care needs of the various specialties and changes in resident responsibility as training progresses, duty hour requirements should allow for flexibility for different disciplines and different training levels to ensure appropriate resident education and patient safety; for example, allowing exceptions for certain disciplines, as appropriate, to the 16-hour shift limit for first-year residents, or allowing a limited increase to the total number of duty hours when need is demonstrated. g) Resident physicians should be ensured a sufficient duty-free interval prior to returning to duty. h) Duty hour limits must not adversely impact resident physician participation in organized educational activities. Formal educational activities must be scheduled and available within total duty hour limits for all resident physicians, i) Scheduled time providing patient care services of limited or no educational value should be minimized. j) Accurate, honest, and complete reporting of resident duty hours is an essential element of medical professionalism and ethics. k) The medical profession maintains the right and responsibility for self-regulation (one of the key tenets of professionalism) through the ACGME and its purview over graduate medical education, and categorically rejects involvement by the Centers for Medicare & Medicaid Services, The Joint Commission, Occupational Safety and Health Administration, and any other federal or state government bodies in the monitoring and enforcement of duty hour regulations, and opposes any regulatory or legislative proposals to limit the duty hours of practicing physicians. 1) Increased financial assistance for residents/fellows, such as subsidized child care, loan deferment, debt forgiveness, and tax credits, may help mitigate the need for moonlighting. At the same time, resident/fellow physicians in good standing with their programs should be afforded the opportunity for internal and external moonlighting that complies with ACGME policy. m) Program directors should establish guidelines for scheduled work outside of the residency program, such as moonlighting, and must approve and monitor that work such that it does not interfere with the ability of the resident to achieve the goals and objectives of the educational program. n) The costs of duty hour limits should be borne by all health care payers. o) The general public should be made aware of the many contributions of resident/fellow physicians to high-quality patient care and the importance of trainees' realizing their limits (under proper supervision) so that they will be able to competently and independently practice under real-world medical situations. 8. Our AMA is in full support of the collaborative partnership between allopathic and osteopathic professional and accrediting bodies in developing a unified system of residency/fellowship accreditation for all residents and fellows, with the overall goal of ensuring patient safety. CME Rep. 5, A-14

Policy H-310.912, "Residents and Fellows' Bill of Rights"

1. Our AMA continues to advocate for improvements in the ACGME Institutional and Common Program Requirements that support AMA policies as follows: a) adequate financial support for and guaranteed leave to attend professional meetings; b) submission of training verification information to requesting agencies within 30 days of the request; c) adequate compensation with consideration to local cost-of-living factors and years of training, and to include the orientation period; d) health insurance benefits to include dental and vision services; e) paid leave for all purposes (family, educational, vacation, sick) to be no less than six weeks per year; and f) stronger due process guidelines. 2. Our AMA encourages the ACGME to ensure access to educational programs and curricula as necessary to facilitate a deeper understanding by resident physicians of the US health care system and to increase their communication skills. 3. Our AMA regularly communicates to residency and fellowship programs and other GME stakeholders through various publication methods (e.g., the AMA GME e-letter) this Residents and Fellows' Bill of Rights. 4. Our AMA: a) will promote residency and fellowship training programs to evaluate their own institution's process for repayment and develop a leaner approach. This includes disbursement of funds by direct deposit as opposed to a paper check and an online system of applying for funds; b) encourages a system of expedited repayment for purchases of \$200 or less (or an equivalent institutional threshold), for example through payment directly from their residency and fellowship programs (in contrast to following traditional workflow for reimbursement); and c) encourages training programs to develop a budget and strategy for planned expenses versus unplanned expenses, where planned expenses should be estimated using historical data, and should include trainee reimbursements for items such as educational materials, attendance at conferences, and entertaining applicants. Payment in advance or within one month of document submission is strongly recommended. 5. Our AMA encourages teaching institutions to explore benefits to residents and fellows that will reduce personal cost of living expenditures, such as allowances for housing, childcare, and transportation. 6. Our AMA adopts the following 'Residents and Fellows' Bill of Rights' as applicable to all resident and fellow physicians in ACGME-accredited training programs:

RESIDENTS AND FELLOWS' BILL OF RIGHTS

Residents and fellows have a right to:

A. An education that fosters professional development, takes priority over service, and leads to independent practice. With regard to education, residents and fellows should expect: (1) A graduate medical education experience that facilitates their professional and ethical development, to include regularly scheduled didactics for which they are released from clinical duties. Service obligations should not interfere with educational opportunities and clinical education should be given priority over service obligations; (2) Faculty who devote sufficient time to the educational program to fulfill their teaching and supervisory responsibilities; (3) Adequate clerical and clinical support services that minimize the extraneous, time-consuming work that draws attention from patient care issues and offers no educational value; (4) 24-hour per day access to information resources to educate themselves further about appropriate patient care; and (5) Resources that will allow them to pursue scholarly activities to include financial support and education leave to attend professional meetings. B. Appropriate supervision by qualified faculty with progressive resident responsibility toward independent practice. With regard to supervision, residents and fellows should expect supervision by physicians and non-physicians who are adequately qualified and which allows them to assume progressive responsibility appropriate to their level of education, competence, and experience. C. Regular and timely feedback and evaluation based on valid assessments of resident performance. With regard to evaluation and assessment processes, residents and fellows should expect: (1) Timely and substantive evaluations during each rotation in which their competence is objectively assessed by faculty who have directly supervised their work; (2) To evaluate the faculty and the program confidentially and in writing at least once annually and expect that the training program will address deficiencies revealed by these evaluations in a timely fashion; (3) Access to their training file and to be made aware of the contents of their file on an annual basis; and (4) Training programs to complete primary verification/credentialing forms and recredentialing forms, apply all required signatures to the forms, and then have the forms permanently secured in their educational files at the completion of training or a period of training and, when requested by any organization involved in credentialing process, ensure the submission of those documents to the requesting organization within thirty days of the request. D. A safe and supportive workplace with appropriate facilities. With regard to the workplace, residents and fellows should have access to: (1) A safe workplace that enables them to fulfill their clinical duties and educational obligations; (2) Secure, clean, and comfortable on-call rooms and parking facilities which are secure and well-lit; (3) Opportunities to participate on committees whose actions may affect their education, patient care, workplace, or contract. E. Adequate compensation and benefits that provide for resident well-being and health. (1) With regard to contracts, residents and fellows should receive: a. Information about the interviewing residency or fellowship program including a copy of the currently used contract clearly outlining the conditions for (re)appointment, details of remuneration, specific responsibilities including call obligations, and a detailed protocol for handling any grievance; and b. At least four months advance notice of contract non-renewal and the reason for non-renewal. (2) With regard to compensation, residents and fellows should receive: a. Compensation for time at orientation; and b. Salaries commensurate with their level of training and experience, and that reflect cost of living differences based on geographical differences. (3) With Regard to Benefits, Residents and Fellows Should Receive: a. Quality and affordable comprehensive medical, mental health, dental, and vision care; b. Education on the signs of excessive fatigue, clinical depression, and substance abuse and dependence; c. Confidential access to mental health and substance abuse services; d. A guaranteed, predetermined amount of paid vacation leave, sick leave, maternity and paternity leave and educational leave during each year in their training program the total amount of which should not be less than six weeks; and e. Leave in compliance with the Family and Medical Leave Act. F. Duty hours that protect patient safety and facilitate resident well-being and education. With regard to duty hours, residents and fellows should experience: (1) A reasonable work schedule that is in compliance with duty-hour requirements set forth by the ACGME or other relevant accrediting body; and (2) At-home call that is not so frequent or demanding such that rest periods are significantly diminished or that duty-hour requirements are effectively circumvented. G. Due process in cases of allegations of misconduct or poor performance. With regard to the complaints and appeals process, residents and fellows should have the opportunity to defend themselves against any allegations presented against them by a patient, health professional, or training program in accordance with the due process guidelines established by the AMA. H. Access to and protection by institutional and accreditation authorities when reporting violations. With regard to reporting violations to the ACGME, residents and fellows should: (1) Be informed by their program at the beginning of their training and again at each semi-annual review of the resources and processes available within the residency program

for addressing resident concerns or complaints, including the program director, Residency Training Committee, and the designated institutional official; (2) Be able to file a formal complaint with the ACGME to address program violations of residency training requirements without fear of recrimination and with the guarantee of due process; and (3) Have the opportunity to address their concerns about the training program through confidential channels, including the ACGME concern process and/or the annual ACGME Resident Survey.

CME Rep. 8, A-11 Appended: Res. 303, A-14 Reaffirmed: Res. 915, I-15 Appended: CME Rep. 04, A-16

Policy H-310.979, "Resident Physician Working Hours and Supervision"

(1) Our AMA supports the following principles regarding the supervision of residents and the avoidance of the harmful effects of excessive fatigue and stress: (a) Exemplary patient care is a vital component for any program of graduate medical education. Graduate medical education enhances the quality of patient care in the institution sponsoring an accredited residency program. Graduate medical education must never compromise the quality of patient care. (b) Institutions sponsoring residency programs and the director of each program must assure the highest quality of care for patients and the attainment of the program's educational objectives for the residents. (c) Institutional commitment to graduate medical education must be evidenced by compliance with Section III.B.4 of the ACGME Institutional Requirements, effective July 1, 2007: The sponsoring institution's GME Committee must [m]onitor programs' supervision of residents and ensure that supervision is consistent with: (i) Provision of safe and effective patient care; (ii) Educational needs of residents; (iii) Progressive responsibility appropriate to residents' level of education, competence, and experience; and (iv) Other applicable Common and specialty/subspecialty specific Program Requirements. (d) The program director must be responsible for the evaluation of the progress of each resident and for the level of responsibility for the care of patients that may be safely delegated to the resident. (e) Each patient's attending physician must decide, within guidelines established by the program director, the extent to which responsibility may be delegated to the resident, and the appropriate degree of supervision of the resident's participation in the care of the patient. The attending physician, or designate, must be available to the resident for consultation at all times. (f) The program director, in cooperation with the institution, is responsible for maintaining work schedules for each resident based on the intensity and variability of assignments in conformity with Residency Review Committee (RRC) recommendations, and in compliance with the ACGME duty hour standards. (g) The program director, with institutional support, must assure for each resident effective counseling as stated in Section II.D.4.k of the Institutional requirements: "Counseling services: The Sponsoring Institution should facilitate residents' access to confidential counseling, medical, and psychological support services." (h) As stated in the ACGME Institutional Requirements (II.F.2.a-c), "The Sponsoring Institution must provide services and develop health care delivery systems to minimize residents' work that is extraneous to their GME programs' educational goals and objectives." These include patient support services, laboratory/pathology/radiology services, and medical records. (i) Is neither feasible nor desirable to develop universally applicable and precise requirements for supervision of residents. As stated in the ACGME Common Program Requirements (VI.B) "the program must ensure that qualified faculty provide appropriate supervision of residents in patient care activities." (j) Individual resident compensation and benefits must not be compromised or decreased as a result of these recommended changes in the graduate medical education system. (2) These problems should be addressed within the present system of graduate medical education, without regulation by agencies of government.

CME Rep. C, I-87 Modified: Sunset Report, I-97 Modified and Reaffirmed: CME Rep. 2, A-08

Patient Safety"

Our American Medical Association will actively participate in ongoing efforts to monitor the impact of resident duty hour limitations to ensure that patient safety and physician well-being are not jeopardized by excessive demands on post-residency physicians.

Policy D-310.987, "Impact of ACGME Resident Duty Hour Limits on Physician Well-Being and

Res. 314, A-03 Reaffirmation A-12

REPORT OF THE BOARD OF TRUSTEES

B of T Report 9-I-19

Subject:	Opioid Mitigation (Resolution 919-I-18)
Presented	l by: Jesse M. Ehrenfeld, MD, MPH, Chair
Referred	to: Reference Committee B
INTRODU	JCTION
	8 Interim Meeting, the House of Delegates referred Resolution 919-I-18, "Opioid," introduced by the Indiana Delegation, which asked:
based o	ur American Medical Association review the following opioid mitigation strategies on their effectiveness in Huntington, WV, and Clark County, IN, and provide ack concerning their utility in dealing with opioids:
and	de creation of an opioid overdose team that decreases the risk of future overdose doverdose death, increases access to opioid-related services and increases the telihood that an individual will pursue drug rehabilitation.
no	needle exchange program that is open multiple days a week and is mobile offers t only a source for needles but also Narcan, other supplies, health care and formation.
det all	the creation of a drug court that allows a judge to have greater flexibility in termining the legal consequences of an arrest for an opioid-related crime. It also ows for the judicial patience necessary to deal with the recidivism of this pulation.
	fering more acute-care inpatient drug rehab beds, although those ready for eatment need to be willing to travel significant distances to get to a treatment bed.
	ake available Narcan intranasal spray OTC through pharmacies and the syringe change, overdose team, etc.
	acourage prevention education in K-12 programs that uses multiple media with ti-drug messaging delivered in the school system but also in the home.
This report	t takes each element of Resolution 919-I-18 and discusses relevant information.

Additional discussion of the programs in Huntington, West Virginia and Clark County, Indiana is

provided, as well as the relationship between the programs and existing AMA policy, ongoing

AMA advocacy and other activities. This report makes several recommendations.

DISCUSSION

At a threshold level, determining the "effectiveness" of any program, initiative, treatment or policy aimed at ending the nation's opioid epidemic must focus on three main areas. First, does the program, initiative, treatment or policy result in improved care for patients with pain and/or evidence-based treatment for opioid use disorder? Second, does the program, initiative, treatment or policy increase access to evidence-based care for patients with pain and/or care for a person with pain or with a substance use disorder? And third, does the program, initiative, treatment or policy result in fewer people overdosing and dying?

This is not to suggest that these three areas are the only important metrics to consider, but they are three that are uniquely focused on improving patient outcomes and reversing the nation's opioid-related death toll. Using these three metrics, however, provides a consistent lens through which an evaluation can be made. At the same time, it is challenging to suggest that the programs underway in Huntington, West Virginia and Clark County, Indiana can easily be replicated in other jurisdictions. This is due to a variety of factors including support from policymakers and the general public, availability of state and federal resources and the unique socioeconomic, demographic, racial and ethnic differences between communities. In other words, what works in one community may provide lessons, but it may not be easily transferable to another community.

The AMA commends the efforts of Clark County, Indiana and Huntington, West Virginia, for their efforts to enhance access to treatment for opioid use disorder and reduce opioid-related morbidity and mortality.

Opioid overdose response teams

The City of Huntington, West Virginia was awarded a \$2 million federal grant in January 2017 to support, among other things, a "Quick Response Team" (QRT) to help address the city's opioid epidemic. The QRT is a multidisciplinary team that includes representatives from law enforcement, a paramedic, a faith-based leader and a health care provider. After an individual experiences an overdose and lives, the QRT visits the individual at the person's home. (Individuals also can be referred to the QRT without having to first experience an overdose.) According to news reports, the QRT provides non-judgmental information and assessment to provide referrals to treatment or other services. Data suggest that overdose has declined in Huntington, and the QRT is one of the reasons. The use of QRTs is not unique to the City of Huntington, and in the communities where it has been used, the results appear positive. One of the common features of the QRTs and similarly named efforts is that they are largely funded as grant or pilot programs. It is not clear whether the QRT model could be scaled to larger communities.

Needle and syringe exchange programs

 The AMA has clear policy in support of the establishment of needle and syringe exchange programs, including encouraging state medical societies to support legislation and other efforts to provide injection drug users with needles and syringes without a prescription. This also includes protecting those who distribute needles and syringes from prosecution. The Clark County, Indiana Health Department correctly states "[p]ersons who inject drugs can substantially reduce their risk of getting and transmitting HIV, viral hepatitis and other blood borne infections by using a sterile needle and syringe for every injection." According to the National Institute on Drug Abuse (NIDA):

People who engage in drug use or high-risk behaviors associated with drug use put themselves at risk for contracting or transmitting viral infections such as human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), or hepatitis. This is because viruses spread through blood or other body fluids. It happens primarily in two ways: (1) when people inject drugs and share needles or other drug equipment and (2) when drugs impair judgment and people have unprotected sex with an infected partner. This can happen with both men and women.⁵

NIDA also encourages use of the North American Syringe Exchange Network to help identify where needle and syringe exchange programs are available. The Centers for Disease Control and Prevention (CDC) points to numerous benefits of needle and syringe service programs (SSP), including reducing the risk of infection, preventing outbreaks and preventing viral hepatitis, HIV, endocarditis and other infections. The CDC also notes that SSPs "serve as a bridge to other health services including, hepatitis C virus and HIV diagnosis and treatment and MAT for substance use." In addition, according to the CDC, "people who inject drugs who regularly use an SSP are more than five times as likely to enter treatment for a substance use disorder and nearly three times as likely to report reducing or discontinuing injection as those who have never used an SSP. SSPs do not increase illegal drug use or crime."

 One of the issues that has arisen with needle and syringe exchange services is that while some states and municipalities may allow distribution of sterile needles and syringes, the law may be less clear about the harm reduction organization possessing used needles and syringes. The AMA has model legislation promoting needle and syringe exchange, but it has not been updated since May 2000, and would benefit from revisions to reflect current public health research and AMA policy.

Legal consequences for an opioid-related crime

The AMA Opioid Task Force (Task Force) recently issued a new recommendation that emphasizes that:

all persons entering jails or prisons (both for men's and women's facilities), while incarcerated, and upon release, will benefit from enhanced opioid use disorder screening protocols to identify those persons arrested if they are currently on medication assisted treatment (MAT), or would like to begin treatment.

Furthermore, the Task Force also "supports the use of evidence-based protocols for maintaining continuity of care for persons released from jail or prison, including—as necessary—enrollment in Medicaid, coordination with peer counseling or other services to ensure the person has linkages to treatment providers in the community, and other such services so as to maintain access to and a continuum of care to sustain and promote recovery." Directly relevant to Resolution 919-I-18, the Task Force recommendation states, "[t]his recommendation also applies drug courts and other diversion services to support evidence-driven care for persons with an opioid use disorder."

The Board strongly agrees with the need for the judicial system and correctional settings to view those with an opioid use disorder through a public health and medical lens. For example, AMA policy supports pregnant women who use drugs to receive treatment rather than be subject to criminal sanctions. Moreover, recent AMA advocacy has included strong support for increased access to MAT in jails and prisons¹⁰ and the AMA was the lead amicus in a case supporting a person's right to receive MAT in a correctional facility.¹¹ Thus, it is not just an "opioid-related crime" that should be part of this discussion, but protection for evidence-based medical treatment for those with an opioid use disorder.

Sites of care for persons with a substance use disorder

One of the primary challenges in ending the nation's opioid epidemic remains the inability of most patients to obtain evidence-based care for a serious mental illness or substance use disorder. Of the nearly 57 million adults in the United States with a mental or substance use disorder, nearly 40 million did not receive any treatment in the previous year, according to the 2017 National Survey on Drug Use and Health (NSDUH). Drope than 92 percent of those 12 and older did not receive treatment for a substance use disorder, according to the NSDUH.

 The fourth element of Resolution 919-I-18 raises multiple issues concerning sites of care, capacity of insurance networks, available addiction medicine and psychiatric care providers and related geographic realities of the availability of treatment providers. It would be challenging for any report to sufficiently address these complicated issues. In Huntington, West Virginia, securing enough local beds for acute or long-term care is an ongoing challenge. ¹⁴ In Clark County, Indiana, for example, local emergency departments work to either admit medically unstable patients for treatment, or a patient may be assessed to be cleared for outpatient management.

Capacity to treat all patients who require it, however, is an issue that affects the nation. While network adequacy laws require a sufficient number of addiction medicine and psychiatric physicians in a patient's network, health insurance companies are falling far short of their obligation and enforcement of these requirements is lacking. Moreover, payers also are falling short of compliance with state and federal mental health and substance use disorder parity laws.¹⁵

AMA advocacy in this regard has been substantial and multipronged—focusing on both increasing capacity and increasing payers' demand for mental health and substance use disorder providers. The AMA is working at the state and federal levels to strengthen network adequacy requirements and enforcement and promote meaningful oversight and enforcement of mental health and substance use disorder parity laws. AMA has partnered with the American Psychiatric Association, American Society of Addiction Medicine and many other organizations in the Federation to simultaneously address capacity and access and will continue to do so.

Naloxone has saved tens of thousands of lives

 Naloxone is a lifesaving opioid antagonist that can reverse the effects of an opioid-related overdose. It has no potential for abuse. Naloxone is a 40-year old medication used mainly by first responders and medical staff. Due to its history of safe and effective use, states have enacted standing orders and other laws that permit anyone to obtain a naloxone prescription. The aim of such laws is to provide civilian bystanders who witness an overdose the ability to utilize the overdose reversing medication and save a life. Hundreds of towns and cities have seen the benefits of naloxone firsthand.

A 2017 study found that of opioid overdoses, bystanders were present 40 percent of the time, but naloxone was rarely administered until first responders arrived. Between 2012 to 2016, the rate of emergency medical services (EMS) administered naloxone events increased by 75.1 percent (from 573.6 to 1004.4 administrations per 100,000 EMS events). It is not known how often EMS or others administer multiple doses to a person experiencing an opioid-related overdose. Additionally, in 2018, the number of naloxone prescriptions reached a record high in the United States to more than 598,000 prescriptions, a 107 percent increase from 2017 and a 338 percent increase from 2016. While it has been documented that naloxone can save lives, it is unknown how often it is used by all stakeholders or the number of naloxone administrations that are saving lives. 19

AMA advocacy and partnership with harm reduction advocates and other stakeholders has resulted in every state enacting laws to increase availability of naloxone to patients, bystanders, first responders and others who may be in a position to help someone experiencing an overdose. AMA policy also supports standing orders, strong Good Samaritan protections, needle and syringe exchange and other harm reduction efforts. The AMA supports all forms of naloxone being made available—and does not endorse any specific brand or route of administration. Further, the AMA has called for naloxone manufacturers to submit applications for naloxone to receive over-the-counter status from the U.S. Food and Drug Administration. Moreover, the Task Force has been urging physicians to co-prescribe naloxone as one of its first recommendations in 2015²⁰, and AMA leadership emphasizes this message in nearly every public speaking engagement. These efforts must continue.

Education and prevention efforts for children and young adults

In reviewing the effectiveness of programs that "[e]ncourage prevention education in K-12 programs that uses multiple media with anti-drug messaging delivered in the school system but also in the home," two main themes emerge. First, education programs in Huntington, West Virginia and Clark County, Indiana do not exist in a vacuum. That is, the youth-focused education programs are part of both county- and state-wide efforts to increase awareness of the dangers of drug use. Second, it is not clear whether the programs are having a targeted and beneficial effect on reducing youth drug use or mortality. The State of Indiana does, however, promote a wide range of resources for parents ranging from "What every parent needs to know about Indiana's Opioid Epidemic" to "Indiana State Department of Health's Tips on Substance Use During Pregnancy: How to Have a Healthier Baby" to a "National Institute of Health 2017 National Drug & Alcohol IQ Challenge." Huntington, West Virginia is also engaged in a wide number of areas ranging from programs aimed at high school and local college students, providing resources for parents, and working with multiple public health and law enforcement stakeholders. 22

It is worth highlighting that AMA already has clear policy in support of a public health approach to: reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications; increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction (Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction").

AMA POLICY

Each of the areas covered in this report also has broad support in current AMA policy. This includes policy that "encourages all communities to establish needle exchange programs," and supports "legislation providing funding for needle exchange programs for injecting drug users" (Policy H-95.958, "Syringe and Needle Exchange Programs"). Current policy (and AMA model state legislation) also includes "support and endorse policies and legislation that provide protections for callers or witnesses seeking medical help for overdose victims; and (2) will promote 911 Good Samaritan policies through legislative or regulatory advocacy at the local, state, and national level" (Policy D-95.977, "911 Good Samaritan Laws").

AMA also supports a public health—not criminal—approach to treatment for those who use illicit drugs or misuse prescription medication. This includes policy whereby "transplacental drug transfer should not be subject to criminal sanctions or civil liability" (Policy H-420.962, "Perinatal Addiction - Issues in Care and Prevention"). It also includes support for "the establishment of drug

courts as an effective method of intervention for individuals with addictive disease who are convicted of nonviolent crimes; and encourages legislators to establish drug courts at the state and local level in the United States" (Policy H-100.955, "Support for Drug Courts").

AMA has extensive policy in support of widespread access to naloxone, including support for "legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery" (Policy H-95.932, "Increasing Availability of Naloxone").

Current AMA policy also broadly covers parity issues, including support for "health care reform that meets the needs of all Americans including people with mental illness and substance use/addiction disorders and will advocate for the inclusion of full parity for the treatment of mental illness and substance use/addiction disorders in all national health care reform legislation." (Policy H-165.888, "Evaluating Health System Reform Proposals") (Also see Policy D-180.998, "Insurance Parity for Mental Health and Psychiatry," Policy H-185.974, "Parity for Mental Illness, Alcoholism, and Related Disorders in Medical Benefits Programs.")

RECOMMENDATIONS

The Board recommends that the following recommendation be adopted in lieu of Resolution 919-I-18, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) encourage relevant federal agencies to evaluate and report on outcomes and best practices related to federal grants awarded for the creation of Quick Response Teams and other innovative local strategies to address the opioid epidemic, and that the AMA share that information with the Federation; (Directive to Take Action)

2. That our AMA update model state legislation regarding needle and syringe exchange to state and specialty medical societies; (Directive to Take Action)

3. That our AMA amend Policy H-100.955, "Support for Drug Courts;"

Our AMA: (1) supports the establishment of drug courts as an effective method of intervention for individuals with addictive disease who are convicted of nonviolent crimes; and (2) encourages legislators to establish drug courts at the state and local level in the United States; and (3) encourages drug courts to rely upon evidence-based models of care for those who the judge or court determine would benefit from intervention rather than incarceration. (Modify Current HOD Policy)

4. That our AMA urge state and federal policymakers to enforce applicable mental health and substance use disorder parity laws; (Directive to Take Action)

5. That our AMA reaffirm Policy H-95.932, "Increasing Availability of Naloxone;" and (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction." (Reaffirm HOD Policy)

Fiscal Note: Less than \$500

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- ³ Quick Response Teams that appear to function in makeup and approach similar to that operated by the City of Huntington also are working in Cuyahoga Falls, Ohio; Cape Fear, North Carolina; and other cities and towns.
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- ⁶ North American Syringe Exchange Network, https://nasen.org/
- ⁷ U.S. Centers for Disease Control and Prevention, "Summary of Information on The Safety and Effectiveness of Syringe Services Programs (SSPs)." Last accessed July 25, 2019. Available at https://www.cdc.gov/ssp/syringe-services-programs-summary.html
- ⁸ See, for example, Thometz, Kristen, "Illinois Bill Seeks to Legalize Syringe Exchanges Statewide," WTTW, May 17, 2019. Available at https://news.wttw.com/2019/05/17/illinois-bill-seeks-legalize-syringe-exchanges.
- ⁹ AMA Opioid Task Force Recommendations for Policymakers. May 30, 2019. Available at https://www.end-opioid-epidemic.org/recommendations-for-policymakers/
- ¹⁰ AMA and Vermont Medical Society joint letter to the Vermont Legislature. "American Medical Association and Vermont Medical Society strong support for Senate Bill 166, An act relating to the provision of medication-assisted treatment for inmates," February 21, 2018. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-2-21-AMA-VMS-Letter-in-support-of-VT-SB-166-FINAL.pdf
- ¹¹ Smith v. Aroostook County, 19-1340P (1st Cir. 2019). See order at https://www.aclumaine.org/sites/default/files/field_documents/smith_aroostook_order.pdf
- ¹² 2017 National Survey on Drug Use and Health (NSDUH). U.S. Substance Abuse and Mental Health Services Administration. Report available at https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report
- ¹³ "The National Survey on Drug Use and Health: 2017." Elinore F. McCance-Katz MD, PhD, Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. Presentation available at https://www.samhsa.gov/data/sites/default/files/nsduh-ppt-09-2018.pdf
- ¹⁴ See, for example, Joseph, Andrew, "26 overdoses in just hours: Inside a community on the front lines of the opioid epidemic." STAT. August 22, 2016. Available at https://www.statnews.com/2016/08/22/heroin-huntington-west-virginia-overdoses/
- ¹⁵ See, for example, Milliman Research Report, "Addiction and mental health vs. physical health: Analyzing disparities in network use and provider reimbursement rates," December 2017. Available at https://www.milliman.com/uploadedFiles/insight/2017/NQTLDisparityAnalysis.pdf
- ¹⁶ Mattson C, O'Donnell J, Kariisa M, Seth P, Scholl L, Gladden R. Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016-June 2017. *MMWR Morb Mortal Wkly Rep.* 2018;67:945-951.
- ¹⁷ Cash RE, Kinsman J, Crowe RP, Rivard MK, Faul M, Panchal AR. Naloxone Administration Frequency During Emergency Medical Service Events United States, 2012-2016. *MMWR Morb Mortal Wkly Rep.* 2018;67(31):850-853.
- ¹⁸ American Medical Association. AMA Opioid Task Force 2019 Progress Report. 2019; https://www.end-opioid-epidemic.org/wp-content/uploads/2019/06/AMA-Opioid-Task-Force-2019-Progress-Report-web-1.pdf. Accessed July 1, 2019.
- ¹⁹ Office of U.S. Surgeon General. U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose. 2018; https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.

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²⁰ See, "Help save lives: Co-prescribe naloxone to patients at risk of overdose," AMA Opioid Task Force recommendation. Available at https://www.end-opioid-epidemic.org/wp-content/uploads/2017/08/AMA-Opioid-Task-Force-naloxone-one-pager-updated-August-2017-FINAL-1.pdf
²¹ Information for Parents, Indiana State Department of Health. Available at

https://www.in.gov/isdh/27372.htm

²² See, for example, the plan discussed by the City of Huntington, West Virginia, available at http://www.cityofhuntington.com/assets/pdf/MODCP two year plan May 2017.pdf

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201

(I-19)

Introduced by: Medical Student Section

Subject: Advocating for the Standardization and Regulation of Outpatient Addiction

Rehabilitation Facilities

Referred to: Reference Committee B

Whereas, Substance Use Disorder (SUD) affects over 20.2 million people in America and have been shown to cause detrimental effects on mental and physical health¹; and

Whereas, The Centers for Disease Control and Prevention declared the opioid epidemic a public health crisis, with over 200,000 deaths resulting from the epidemic in 2018²; and

Whereas, There are minimal standards for outpatient addiction rehabilitation facilities on a state and national level, which is uncharacteristic in other outpatient settings³; and

Whereas, There is a lack of evidence-based practices within outpatient addiction rehabilitation centers despite solid evidence of the efficacy of alternative treatments^{4, 5}; and

Whereas, The fraudulent activity of outpatient addiction rehabilitation centers is a problem that faces many states across the country and has led to federal prosecutions in California and Florida^{6, 7}; and

Whereas, The lack of regulation of outpatient addiction rehabilitation centers has led to facilities promoting unconventional and non-evidence-based therapies as effective and proven methods for treating SUDs^{3, 8}; and

Whereas, The lack of regulation of outpatient addiction rehabilitation centers and their affiliates has led to the exploitation of patients and their insurance for monetary gain in the form of disbursements for sober homes who send patients to the respective facilities^{6, 7, 9}; and

Whereas, The success of patients maintaining sobriety and improved social outcomes is largely dependent on continuing outpatient care following initial treatment¹⁰; and

Whereas, Meta-analysis and systematic review suggest that addiction rehabilitation can be made substantially more efficacious by increasing availability of simultaneous psychosocial and medication-based interventions^{11, 12}; and

Whereas, Providing medication assisted treatment for SUDs after an inpatient stay or detoxification stay may help prevent future readmissions¹³; therefore be it

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1 RESOLVED, That our American Medical Association advocate for the expansion of federal

2 regulations of outpatient addiction rehabilitation centers in order to provide patient and

3 community protection in line with evidence-based care. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Substance Use and Substance Use Disorders H-95.922

Our AMA: (1) will continue to seek and participate in partnerships designed to foster awareness and to promote screening, diagnosis, and appropriate treatment of substance misuse and substance use disorders;

(2) will renew efforts to: (a) have substance use disorders addressed across the continuum of medical education; (b) provide tools to assist physicians in screening, diagnosing, intervening, and/or referring patients with substance use disorders so that they have access to treatment; (c) develop partnerships with other organizations to promote national policies to prevent and treat these illnesses, particularly in adolescents and young adults; and (d) assist physicians in becoming valuable resources for the general public, in order to reduce the stigma and enhance knowledge about substance use disorders and to communicate the fact that substance use disorder is a treatable disease; and (3) will support appropriate federal and state legislation that would enhance the prevention, diagnosis, and treatment of substance use disorders.

Citation: CSAPH Rep. 01, A-18;

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Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction D-95.981

- 1. Our AMA:
- a. will collaborate with relevant medical specialty societies to develop continuing medical education curricula aimed at reducing the epidemic of misuse of and addiction to prescription controlled substances, especially by youth;
- b. encourages medical specialty societies to develop practice guidelines and performance measures that would increase the likelihood of safe and effective clinical use of prescription controlled substances, especially psychostimulants, benzodiazepines and benzodiazepines receptor agonists, and opioid analgesics;
- c. encourages physicians to become aware of resources on the nonmedical use of prescription controlled substances that can assist in actively engaging patients, and especially parents, on the benefits and risks of such treatment, and the need to safeguard and monitor prescriptions for controlled substances, with the intent of reducing access and diversion by family members and friends;
- d. will consult with relevant agencies on potential strategies to actively involve physicians in being a part of the solution to the epidemic of unauthorized/nonmedical use of prescription controlled substances; and e. supports research on: (i) firmly identifying sources of diverted prescription controlled substances so that solutions can be advanced; and (ii) issues relevant to the long-term use of prescription controlled substances.
- 2. Our AMA, in conjunction with other Federation members, key public and private stakeholders, and pharmaceutical manufacturers, will pursue and intensify collaborative efforts involving a public health approach in order to:
- a. reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications;
- b. increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and
- c. reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction.

Citation: (CSAPH Rep. 2, I-08; Appended: Res. 517, A-15; Reaffirmed: BOT Rep. 5, I-15)

Medicaid Substance Use Disorder Coverage H-290.962

- 1. Our AMA will advocate that the Centers for Medicare and Medicaid Services provide expanded Medicaid payment coverage for the medical management and treatment of all substance use disorders.
- 2. Our AMA will advocate for clear billing and coding processes regarding the medical management and treatment of all substance use disorders.
- 3. Our AMA recognizes the expertise of addiction specialist physicians and the importance of improving access to management and treatment of addiction services with Medicaid payment for all physician specialties.

Citation: Res. 125, A-17;

Modernizing Privacy Regulations for Addiction Treatment Records H-315.965

Our AMA supports: (1) regulatory and legislative changes that better balance patients' privacy protections against the need for health professionals to be able to offer appropriate medical services to patients with substance use disorders; (2) regulatory and legislative changes that enable physicians to fully collaborate with all clinicians involved in providing health care services to patients with substance use disorders; and (3) continued protections against the unauthorized disclosure of substance use disorder treatment records outside the healthcare system.

Citation: Res. 224, I-17

Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder D-95.968

Our AMA will: (1) advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities; and (2) develop a public awareness campaign to increase awareness that medical treatment of substance use disorder with medication-assisted treatment is a first-line treatment for this chronic medical disease.

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Citation: Res. 222, A-18;

Substance Use Disorders During Pregnancy H-420.950

Our AMA will: (1) oppose any efforts to imply that the diagnosis of substance use disorder during pregnancy represents child abuse; (2) support legislative and other appropriate efforts for the expansion and improved access to evidence-based treatment for substance use disorders during pregnancy; (3) oppose the removal of infants from their mothers solely based on a single positive prenatal drug screen without appropriate evaluation; and (4) advocate for appropriate medical evaluation prior to the removal of a child, which takes into account (a) the desire to preserve the individual's family structure, (b) the patient's treatment status, and (c) current impairment status when substance use is suspected. Citation: Res. 209, A-18; Modified: Res. 520, A-19

Survey of Addiction Treatment Centers' Availability H-95.926

Our AMA: (1) encourages the Substance Abuse and Mental Health Services Administration (SAMHSA) to use its national surveys to increase the information available on the type of insurance (e.g., Medicaid, Medicare, private insurance) accepted by substance use disorder treatment programs listed in SAMHSA's treatment locators; (2) encourages physicians who are authorized to provide medication assisted treatment to opt in to be listed publicly in SAMHSA's treatment locators; and (3) encourages SAMHSA to include private and group practice physicians in its online treatment locator for addiction treatment facilities.

Citation: CMS Rep. 04, A-17

Role of Self-Help in Addiction Treatment H-95.951

The AMA: (1) recognizes that (a) patients in need of treatment for alcohol or other substance use disorders should be treated for these medical conditions by qualified professionals in a manner consonant with accepted practice guidelines and patient placement criteria; and (b) self-help groups are valuable resources for many patients and their families and should be utilized by physicians as adjuncts to a treatment plan; and (2) urges managed care organizations and insurers to consider self-help as a complement to, not a substitute for, treatment directed by professionals, and to refrain from using their patient's involvement in self-help activities as a basis for denying authorization for payment for professional treatment of patients and their families who need such care.

Citation: Res. 713, A-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18

Federal Drug Policy in the United States H-95.981

The AMA, in an effort to reduce personal and public health risks of drug abuse, urges the formulation of a comprehensive national policy on drug abuse, specifically advising that the federal government and the nation should: (1) acknowledge that federal efforts to address illicit drug use via supply reduction and enforcement have been ineffective (2) expand the availability and reduce the cost of treatment programs for substance use disorders, including addiction; (3) lead a coordinated approach to adolescent drug education; (4) develop community-based prevention programs for youth at risk; (5) continue to fund the Office of National Drug Control Policy to coordinate federal drug policy; (6) extend greater protection against discrimination in the employment and provision of services to drug abusers; (7) make a long-term commitment to expanded research and data collection; (8) broaden the focus of national and local policy from drug abuse to substance abuse; and (9) recognize the complexity of the problem of substance abuse and oppose drug legalization.

Perinatal Addiction - Issues in Care and Prevention H-420.962

Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant and breastfeeding women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant and breastfeeding women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and

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breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care.

Citation: (BOT Rep. NNN, A-88; Reaffirmed: CLRPD 1, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 2, I-13)

Promotion of Better Pain Care D-160.981

- 1. Our AMA: (a) will express its strong commitment to better access and delivery of quality pain care through the promotion of enhanced research, education and clinical practice in the field of pain medicine; and (b) encourages relevant specialties to collaborate in studying the following: (i) the scope of practice and body of knowledge encompassed by the field of pain medicine; (ii) the adequacy of undergraduate, graduate and post graduate education in the principles and practice of the field of pain medicine, considering the current and anticipated medical need for the delivery of quality pain care; (iii) appropriate training and credentialing criteria for this multidisciplinary field of medical practice; and (iv) convening a meeting of interested parties to review all pertinent matters scientific and socioeconomic.
- 2. Our AMA encourages relevant stakeholders to research the overall effects of opioid production cuts.
- 3. Our AMA strongly urges the US Drug Enforcement Administration to base any future reductions in aggregate production quotas for opioids on actual data from multiple sources, including prescribing data, and to proactively monitor opioid quotas and supply to prevent any shortages that might develop and to take immediate action to correct any shortages.
- 4. Our AMA encourages the US Drug Enforcement Administration to be more transparent when developing medication production guidelines.
- 5. Our AMA and the physician community reaffirm their commitment to delivering compassionate and ethical pain management, promoting safe opioid prescribing, reducing opioid-related harm and the diversion of controlled substances, improving access to treatment for substance use disorders, and fostering a public health based-approach to addressing opioid-related morbidity and mortality. Citation: Res. 321, A-08; Appended: Res. 522, A-10; Reaffirmed in lieu of Res. 518, A-12; Reaffirmed: BOT Rep. 19, A-16; Reaffirmed in lieu of Res. 117, A-16; Appended: Res. 927, I-16; Appended: Res. 526, A-17; Modified: BOT Action in response to referred for decision Res. 927, I-16; Reaffirmed: Res. 235, I-18; Reaffirmed in lieu of: Res. 228, I-18; Reaffirmation: A-19;

Community-Based Treatment Centers H-160.963

Our AMA supports the use of community-based treatment centers for substance abuse, emotional disorders and developmental disabilities.

Citation: (BOT Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 202

(I-19)

Introduced by: Medical Student Section

Subject: Support for Veterans Courts

Referred to: Reference Committee B

Whereas, Veterans Courts are specialized state and local courts that provide alternatives to incarceration for veterans in the criminal justice system^{1,2,3}; and

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Whereas, Alternatives to incarceration can include treatment for medical illnesses that may be related to a veteran's military service and that may have caused the veteran to commit a criminal offense^{1,2,3}; and

Whereas, These illnesses can include neurological and psychiatric conditions such as cognitive impairment, traumatic brain injury (TBI), depressive disorders, anxiety disorders, post-traumatic stress disorder (PTSD), chronic fatigue syndrome, attention-deficit and hyperactivity disorders, intermittent explosive disorder, and substance use disorders (SUDs)^{1,3,4,5}; and

Whereas, Veterans Courts are based on the model provided by mental health treatment courts and drug courts, but they also provide specialized programs, resources, and personnel to support veterans based on their unique life experiences³; and

Whereas, The US Department of Veterans Affairs (VA) found 551 Veterans Court programs nationwide in 2018²; and

Whereas, The VA requires every VA-affiliated medical center in the US to have a Veterans Justice Outreach specialist to work with veterans in the criminal justice system, including with Veterans Courts²; and

Whereas, Veterans comprise approximately 8% of all federal and state prison inmates⁶; and

Whereas, 64% of incarcerated veterans were sentenced for violent offenses, compared to 48% of incarcerated non-veterans⁶; and

Whereas, Over 25% of a sample of non-deployed Army personnel were found to have psychiatric disorders, and over 11% were found to have multiple psychiatric disorders⁴; and

Whereas, 11-30% of veterans of the Iraq, Afghanistan, Gulf, and Vietnam wars have experienced PTSD, and 27% of veterans with PTSD have co-occurring SUDs^{7.8}; and

Whereas, Over 20% of a sample of veterans of Iraq and Afghanistan were found to have mental illness, and over 10% were found to have co-occurring TBI and PTSD⁹; and

Whereas, PTSD and alcohol misuse were found to be associated with violent and physically aggressive behavior in a sample of veterans of Iraq and Afghanistan¹⁰; and

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Whereas, Studies have found that treatment offered by Veterans Courts results in declines in recidivism rates by 12%; decreased symptoms of PTSD, depression, substance use, and sleep disturbances; and improvements in emotional and social well-being 11,12,13; and

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Whereas, Existing AMA policy "supports the establishment of drug courts" for individuals with SUDs¹⁴; therefore be it

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RESOLVED, That our American Medical Association support the use of Veterans Courts as a method of intervention for veterans who commit criminal offenses that may be related to a neurological or psychiatric disorder. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Support for Drug Courts H-100.955

Our AMA: (1) supports the establishment of drug courts as an effective method of intervention for individuals with addictive disease who are convicted of nonviolent crimes; and (2) encourages legislators to establish drug courts at the state and local level in the United States. Citation: (Res. 201, A-12)

Court-Initiated Medical Treatments in Criminal Cases E-9.7.2

Court-initiated medical treatments raise important questions as to the rights of prisoners, the powers of judges, and the ethical obligations of physicians. Although convicted criminals have fewer rights and protections than other citizens, being convicted of a crime does not deprive an offender of all protections under the law. Court-ordered medical treatments raise the question whether professional ethics permits physicians to cooperate in administering and overseeing such treatment. Physicians have civic duties, but medical ethics do not require a physician to carry out civic duties that contradict fundamental principles of medical ethics, such as the duty to avoid doing harm.

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In limited circumstances physicians can ethically participate in court-initiated medical treatments. Individual physicians who provide care under court order should:

- (a) Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control.
- (b) Treat patients based on sound medical diagnoses, not court-defined behaviors. While a court has the authority to identify criminal behavior, a court does not have the ability to make a medical diagnosis or to determine the type of treatment that will be administered. When the treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, the physician's diagnosis must be confirmed by an independent physician or a panel of physicians not responsible to the state. A second opinion is not necessary in cases of court-ordered counseling or referrals for psychiatric evaluations.
- (c) Decline to provide treatment that is not scientifically validated and consistent with nationally accepted guidelines for clinical practice.
- (d) Be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given. AMA Principles of Medical Ethics: I, III; Issued: 2016; Mod: 2017.

Expansion of US Veterans' Health Care Choices H-510.983

- 1. Our AMA will continue to work with the Veterans Administration (VA) to provide quality care to veterans.
- 2. Our AMA will continue to support efforts to improve the Veterans Choice Program (VCP) and make it a permanent program.
- 3. Our AMA encourages the VA to continue enhancing and developing alternative pathways for veterans to seek care outside of the established VA system if the VA system cannot provide adequate or timely care, and that the VA develop criteria by which individual veterans may request alternative pathways.
- 4. Our AMA will support consolidation of all the VA community care programs.
- 5. Our AMA encourages the VA to use external assessments as necessary to identify and address systemic barriers to care.
- 6. Our AMA will support interventions to mitigate barriers to the VA from being able to achieve its mission.
- 7. Our AMA will advocate that clean claims submitted electronically to the VA should be paid within 14 days and that clean paper claims should be paid within 30 days.
- 8. Our AMA encourages the acceleration of interoperability of electronic personal and medical health records in order to ensure seamless, timely, secure and accurate exchange of information between VA and non-VA providers and encourage both the VA and physicians caring for veterans outside of the VA to exchange medical records in a timely manner to ensure efficient care.
- 9. Our AMA encourages the VA to engage with physicians providing care in the VA system to explore and develop solutions on improving the health care choices of veterans.
- 10. Our AMA will advocate for new funding to support expansion of the Veterans Choice. Citation: CMS Rep. 06, A-17

Access to Health Care for Veterans H-510.985

Our American Medical Association: (1) will continue to advocate for improvements to legislation regarding veterans' health care to ensure timely access to primary and specialty health care within close proximity to a veteran's residence within the Veterans Administration health care system; (2) will monitor implementation of and support necessary changes to the Veterans Choice Program's "Choice Card" to ensure timely access to primary and specialty health care within close proximity to a veteran's residence outside of the Veterans Administration health care system; (3) will call for a study of the Veterans Administration health care system by appropriate entities to address access to care issues experienced by veterans; (4) will advocate that the Veterans Administration health care system pay private physicians a minimum of 100 percent of Medicare rates for visits and approved procedures to ensure adequate access to care and choice of physician; (5) will advocate that the Veterans Administration health care system hire additional primary and specialty physicians, both full and part-time, as needed to provide care to veterans; and (6) will support, encourage and assist in any way possible all organizations, including but not limited to, the Veterans Administration, the Department of Justice, the Office of the Inspector General and The Joint Commission, to ensure comprehensive delivery of health care to our nation's veterans. Citation: Sub. Res. 111, A-15; Reaffirmed: CMS Rep. 06, A-17

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Ensuring Access to Care for our Veterans H-510.986

- 1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans.
- 2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner.
- 3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
- 4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the registry be made available to the veterans in their community and the local Veterans Administration.
- 5. Our AMA will strongly advocate that the Veterans Health Administration and Congress develop and implement necessary resources, protocols, and accountability to ensure the Veterans Health Administration recruits, hires and retains physicians and other health care professionals to deliver the safe, effective and high-quality care that our veterans have been promised and are owed. Citation: Res. 231, A-14; Reaffirmation A-15; Reaffirmed: Sub. Res. 709, A-15; Modified: Res. 820, I-18

Health Care Policy for Veterans H-510.990

Our AMA encourages the Department of Veterans Affairs to continue to explore alternative mechanisms for providing quality health care coverage for United States Veterans, including an option similar to the Federal Employees Health Benefit Program (FEHBP).

Citation: (Sub. Res.115, A-00; Reaffirmation I-03; Reaffirmed: CMS Rep. 4, A-13)

Veterans Administration Health System H-510.991

Our AMA supports approaches that increase the flexibility of the Veterans Health Administration to provide all veterans with improved access to health care services.

Citation: CMS Rep. 8, A-99; Reaffirmed: CMS Rep. 5, A-09; Reaffirmed: CMS Rep. 01, A-19

Ethics Reform Act of 1989 (PL 101194) H-510.994

It is the policy of the AMA to work with representatives of [the] Central Office, Department of Veterans Affairs, to develop provisions to exclude either by regulation or by legislation part-time Department of Veterans Affairs physicians (as well as attending and consulting physicians) from the provisions of the Ethics Reform Act of 1989.

Citation: (Res. 254, A-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: BOT Rep. 6, A-10)

Budgetary and Management Needs of the Veterans Health Administration H-510.995

Our AMA urges Congress and the President to provide the VHA: (1) with funding sufficient to allow its hospitals and clinics to provide proper care to the patients the VHA is mandated to treat; and (2) with maximum flexibility in eliminating unneeded or duplicative services and in closing clinics or hospitals. Citation: (BOT Rep. EE, A-89; Reaffirmed: Sunset Report, A-00; Modified: CMS Rep. 6, A-10)

Veterans Health Administration Health Care System D-510.999

Our AMA will: (1) urge state medical associations to encourage their members to advise patients who qualify for Veterans Health Administration (VHA) care of the importance of facilitating the flow of clinical information among all of the patient's health care providers, both within and outside the VHA system; (2) facilitate collaborative processes between state medical associations and VHA regional authorities, aimed at generating regional and institutional contacts to serve as single points of access to clinical information about veterans receiving care from both private physicians and VHA providers; and (3) continue discussions at the national level with the VHA and the Centers for Medicare and Medicaid Services (CMS), to explore the need for and feasibility of legislation to address VHA's payment for prescriptions written by physicians who have no formal affiliation with the VHA.

Citation: (CMS Rep. 1, A-03; Reaffirmed: CMS Rep. 4, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 203

(I-19)

Introduced by: Medical Student Section

Subject: Support Expansion of Good Samaritan Laws

Referred to: Reference Committee B

Whereas, In 2016, drug overdoses killed 63,632 Americans, the leading cause of preventable death in the USA¹⁻³; and

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Whereas, Opioid overdose can be effectively reversed using the opioid antagonist naloxone^{4,5}; and

Whereas, Between 21-68% of overdose bystanders call 911, but many delay or refrain from calling 911 altogether often due to fear of arrest^{6,7}; and

Whereas, 46 states have passed some form of a "Good Samaritan Law" (GSL) as endorsed by our AMA (D-95.977) to provide limited immunity from drug-related offenses to people who seek medical assistance in the event of an overdose⁸; and

Whereas, Many people who use drugs are not aware these laws exist, one study found that two-thirds of those surveyed were unaware of GSLs⁶; and

Whereas, A study in New York found that bystanders with a correct understanding of GSLs were three times more likely to call 911 in the event of an overdose than those who had incorrect knowledge about GSLs⁹; and

Whereas, GSLs provide variable legal protection by state, which may confer protection against prosecution for specific crimes such as the possession of illicit/controlled substances, paraphernalia, and/or parole/pretrial/probation violations^{6,10,11}; and

Whereas, A drug-induced homicide is defined as a crime in which a person delivered or provided drugs to another person that resulted in their death¹²; and

Whereas, GSLs do not provide protections for drug-induced homicide^{7,13}; and

Whereas, Only Vermont and Delaware have specific laws that provide immunity for druginduced homicide if a person seeks medical assistance¹⁰; and

Whereas, Some states have enacted "911 Medical Amnesty Laws" to protect individuals from arrest, prosecution or conviction of certain drug offenses if the evidence results from seeking medical assistance for someone thought to be suffering from a drug overdose¹⁴; and

Whereas, The enactment of aforementioned medical amnesty policies in cases of underage drinking have been shown to not increase consumption¹⁵; and

Resolution: 203 (I-19) Page 2 of 4

Whereas, As of 2016, 40 states had implemented medical amnesty laws protecting minors in alcohol related emergencies¹⁶; and

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Whereas, Implementation of Medical Amnesty Protocols (MAP) did not result in increased drinking, overall consumption, or the incidence of physiological consequences¹⁷; and

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Whereas, After the creation of MAP, Cornell students showed an increased willingness to seek help for alcohol related emergencies, and there was a 61% decrease in the students who cited fear of getting in trouble as the reason they did not call for help¹⁵; and

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Whereas, The number of prosecutions of drug-induced homicide across the country has increased over 300% since 2011, with the Midwest accounting for a large portion of this increase; family members, friends, and partners are the frequent victims of these prosecutions^{10,18–20}; and

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Whereas, Increases in drug-induced homicide prosecutions are correlated with increases in fatal overdose rates and studies suggest this may be due to increased fear of calling for help^{7,10,18}; and

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Whereas, Research suggests that a lack of Good Samaritan laws can lead to conditions in which there are higher opioid-related deaths and decreased medical interventions--representing a real public health concern²¹; therefore be it

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RESOLVED, That our American Medical Association amend Policy D-95.977 by addition and deletion to read as follows:

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911 Good Samaritan Laws, D-95.977

Our AMA: (1) will support and endorse policies and legislation that provide protections for callers or witnesses seeking medical help for overdose victims; and (2) will promote 911 Good Samaritan policies through legislative or regulatory advocacy at the local, state, and national level; and (3) will work with the relevant organizations and state societies to raise awareness about the existence and scope of Good Samaritan Laws. (Modify Current HOD Policy)

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Fiscal note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

911 Good Samaritan Laws D-95.977

Our AMA: (1) will support and endorse policies and legislation that provide protections for callers or witnesses seeking medical help for overdose victims; and (2) will promote 911 Good Samaritan policies through legislative or regulatory advocacy at the local, state, and national level.

Citation: (Res. 225, A-14)

Prevention of Opioid Overdose D-95.987

- 1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
- 2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.
- 3. Our AMA will support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18

Harm Reduction Through Addiction Treatment H-95.956

The AMA endorses the concept of prompt access to treatment for chemically dependent patients, regardless of the type of addiction, and the AMA will work toward the implementation of such an approach nationwide. The AMA affirms that addiction treatment is a demonstrably viable and efficient method of reducing the harmful personal and social consequences of the

Page 4 of 4

inappropriate use of alcohol and other psychoactive drugs and urges the Administration and Congress to provide significantly increased funding for treatment of alcoholism and other drug dependencies and support of basic and clinical research so that the causes, mechanisms of action and development of addiction can continue to be elucidated to enhance treatment efficacy.

Citation: (Res. 411, A-95; Appended: Res. 405, I-97; Reaffirmation I-03; Reaffirmed: CSAPH Rep. 1, A-13)

Increasing Availability of Naloxone H-95.932

- 1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
- 2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
- 3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
- 4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
- 5. Our AMA supports liability protections for physicians and other health care professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law
- 6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.
- 7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
- 8. Our AMA supports the widespread implementation of easily accessible Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions) throughout the country following distribution and legislative edicts similar to those for Automated External Defibrillators.
- 9. Our AMA supports the legal access to and use of naloxone in all public spaces regardless of whether the individual holds a prescription.

Citation: BOT Rep. 22, A-16; Modified: Res. 231, A-17; Modified: Speakers Rep. 01, A-17; Appended: Res. 909, I-17; Reaffirmed: BOT Rep. 17, A-18; Modified: Res. 524, A-19

Support for Medical Amnesty Policies for Underage Alcohol Intoxication H-30.938
Our AMA supports efforts among universities, hospitals, and legislators to establish medical amnesty policies that protect underage drinkers from punishment for underage drinking when seeking emergency medical attention for themselves or others.
Citation: (Res. 202, A-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 204

(I-19)

Introduced by New York

Subject: AMA Position on Payment Provisions in Health Insurance Policies

Referred to: Reference Committee B

Whereas, Certain health insurance policies require payments be sent to patients rather than physicians; and

2 3 4

Whereas, These policies occur primarily in out-of-network care settings, making it more difficult for the physician to collect payment for service rendered to the patient; and

5 6 7

Whereas, Health insurance companies are more frequently inserting provisions into their plan documents that prevent a patient from assigning their benefits to their doctor; and

8 9 10

Whereas, Such 'anti-assignment' provisions significantly harm both doctor and patient, are fundamentally unfair and have benefit only for the insurance company; therefore be it

11 12 13

RESOLVED, That our American Medical Association seek legislation to ban anti-assignment provisions in health insurance plans (Directive to Take Action); and be it further

14 15

16 RESOLVED, That our AMA support legislation requiring health insurers to issue payment 17 directly to the physician when the patient or patient representative signs an agreement which 18 permits payment directly to the physician. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/19/19

RELEVANT AMA POLICY

Health Plan Payment of Patient Cost-Sharing D-180.979

Our AMA will: (1) support the development of sophisticated information technology systems to help enable physicians and patients to better understand financial obligations; (2) encourage states and other stakeholders to monitor the growth of high deductible health plans and other forms of cost-sharing in health plans to assess the impact of such plans on access to care, health outcomes, medical debt, and provider practice sustainability; (3) advocate for the inclusion of health insurance contract provisions that permit network physicians to collect patient cost-sharing financial obligations (eg, deductibles, co-payments, and co-insurance) at the time of service; and (4) monitor programs wherein health plans and insurers bear the responsibility of collecting patient co-payments and deductibles.

CMS Rep. 09, A-19;

Page 2 of 2

Requiring Third Party Reimbursement Methodology be Published for Physicians H-185,975

Our AMA: (1) urges all third party pavers and self-insured plans to publish their payment policies, rules, and fee schedules; (2) pursues all appropriate means to make publication of payment policies and fee schedules a requirement for third party payers and self-insured plans; (3) will develop model state and federal legislation that would require that all third party payers and self-insured plans publish all payment schedule updates, and changes at least 60 days before such changes in payment schedules are enacted, and that all participating physicians be notified of such changes at least 60 days before changes in payment schedules are enacted; (4) seeks legislation that would mandate that insurers make available their complete payment schedules, coding policies and utilization review protocols to physicians prior to signing a contract and at least 60 days prior to any changes being made in these policies; (5) works with the National Association of Insurance Commissioners, develop model state legislation, as well developing national legislation affecting those entities that are subject to ERISA rules; and explore the possibility of adding payer publication of payment policies and fee schedules to the Patient Protection Act; and (6) supports the following requirements: (a) that all payers make available a copy of the executed contract to physicians within three business days of the request; (b) that all health plan EOBs contain documentation regarding the precise contract used for determining the reimbursement rate; (c) that once a year, all contracts must be made available for physician review at no cost; (d) that no contract may be changed without the physician's prior written authorization; and (e) that when a contract is terminated pursuant to the terms of the contract, the contract may not be used by any other payer. Sub. Res. 805, I-95; Appended: Res. 117, A-98; Reaffirmation A-99; Appended: Res. 219, and Reaffirmed: CMS Rep. 6, A-00; Reaffirmation I-01; Reaffirmed and Appended: Res. 704, A-03; Reaffirmation I-04; Reaffirmation A-08; Reaffirmation I-08; Reaffirmed: CMS Rep. 3, I-09; Reaffirmation A-14

Update on HSAs, HRAs, and Other Consumer-Driven Health Care Plans H-165.849

- 1. Our AMA opposes health plan requirements that require physicians to bill patients for out-of-pocket payments and do not allow physicians to collect these payments in a more efficient manner, such as collecting at point-of-service, establishing systems of electronic transfers from a patient's account, or offering cash discounts for expedited payment, particularly for patients enrolled in health savings accounts (HSAs), health reimbursement arrangements (HRAs), and other consumer-directed health care plans.
- 2. Our AMA will engage in a dialogue with health plan representatives (e.g., America's Health Insurance Plans, Blue Cross and Blue Shield Association) about the increasing difficulty faced by physician practices in collecting co-payments and deductibles from patients enrolled in high-deductible health plans.

CMS Rep. 3, I-05; Reaffirmed: CMS Rep. 1, A-15; Appended: BOT Action in response to referred for decision Res. 805, I-16; Reaffirmed: CMS Rep. 09, A-19;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 205

(I-19)

Introduced by: Virginia, American Association of Clinical Urologists, West Virginia,

New Jersey, Maryland, Alabama, Georgia, District of Columbia, Kentucky, Oklahoma, American Urological Association, Mississippi, Delaware, Illinois

Subject: Co-Pay Accumulators

Referred to: Reference Committee B

1 Whereas, Virginia is the first state in the nation to pass legislation regulating Co-Pay

2 Accumulators. Under a Co-Pay Accumulator program the value of a manufacturer's copay

3 coupon is unable to be counted towards the beneficiary's deductible or out of pocket maximum.

4 Once the coupon's value is exhausted, the beneficiary is still responsible for the deductible

5 before plan benefits commence; and

6 7

8

9

Whereas, Virginia Law, effective January 1, 2020, states "When calculating an enrollee's overall contribution to any out of pocket maximum, deductible, copayment, coinsurance, or other cost-sharing requirement under a health plan, a carrier shall include any amounts paid by the enrollee or paid on behalf of the enrollee by another person"; and

10 11 12

13

Whereas, Two other states, including West Virginia and Arizona, have passed similar legislation in Spring of 2019 prohibiting health insurance plans from enacting co-pay accumulator policies that do not count third-party financial assistance toward a patient's out-of-pocket expenses; and

14 15 16

Whereas, Several other states, including Illinois, Connecticut, Indiana, Kentucky, and North Carolina are considering passing their own laws to ban copay accumulator programs; therefore be it

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17

RESOLVED, That our American Medical Association develop model state legislation based on the recent law enacted in Virginia regarding Co-Pay Accumulators. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 08/29/19

VIRGINIA ACTS OF ASSEMBLY -- 2019 SESSION

CHAPTER 661

An Act to amend and reenact §§ 38.2-4214 and 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding in Article 1 of Chapter 34 of Title 38.2 a section numbered 38.2-3407.20, relating to health plans; calculation of enrollee's contribution to out-of-pocket maximum or cost-sharing requirement.

[H 2515]

Approved March 21, 2019

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-4214 and 38.2-4319 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 1 of Chapter 34 of Title 38.2 a section numbered 38.2-3407.20 as follows:

§ 38.2-3407.20. Calculation of enrollee's contribution to out-of-pocket maximum or cost-sharing requirement.

A. As used in this section:

"Carrier" shall have the meaning set forth in § 38.2-3407.10; however, "carrier" also includes any person required to be licensed under this title that offers or operates a managed care health insurance plan subject to Chapter 58 (§ 38.2-5800 et seq.) or that provides or arranges for the provision of health care services, health plans, networks, or provider panels that are subject to regulation as the business of insurance under this title.

"Cost sharing" means any coinsurance, copayment, or deductible.

"Enrollee" means any person entitled to health care services from a carrier.

"Health care services" means items or services furnished to any individual for the purpose of

preventing, alleviating, curing, or healing human illness, injury, or physical disability.

"Health plan" means any individual or group health care plan, subscription contract, evidence of coverage, certificate, health services plan, medical or hospital services plan, accident and sickness insurance policy or certificate, managed care health insurance plan, or other similar certificate, policy, contract, or arrangement, and any endorsement or rider thereto, to cover all or a portion of the cost of persons receiving covered health care services, that is subject to state regulation and that is required to be offered, arranged, or issued in the Commonwealth by a carrier licensed under this title. "Health plan" does not mean (i) coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP), 5 U.S.C. § 8901 et seq. (federal employees), or 10 U.S.C. § 1071 et seq. (TRICARE); or (ii) accident only, credit or disability insurance, long-term care insurance, TRICARE supplement, Medicare supplement, or workers' compensation coverages.

- B. To the extent permitted by federal law and regulation, when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement under a health plan, a carrier shall include any amounts paid by the enrollee or paid on behalf of the enrollee by another person.
- C. This section shall apply with respect to health plans that are entered into, amended, extended, or renewed on or after January 1, 2020.
- D. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and regulations as it may deem necessary to implement this section.

§ 38.2-4214. Application of certain provisions of law.

No provision of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-218 through 38.2-225, 38.2-230, 38.2-325, 38.2-305, 38.2-316, 38.2-316.1, 38.2-322, 38.2-325, 38.2-326, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, 38.2-700 through 38.2-705, 38.2-900 through 38.2-904, 38.2-1017, 38.2-1018, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1315.1, 38.2-1317 through 38.2-1328, 38.2-1334, 38.2-1340, 38.2-1400 through 38.2-1442, 38.2-1446, 38.2-1447, 38.2-1800 through 38.2-1836, 38.2-3400, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3405.1, 38.2-3406.1, 38.2-3406.2, 38.2-3407.1 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.19 38.2-3407.20, 38.2-3409, 38.2-3411 through 38.2-3419.1, 38.2-3407.1 through 38.2-3407.20, 38.2-3514.1, 38.2-3510, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, §§ 38.2-3516 through 38.2-3520 as they apply to Medicare supplement policies, §§ 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3524.1, 38.2-3541 through 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 35.1 (§ 38.2-3556 et seq.), §§ 38.2-3600 through 38.2-3607, Chapter 52

(§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), and Chapter 58 (§ 38.2-5800 et seq.) of this title shall apply to the operation of a plan.

§ 38.2-4319. Statutory construction and relationship to other laws.

- A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-316.1, 38.2-322, 38.2-325, 38.2-326, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.), 5 (§ 38.2-1322 et seq.), 5.1 (§ 38.2-1334.3 et seq.), and 5.2 (§ 38.2-1334.11 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.), 2 (§ 38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, Chapter 15 (§ 38.2-1500 et seq.), Chapter 17 (§ 38.2-1700 et seq.), §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3406.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.19 38.2-3407.20, 38.2-3411, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.17, 38.2-3419.1, 38.2-3430.1 through 38.2-3454, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3540.2, 38.2-3541.2, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 35.1 (§ 38.2-3556 et seq.), Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), and Chapter 58 (§ 38.2-5800 et seq.) shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) except with respect to the activities of its health maintenance organization.
- B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-322, 38.2-322, 38.2-325, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.), 5 (§ 38.2-1322 et seq.), 5.1 (§ 38.2-1334.3 et seq.), and 5.2 (§ 38.2-13441 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.), 2 (§ 38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6, 38.2-3407.6; 38.2-3407.9, 38.2-3407.9; 01, and 38.2-3407.9; 02, subdivisions F 1, F 2, and F 3 of § 38.2-3407.10, §§ 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13; 1, 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3514.1, 38.2-3514.1, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2, 38.2-3540.2 through 38.2-3520.1 through 38.2-3520.2 through 38.2-3520.4 to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter or health services plan licensed and regulated in conformance with the insurance laws or Chapter or health services plan licensed and regulated in conformance with the insurance laws or Chapter or health s
- C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.
- D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.
- E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.
- F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Access to Healthcare:

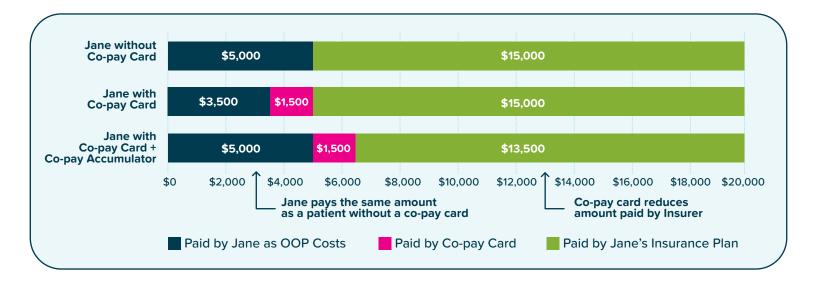
Co-pay Accumulator Programs

What is a Co-pay Accumulator Program?

- » A co-pay accumulator program—also known as an accumulator adjustment program—is a new kind of policy being adopted by some insurance plans.
- These programs change the way a patient's out-of-pocket (OOP) medication costs are added up (accumulated) and applied toward meeting the OOP maximum under their insurance policy.
- » OOP drug costs are the part of a patient's medication expenses not covered by insurance.
- **Deductibles**, **co-payments** and **coinsurance** are three types of OOP drug costs:
 - A **deductible** is the amount that a patient must pay before their insurance plan begins covering the cost of their medications.
 - A co-payment is a flat fee (ex: \$10) that patients pay each time they fill a prescription.
 - Coinsurance is a percentage of the cost of each prescription that is filled.
 - Depending on the cost of the drug, some insurance plans have levels or "tiers" of co-payments/coinsurance, with higher OOP costs for more expensive drugs.

What Are Co-pay Cards and How Have They Been Used in the Past?

- » Some drug manufacturers offer co-pay cards to help underinsured patients afford their prescription medications.
 - Only patients with commercial insurance can use these cards.
- » Many patients use co-pay cards to help pay their deductibles, co-pays or coinsurance, and reduce their OOP drug costs.
- The illustration below shows the impact of a \$1,500 co-pay card on the OOP drug costs for a hypothetical patient, Jane, with multiple sclerosis, who has:
 - \$20,000 in drug costs for the year.
 - An insurance policy with maximum OOP costs of \$5,000 (deductible + co-pays + coinsurance).
- » Without a co-pay card, Jane would need to pay \$5,000 in OOP costs to access her medications, with insurance covering the remaining \$15,000.
- With a co-pay card, she would need to pay only \$3,500 in OOP costs for the year.



What Happens to Patients Under Co-pay Accumulator Programs?

- » Co-pay accumulator programs prevent patients from using co-pay cards to cover their OOP drug costs.
- » In the example above, Jane no longer benefits from her \$1,500 co-pay card.
 - She must pay the full \$5,000 in OOP costs to access her medications.
 - These are the same OOP costs that would be paid by Jane without a co-pay card.
- » For some patients, the extra OOP drug costs that are incurred under co-pay accumulator programs will make their prescription medications unaffordable. Many of these patients will:
 - Stop their treatment.
 - Reduce their dose, skip doses or cut pills to make their medication last longer.
 - Be forced to choose between staying on their medication and covering other costs such as food, housing and utilities.

Who is Affected by Co-pay Accumulator Programs?

- » Patients with commercial insurance—especially those who get insurance through their employers or through the Affordable Care Act.
- Co-pay accumulator programs are especially challenging for patients who:
 - Require expensive medications.
 - Have health insurance plans with high deductibles or high co-payments/coinsurance.
 - Are economically vulnerable.
- » Many patients do not know that their health plans have co-pay accumulator programs until they get to the pharmacy counter and are confronted with unexpected OOP drug expenses.



Steps You Can Take

- » Find out if your health insurance plan has a co-pay accumulator program.
- » Be sure you know your plan's annual deductible and the co-payments/coinsurance for the medications you take so that you understand what your OOP drug costs will be for your prescription medications.
- Talk to your benefits manager or health plan about how the co-pay accumulator program impacts your ability to remain on your treatment.
- Inform your healthcare provider that your insurance plan has a co-pay accumulator program, and how the program impacts your ability to cover the OOP costs for your medications.
- » Share your story with a patient advocacy group.

The PAN Foundation

The mission of the PAN Foundation is to help underinsured people with life-threatening, chronic and rare diseases get the medications and treatment they need by paying for their out-of-pocket costs and advocating for improved access and affordability.

For more information about the PAN Foundation, visit www.panfoundation.org.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 206

(I-19)

Introduced by: International Medical Graduates Section

Minority Affairs Section

Subject: Improvement of Healthcare Access in Underserved Areas by Retaining and

Incentivizing IMG Physicians

Referred to: Reference Committee B

Whereas, One in four of the practicing physician workforce in the United States of America are trained at an international medical school¹; and

Whereas, 41% of the international medical graduates (IMG) serve in the primary care disciplines, as defined by the Association of American Medical Colleges (AAMC), including internal medicine, family medicine, pediatrics and geriatrics²; and

Whereas, An American Medical Association and American Osteopathic Association database study showed that the IMGs are more likely to serve in the rural persistent poverty areas in primary care, compared to their U.S, counterparts and DOs³; and

Whereas, By 2030, an estimated shortage of between 14,800 and 49,300 primary care physicians has been projected by a recent American Association of Medical Colleges report⁴; and

Whereas, The U.S. population aged over 65 is estimated to grow over 50% by 2030 and one third of the currently active physicians will be older than 65 in the next decade⁴; and

Whereas, If people in the underserved and rural areas and people without insurance would use healthcare the same way as the people with insurance and the people in the metropolitan areas; an additional 31,600 physicians were needed in 2016⁴; and

Whereas, Critical access hospitals in underserved areas continue to face a crisis due to uncompensated care and limited retention of physicians; and

Whereas, The residents of the rural and underserved areas tend to be older, more chronically ill, of a lower socioeconomic background and uninsured⁵, resulting in significant disparities in rural and urban health care status and life expectancy⁶; and

Whereas, The overall number of U.S. medical graduates choosing careers as general internist has declined over many years and retention of general practice physicians remained a persistent challenge in improving health care access in these areas⁷; and

Page 2 of 5

1 Whereas, A current Conrad 30 Reauthorization Bill (Senate Bill S948) has proposed a pathway 2

- for IMGs to serve in the federally designated health professional shortage area (HPSA) with a
- 3 majority of Medicare/Medicaid and uninsured population for a longer duration, an increased
- 4 number of IMGs to be available in each state to serve in these areas and have incentives to

serve and settle in these areas; therefore be it

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RESOLVED. That our American Medical Association support efforts to retain and incentivize international medical graduates serving in federally designated health professional shortage areas after the current allocated period. (Directive to Take Action).

Fiscal Note: Minimal - less than \$1,000

Received: 10/01/19

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RELEVANT AMA POLICY

US Physician Shortage H-200.954

Our AMA:

- (1) explicitly recognizes the existing shortage of physicians in many specialties and areas of the US;
- (2) supports efforts to quantify the geographic maldistribution and physician shortage in many specialties;
- (3) supports current programs to alleviate the shortages in many specialties and the maldistribution of physicians in the US:
- (4) encourages medical schools and residency programs to consider developing admissions policies and practices and targeted educational efforts aimed at attracting physicians to practice in underserved areas and to provide care to underserved populations;
- (5) encourages medical schools and residency programs to continue to provide courses, clerkships, and longitudinal experiences in rural and other underserved areas as a means to support educational program objectives and to influence choice of graduates' practice locations;
- (6) encourages medical schools to include criteria and processes in admission of medical students that are predictive of graduates' eventual practice in underserved areas and with underserved populations;
- (7) will continue to advocate for funding from public and private payers for educational programs that provide experiences for medical students in rural and other underserved areas;
- (8) will continue to advocate for funding from all payers (public and private sector) to increase the number of graduate medical education positions in specialties leading to first certification;
- (9) will work with other groups to explore additional innovative strategies for funding graduate medical education positions, including positions tied to geographic or specialty need;
- (10) continues to work with the Association of American Medical Colleges (AAMC) and other relevant groups to monitor the outcomes of the National Resident Matching Program; and
- (11) continues to work with the AAMC and other relevant groups to develop strategies to address the current and potential shortages in clinical training sites for medical students.
- (12) will: (a) promote greater awareness and implementation of the Project ECHO (Extension for Community Healthcare Outcomes) and Child Psychiatry Access Project models among academic health

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centers and community-based primary care physicians; (b) work with stakeholders to identify and mitigate barriers to broader implementation of these models in the United States; and (c) monitor whether health care payers offer additional payment or incentive payments for physicians who engage in clinical practice improvement activities as a result of their participation in programs such as Project ECHO and the Child Psychiatry Access Project; and if confirmed, promote awareness of these benefits among physicians. Citation: Res. 807, I-03; Reaffirmation I-06; Reaffirmed: CME Rep. 7, A-08; Appended: CME Rep. 4, A-10; Appended: CME Rep. 16, A-10; Reaffirmation: I-12; Reaffirmation A-13; Appended: Res. 922, I-13; Modified: CME Rep. 7, A-14; Reaffirmed: CME Rep. 03, A-16; Appended: Res. 323, A-19

Principles of and Actions to Address Primary Care Workforce H-200.949

- 1. Our patients require a sufficient, well-trained supply of primary care physicians--family physicians, general internists, general pediatricians, and obstetricians/gynecologists--to meet the nation's current and projected demand for health care services.
- 2. To help accomplish this critical goal, our American Medical Association (AMA) will work with a variety of key stakeholders, to include federal and state legislators and regulatory bodies; national and state specialty societies and medical associations, including those representing primary care fields; and accreditation, certification, licensing, and regulatory bodies from across the continuum of medical education (undergraduate, graduate, and continuing medical education).
- 3. Through its work with these stakeholders, our AMA will encourage development and dissemination of innovative models to recruit medical students interested in primary care, train primary care physicians, and enhance both the perception and the reality of primary care practice, to encompass the following components: a) Changes to medical school admissions and recruitment of medical students to primary care specialties, including counseling of medical students as they develop their career plans; b) Curriculum changes throughout the medical education continuum; c) Expanded financial aid and debt relief options; d) Financial and logistical support for primary care practice, including adequate reimbursement, and enhancements to the practice environment to ensure professional satisfaction and practice sustainability; and e) Support for research and advocacy related to primary care.
- 4. Admissions and recruitment: The medical school admissions process should reflect the specific institution's mission. Those schools with missions that include primary care should consider those predictor variables among applicants that are associated with choice of these specialties.
- 5. Medical schools, through continued and expanded recruitment and outreach activities into secondary schools, colleges, and universities, should develop and increase the pool of applicants likely to practice primary care by seeking out those students whose profiles indicate a likelihood of practicing in primary care and underserved areas, while establishing strict guidelines to preclude discrimination.
- 6. Career counseling and exposure to primary care: Medical schools should provide to students career counseling related to the choice of a primary care specialty, and ensure that primary care physicians are well-represented as teachers, mentors, and role models to future physicians.
- 7. Financial assistance programs should be created to provide students with primary care experiences in ambulatory settings, especially in underserved areas. These could include funded preceptorships or summer work/study opportunities.
- 8. Curriculum: Voluntary efforts to develop and expand both undergraduate and graduate medical education programs to educate primary care physicians in increasing numbers should be continued. The establishment of appropriate administrative units for all primary care specialties should be encouraged.
- 9. Medical schools with an explicit commitment to primary care should structure the curriculum to support this objective. At the same time, all medical schools should be encouraged to continue to change their curriculum to put more emphasis on primary care.
- 10. All four years of the curriculum in every medical school should provide primary care experiences for all students, to feature increasing levels of student responsibility and use of ambulatory and community-based settings.
- 11. Federal funding, without coercive terms, should be available to institutions needing financial support to expand resources for both undergraduate and graduate medical education programs designed to increase the number of primary care physicians. Our AMA will advocate for public (federal and state) and private payers to a) develop enhanced funding and related incentives from all sources to provide education for medical students and resident/fellow physicians, respectively, in progressive, community-based models of integrated care focused on quality and outcomes (such as the patient-centered medical home and the chronic care model) to enhance primary care as a career choice; b) fund and foster innovative pilot programs that change the current approaches to primary care in undergraduate and graduate medical education, especially in urban and rural underserved areas; and c) evaluate these

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efforts for their effectiveness in increasing the number of students choosing primary care careers and helping facilitate the elimination of geographic, racial, and other health care disparities.

- 12. Medical schools and teaching hospitals in underserved areas should promote medical student and resident/fellow physician rotations through local family health clinics for the underserved, with financial assistance to the clinics to compensate their teaching efforts.
- 13. The curriculum in primary care residency programs and training sites should be consistent with the objective of training generalist physicians. Our AMA will encourage the Accreditation Council for Graduate Medical Education to (a) support primary care residency programs, including community hospital-based programs, and (b) develop an accreditation environment and novel pathways that promote innovations in graduate medical education, using progressive, community-based models of integrated care focused on quality and outcomes (such as the patient-centered medical home and the chronic care model).
- 14. The visibility of primary care faculty members should be enhanced within the medical school, and positive attitudes toward primary care among all faculty members should be encouraged.
- 15. Support for practicing primary care physicians: Administrative support mechanisms should be developed to assist primary care physicians in the logistics of their practices, along with enhanced efforts to reduce administrative activities unrelated to patient care, to help ensure professional satisfaction and practice sustainability.
- 16. There should be increased financial incentives for physicians practicing primary care, especially those in rural and urban underserved areas, to include scholarship or loan repayment programs, relief of professional liability burdens, and Medicaid case management programs, among others. Our AMA will advocate to state and federal legislative and regulatory bodies, among others, for development of public and/or private incentive programs, and expansion and increased funding for existing programs, to further encourage practice in underserved areas and decrease the debt load of primary care physicians. The imposition of specific outcome targets should be resisted, especially in the absence of additional support to the schools.
- 17. Our AMA will continue to advocate, in collaboration with relevant specialty societies, for the recommendations from the AMA/Specialty Society RVS Update Committee (RUC) related to reimbursement for E&M services and coverage of services related to care coordination, including patient education, counseling, team meetings and other functions; and work to ensure that private payers fully recognize the value of E&M services, incorporating the RUC-recommended increases adopted for the most current Medicare RBRVS.
- 18. Our AMA will advocate for public (federal and state) and private payers to develop physician reimbursement systems to promote primary care and specialty practices in progressive, community-based models of integrated care focused on quality and outcomes such as the patient-centered medical home and the chronic care model consistent with current AMA Policies H-160.918 and H-160.919.

 19. There should be educational support systems for primary care physicians, especially those practicing
- in underserved areas.

 20. Our AMA will urge urban hospitals, medical centers, state medical associations, and specialty societies to consider the expanded use of mobile health care capabilities.
- 21. Our AMA will encourage the Centers for Medicare & Medicaid Services to explore the use of telemedicine to improve access to and support for urban primary care practices in underserved settings. 22. Accredited continuing medical education providers should promote and establish continuing medical education courses in performing, prescribing, interpreting and reinforcing primary care services.
- 23. Practicing physicians in other specialties--particularly those practicing in underserved urban or rural areas--should be provided the opportunity to gain specific primary care competencies through short-term preceptorships or postgraduate fellowships offered by departments of family medicine, internal medicine, pediatrics, etc., at medical schools or teaching hospitals. In addition, part-time training should be encouraged, to allow physicians in these programs to practice concurrently, and further research into these concepts should be encouraged.
- 24. Our AMA supports continued funding of Public Health Service Act, Title VII, Section 747, and encourages advocacy in this regard by AMA members and the public.
- 25. Research: Analysis of state and federal financial assistance programs should be undertaken, to determine if these programs are having the desired workforce effects, particularly for students from disadvantaged groups and those that are underrepresented in medicine, and to gauge the impact of these programs on elimination of geographic, racial, and other health care disparities. Additional research should identify the factors that deter students and physicians from choosing and remaining in primary care disciplines. Further, our AMA should continue to monitor trends in the choice of a primary care specialty and the availability of primary care graduate medical education positions. The results of these

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and related research endeavors should support and further refine AMA policy to enhance primary care as a career choice.

Citation: CME Rep. 04, I-18

Improving Rural Health H-465.994

- 1. Our AMA (a) supports continued and intensified efforts to develop and implement proposals for improving rural health care, (b) urges physicians practicing in rural areas to be actively involved in these efforts, and (c) advocates widely publicizing AMA's policies and proposals for improving rural health care to the profession, other concerned groups, and the public.
- 2. Our AMA will work with other entities and organizations interested in public health to:
 - Identify and disseminate concrete examples of administrative leadership and funding structures that support and optimize local, community-based rural public health.
 - Develop an actionable advocacy plan to positively impact local, community-based rural public health including but not limited to the development of rural public health networks, training of current and future rural physicians in core public health techniques and novel funding mechanisms to support public health initiatives that are led and managed by local public health authorities.
 - Study efforts to optimize rural public health.

Citation: Sub. Res. 72, I-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Reaffirmed: CEJA Rep. 06, A-18; Appended: Res. 433, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207

(I-19)

Introduced by: Medical Student Section

Subject: Pharmaceutical Advertising in Electronic Health Record Systems

Referred to: Reference Committee B

Whereas, In certain Electronic Health Records (EHR) systems, there exist subtle, yet noticeable advertisements for pharmaceutical drugs; and

Whereas, Pharmaceutical advertising in EHRs generally appears in the administrative, consultation, or prescribing interface of EHR software as text-based advertisements or image-

based banners1; and

Whereas, Advertisements in EHRs can include various types of information, such as treatment suggestions, recommendations for drug initiation and titration protocols, common side effects of medications, formulary coverage information, pictures of devices, and clinical trial-based evidence of a drug's efficacy; and

Whereas, Advertisements can be targeted based on physician specialty, target list, geography, past prescribing behavior, patient demographic, current therapy, or patient diagnosis on ICD-10 codes²; and

Whereas EHR infrastructure raises the obvious concern of whether advertising viewed by a physician within an EHR either consciously or unconsciously influences the physician's treatment³; and

Whereas, Patients may receive suboptimal care if there is physician bias in prescribing medications or treatments advertised in EHRs³; and

Whereas, Advertisements may lead to overprescribing of medications or treatments advertised or under prescribing of a less heavily advertised drug with better efficacy or lower cost³; and

Whereas, There exist a variety of revenue models for EHR systems, including but not limited to upfront costs for software, pay-to-play, data selling and boutique services; and

Whereas, Pharmaceutical advertising can be aimed at either patients (direct to consumer or DTC) or at physicians (direct to physician); and

Whereas, DTC advertising is regulated by the Food and Drug Administration (FDA) Division of Drug Marketing, Advertising and Communications via the Federal Food, Drug and Cosmetic Act of 1938⁷; and

Whereas, In 1969 regulations were passed specifically addressing pharmaceutical advertising to physicians, stating that ads may not be false or misleading, must present balanced

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information of risks and benefits, include facts that are essential to the product's advertised uses, and must present a brief summary that mentions every risk in the product labeling⁸; and

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Whereas, In 2002, the Secretary of Health and Human Services (HHS) passed a ruling that required all draft regulatory letters be reviewed by the FDA's office of chief counsel before they were sent to pharmaceutical companies, resulting in a decrease of warning letters⁹; and

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Whereas, The AMA has nuanced existing policy regarding pharmaceutical companies' interactions with physicians; and

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Whereas, The AMA recognizes that pharmaceutical marketing can unethically influence physicians and endanger the patient/physician relationship if done inappropriately, but when done appropriately may provide benefits to patients; and

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Whereas, Existing AMA policies outline that pharmaceutical influence is only acceptable through certain avenues, and that the point of care deserves special consideration; and

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Whereas, These existing policies underscore that pharmaceutical advertising with the potential to bias physicians must provide a benefit to the patient in order to be acceptable; and

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Whereas, A 2013 review by Manchanda and Honka concludes that detailing (personal advertisement or sales of drugs to physicians by pharmaceutical sales representatives) does change physician prescribing practices in the short-term, however, there is not enough data to conclude whether these prescribing decisions positively or negatively affect patient health outcomes, or how large this effect my be¹⁰; and

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Whereas, The U.S. Food and Drug Administration is limited in their oversight of pharmaceutical advertising practices that may unduly affect patient health and may lack sufficient resources to even complete the regulatory activities that are contained within their mandate; therefore be it

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RESOLVED, That our American Medical Association encourage the Centers for Medicare and Medicaid Services to study the effects of direct-to-physician advertising at the point of care. including advertising in Electronic Health Record Systems (EHRs), on physician prescribing, patient safety, health care costs, and EHR access for small practices (Directive to Take Action); and be it further

RESOLVED. That our AMA study the ethics of direct-to-physician advertising at the point of care, including advertising in EHRs. (Directive to Take Action)

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Fiscal Note: not yet determined

Date Received: 10/01/19

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RELEVANT AMA POLICY

Support of American Drug Industry H-100.995

Our AMA continues to support the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people.

Citation: (Sub. Res. 20, A-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices H-105.988

- 1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
- 2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines:
- (a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
- (b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing.
- (c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
- (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments." is recommended.
- (e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.
- (f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.
- (g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.
- (h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.
- (i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
- (j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.

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- (k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.
- 3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.
- 4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.
- 5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.
- 6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA.
- 7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
- 8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
- 9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion.
- 10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.
- 11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.
- 12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.
- 13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).
- 14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer's suggested retail price of those drugs.

Citation: BOT Rep. 38 and Sub. Res. 513, A-99; Reaffirmed: CMS Rep. 9, Amended: Res. 509, and Reaffirmation I-99; Appended & Reaffirmed: Sub. Res. 503, A-01; Reaffirmed: Res. 522, A-02; Reaffirmed: Res. 914, I-02; Reaffirmed: Sub. Res. 504, A-03; Reaffirmation A-04; Reaffirmation A-05; Modified: BOT Rep. 9, A-06; Reaffirmed in lieu of Res. 514, A-07; BOT Action in response to referred for decision: Res. 927, I-15; Modified: BOT Rep. 09, I-16; Appended: Res. 236, A-17; Reaffirmed in lieu of: Res. 223, A-17; Reaffirmed in lieu of: Res. 112, A-19;

E-9.6.7 Direct-to-Consumer Advertisement of Prescription Drugs

Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patientshealth and safety, and compromising patient physician relationships.

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In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:

- (a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.
- (b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:
- (i) assess and enhance the patients understanding of the test, drug or device;
- (ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.
- (c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.
- (d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.
- (e) Deny requests for an inappropriate test, drug, or device.
- (f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:
- (i) promotes false expectations;
- (ii) does not enhance consumer education;
- (iii) conveys unclear, inaccurate, or misleading health education messages;
- (iv) fails to refer patients to their physicians for additional information;
- (v) does not identify the target population at risk;
- (vi) encourages consumer self-diagnosis and treatment.

Collectively, physicians should:

- (g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.
- (h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:
- (i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;
- (ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;
- (iii) present summary information in language that can be understood by the consumer
- (iv) comply with applicable regulations;
- (v) provide collateral materials to educate both physicians and consumers.

AMA Principles of Medical Ethics: II.III

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

E-9.6.2 Gifts to Physicians from Industry

Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

Gifts to physicians from industry create conditions that carry the risk of subtly biasingor being perceived to biasprofessional judgment in the care of patients.

To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

- (a) Decline cash gifts in any amount from an entity that has a direct interest in physicianstreatment recommendations.
- (b) Decline any gifts for which reciprocity is expected or implied.
- (c) Accept an in-kind gift for the physicians practice only when the gift:
- (i) will directly benefit patients, including patient education; and
- (ii) is of minimal value.
- (d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students, residents, and fellowsparticipation in professional meetings, including educational meetings, provided:
- (i) the program identifies recipients based on independent institutional criteria; and
- (ii) funds are distributed to recipients without specific attribution to sponsors.

AMA Principles of Medical Ethics: II

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

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Sample Medications H-120.991

Our AMA (1) continues to support the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge;

- (2) reiterates that samples of prescription drug products represent valuable benefits to the patients;
- (3) continues to support the availability of drug samples directly to physicians through manufacturers' representatives and other means, with appropriate safeguards to prevent diversion; and
- (4) endorses sample practices that: (a) preclude the sale, trade or offer to sell or trade prescription drug samples; (b) require samples of prescription drug products to be distributed only to licensed practitioners upon written request; and (c) require manufacturers and commercial distributors of samples of prescription drug products and their representatives providing such samples to licensed practitioners to: (i) handle and store samples of prescription drug products in a manner to maintain potency and assure security; (ii) account for the distribution of prescription drug samples by maintaining records of all drug samples distributed, destroyed or returned to the manufacturer or distributor; and (iii) report significant thefts or losses of prescription drug samples.

Citation: (Sub. Res. 17, I-86; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed: Res. 516, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

E-9.2.7 Financial Relationships with Industry in Continuing Medical Education

In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.

Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

- (a) Be transparent about financial relationships that could potentially influence educational activities.
- (b) Provide the information physician-learners need to make critical judgments about an educational activity, including:
- (i) the source(s) and nature of commercial support for the activity; and/or
- (ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
- (iii) what steps have been taken to mitigate the potential influence of financial relationships.
- (c) Protect the independence of educational activities by:
- (i) ensuring independent, prospective assessment of educational needs and priorities;
- (ii) adhering to a transparent process for prospectively determining when industry support is needed;
- (iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
- (iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter:
- (v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individuals specific financial interest is disclosed; and
- (vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

AMA Principles of Medical Ethics: I,V

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The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

E-10.6 Industry Representatives in Clinical Settings

Representatives of medical device manufacturers can play an important role in patient safety and quality of care by providing information about the proper use of their companies devices or equipment and by offering technical assistance to physicians. However, allowing industry representative to be present in clinical settings while care is being given also raises concerns. Their presence can raise pose challenges for patient autonomy, privacy, and confidentiality as well as safety and professionalism in care-giving.

Physicians have a responsibility to protect patient interests and thus have a corresponding obligation to exercise good professional judgment in inviting industry representatives into the clinical setting. Physicians should recognize that in this setting appropriately trained industry representatives function as consultants. Participation by industry representatives should not be allowed to substitute for training physicians to use devices and equipment safely themselves.

Physicians who invite industry representatives into the clinical setting should ensure that:

- (a) The representatives participation will improve the safety and effectiveness of patient care.
- (b) The representatives qualifications to provide the desired assistance have been appropriately screened.
- (c) The patient is aware that an industry representative will facilitate care, has been informed about the scope and nature of the representatives role in care, and has agreed to the representatives participation.
- (d) The representative understands and is committed to upholding medical standards of respect for patient privacy and confidentiality.
- (e) The representative has agreed to abide by the policies of the health care institution governing his or her presence and clinical activities.
- (f) The representative does not exceed the bounds of his or her training, is adequately supervised, and does not engage in the practice of medicine.

AMA Principles of Medical Ethics: I,IV,V

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry D-315.988

Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOs and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data.

Citation: (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05; Reaffirmation A-09; Reaffirmed: Res. 233, A-11)

Impact of Pharmaceutical Advertising on Women's Health D-105.996

- 1. Our AMA urges the US Food and Drug Administration (FDA) to assure that all direct-to-consumer advertising of pharmaceuticals includes information regarding differing effects and risks between the sexes.
- 2. Our AMA urges the FDA to assure that advertising of pharmaceuticals to health care professionals includes specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex.

Citation: Res. 509, A-14;

Hospital Policies on Interactions with Industry H-225.948

1. Our AMA encourages all hospitals to adopt policies governing the interaction of hospital personnel--including both employed physicians and independent members of the medical staff, as well as other hospital staff--with pharmaceutical, medical device, and other industry representatives within the hospital setting. Such policies should: (a) be developed through a collaborative effort of the hospital's organized medical staff, administration,

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and governing body, and approved by the organized medical staff; and (b) be consistent with applicable AMA policy and ethical opinions on the subject of medicine-industry interaction, including but not limited to:

E-1.001 Principles of Medical Ethics

E-5.0591 Patient Privacy and Outside Observers to the Clinical Encounter

E-8.03 Conflicts of Interest: Guidelines

E-8.031 Conflicts of Interest: Biomedical Research

E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials

E-8.047 Industry Representatives in Clinical Settings

E-8.06 Prescribing and Dispensing Drugs and Devices

E-8.061 Gifts to Physicians from Industry

E-9.0115 Financial Relationships with Industry in Continuing Medical Education

H-460.981 University-Industry Cooperative Research Ventures.

2. Our AMA will inform the American Hospital Association of the AMA's position on hospital policies governing the interaction of hospital personnel with pharmaceutical, medical device, and other industry representatives within the hospital setting.

Citation: (BOT Rep. 27, A-14)

E-3.2.4 Access to Medical Records by Data Collection Companies

Information contained in patients' medical records about physicians' prescribing practices or other treatment decisions can serve many valuable purposes, such as improving quality of care. However, ethical concerns arise when access to such information is sought for marketing purposes on behalf of commercial entities that have financial interests in physicianstreatment recommendations, such as pharmaceutical or medical device companies.

Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.

Physicians who propose to permit third-party access to specific patient information for commercial purposes should:

- (a) Only provide data that has been de-identified.
- (b) Fully inform each patient whose record would be involved (or the patients authorized surrogate when the individual lacks decision-making capacity) about the purpose(s) for which access would be granted. Physicians who propose to permit third parties to access the patients full medical record should:
- (c) Obtain the consent of the patient (or authorized surrogate) to permit access to the patient's medical record.
- (d) Prohibit access to or decline to provide information from individual medical records for which consent has not been given.
- (e) Decline incentives that constitute ethically inappropriate gifts, in keeping with ethics guidance. AMA Principles of Medical Ethics: I,II,IV

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 208

(I-19)

Introduced by: Medical Student Section

Subject: Net Neutrality and Public Health

Referred to: Reference Committee B

Whereas, Net neutrality is the principle that Internet Service Providers (ISPs) should treat all content on the internet equally, without discriminating based on the content provided¹; and

Whereas, In 2010, the Open Internet Order was passed by the FCC, which revolved around three basic tenets: transparency, no blocking and no unreasonable discrimination¹; and

Whereas, In 2015, the FCC voted to reclassify broadband internet services as telecommunication services under Title II of the Communications Act, thereby subjecting services to more stringent regulation including bans on content throttling and paid prioritization; and

Whereas, Bandwidth throttling occurs when ISPs intentionally slow down the speed of a specific internet service³; and

Whereas, Paid prioritization occurs when ISPs provide faster internet services to companies who are willing to pay more based off a tiered system for data delivery speed³; and

Whereas, In December 2017, the FCC voted to reverse its prior decision and subsequently passed the Restoring Internet Freedom Initiative,⁴ which removed the classification of broadband services as a telecommunication platform in Title II; and

Whereas, In 2019, the Save the Internet Act of 2019 was introduced in the House of Representatives⁶ and if passed, the bill would reverse the Restoring Internet Freedom Initiative of 2017; and

Whereas, Advocates for the Restoring Internet Freedom Initiative argue that the repeal of net neutrality will promote investment and broadband implementation⁴; and

Whereas, Advocates of the Save the Internet Act express concern that the repeal of net neutrality may stifle competition and give ISPs a disproportionate amount of control over internet access and its functions³; and

Whereas, Existing AMA policy generally promotes increasing patient access to electronic health data, encouraging innovation and competition amongst technology vendors, and removing barriers to internet-based care; and

Whereas, The AMA supports increasing patient access to healthcare information and encourages innovation and competition in electronic healthcare; and

Page 2 of 5

Whereas, The repeal of net neutrality could allow companies to place limits on how, where, and when patients and providers are able to access this healthcare data and allow companies to pursue policies that lessen both innovation and competition in healthcare technology, or increase the cost of healthcare delivery, thus negatively impacting both providers and patients; and

Whereas, Repealing net neutrality creates the possibility that internet service providers could potentially begin charging an additional fee to transmit health data which could add significant costs that may ultimately be passed on to patients, and potentially further cripple the fiscal viability of Medicare and Medicaid; and

Whereas, A non-neutral internet has the potential to raise the barrier of entry for new firms wishing to operate in the healthcare space and to disrupt the natural process of innovation by placing established, well-funded companies at an inherent advantage over those which are smaller and less funded; and

Whereas, The potential exists for internet service providers to establish "fast lanes" which would prioritize delivery of specific data over that of others; and

Whereas, In a non-neutral internet, there would be no compelling force to stop an ISP from giving preference to traffic related to its own companies or services over those of competing firms; and

Whereas, Hospitals could be charged a premium to access these premium networks and costs could potentially get passed on to patients; and

Whereas, Patients, healthcare providers, insurance companies, and taxpayers could face fewer options, lower quality service, and higher costs; and

Whereas, The FCC has yet to make a statement on how a non-neutral internet would specifically impact telehealth and there are no current guidelines or rules from the FCC that will ensure affordability and accessibility of telemedicine; and

Whereas, Although the FCC argued in defense of the net neutrality repeal stating that paid prioritization would benefit latency-sensitive telemedicine, these technologies were already specifically highlighted as eligible for paid prioritization waivers under the previous Open Internet ruling¹⁴; and

Whereas, Paid prioritization has the potential to further drive up cost requirements for mobile health, thus becoming prohibitive for many app developers and users; therefore be it

RESOLVED, That our American Medical Association advocate for policies that ensure internet service providers transmit essential healthcare data no slower than any other data on that network (Directive to Take Action); and be it further

RESOLVED, That our AMA collaborate with the appropriate governing bodies to develop guidelines for the classification of essential healthcare data requiring preserved transmission speeds (Directive to Take Action); and be it further

RESOLVED, That our AMA oppose internet data transmission practices that reduce market competition in the health ecosystem. (Directive to Take Action)

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Fiscal Note: Modest - between \$1,000 - \$5,000

Date Received: 10/01/19

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RELEVANT AMA POLICY:

Health Information Technology Principles H-478.981

Our AMA will promote the development of effective electronic health records (EHRs) in accordance with the following health information technology (HIT) principles. Effective HIT should:

- 1. Enhance physiciansability to provide high quality patient care;
- 2. Support team-based care;
- 3. Promote care coordination;
- 4. Offer product modularity and configurability;
- 5. Reduce cognitive workload;
- 6. Promote data liquidity:
- 7. Facilitate digital and mobile patient engagement; and
- 8. Expedite user input into product design and post-implementation feedback.

Our AMA will AMA utilize HIT principles to:

- 1. Work with vendors to foster the development of usable EHRs;
- 2. Advocate to federal and state policymakers to develop effective HIT policy:
- 3. Collaborate with institutions and health care systems to develop effective institutional HIT policies;
- 4. Partner with researchers to advance our understanding of HIT usability;
- 5. Educate physicians about these priorities so they can lead in the development and use of future EHRs that can improve patient care; and
- 6. Promote the elimination of Information Blocking.

Our AMA policy is that the cost of installing, maintaining, and upgrading information technology should be specifically acknowledged and addressed in reimbursement schedules.

Citation: BOT Rep. 19, A-18; Reaffirmation: A-19;

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Promoting Internet-Based Electronic Health Records and Personal Health Records D-478.979

Our American Medical Association will advocate for the Centers for Medicare & Medicaid Services (CMS) to evaluate the barriers and best practices for those physicians who elect to use a patient portal or interface to a personal health record (PHR) and will work with CMS to educate physicians about the barriers to PHR implementation, how to best minimize risks associated with PHR use and implementation, and best practices for physician use of a patient portal or interface to a PHR. Citation: (BOT Rep. 11, I-11)

Increasing Access to Broadband Internet to Reduce Health Disparities H-478.980

Our AMA will advocate for the expansion of broadband and wireless connectivity to all rural and underserved areas of the United States while at all times taking care to protecting existing federally licensed radio services from harmful interference that can be caused by broadband and wireless services. Citation: Res. 208, I-18;

Innovation to Improve Usability and Decrease Costs of Electronic Health Record Systems for Physicians D-478.976

- 1) Our AMA will: (A) advocate for CMS and the Office of the National Coordinator (ONC) to support collaboration between and among proprietary and open-source EHR developers to help drive innovation in the marketplace; (B) continue to advocate for research and physician education on EHR adoption and design best practices specifically concerning key features that can improve the quality, safety, and efficiency of health care regardless of proprietary or open-source status; and (C) through its partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs-open source and proprietary-to create more transparency and support more informed decision making in the selection of EHRs.
- 2) Our AMA will, through partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and formulate more formal decision making in the selection of EHRs.
- 3) Our AMA will work with AmericanEHR Partners to modify the current survey to better address the economics of EHR use by physicians including the impact of scribes.
- 4) Our AMA will make available the findings of the AmericanEHR Partners' survey and report back to the House of Delegates.

Citation: BOT Rep. 23, A-13; BOT Rep. 24, A-13; Reaffirmed: BOT Rep. 17, A-15; Appended: Res. 603, I-16; Modified: BOT Rep. 20, A-17;

Opposition to Nationalized Health Care H-165.985

Our AMA reaffirms the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care:

- (1) Free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations or promotion.
- (2) Freedom of patients to select and to change their physician or medical care plan, including those patients whose care is financed through Medicaid or other tax-supported programs, recognizing that in the choice of some plans the patient is accepting limitations in the free choice of medical services.
- (3) Full and clear information to consumers on the provisions and benefits offered by alternative medical care and health benefit plans, so that the choice of a source of medical care delivery is an informed one.
- (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service
- (5) Inclusion in all methods of medical care payment of mechanisms to foster increased cost awareness by both providers and recipients of service, which could include patient cost sharing in an amount which does not preclude access to needed care, deferral by physicians of a specified portion of fee income, and voluntary professionally directed peer review.
- (6) The use of tax incentives to encourage provision of specified adequate benefits, including catastrophic expense protection, in health benefit plans.
- (7) The expansion of adequate health insurance coverage to the presently uninsured, through formation of insurance risk pools in each state, sliding-scale vouchers to help those with marginal incomes purchase pool coverage, development of state funds for reimbursing providers of uncompensated care,

Resolution: 208 (I-19)

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and reform of the Medicaid program to provide uniform adequate benefits to all persons with incomes below the poverty level.

(8) Development of improved methods of financing long-term care expense through a combination of private and public resources, including encouragement of privately prefunded long-term care financing to the extent that personal income permits, assurance of access to needed services when personal resources are inadequate to finance needed care, and promotion of family caregiving. Citation: BOT Rep. U, I-88; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmed: CMS Rep. 7, I-97; Reaffirmed by CMS Rep. 9, A-98; Reaffirmed: CMS Rep. 4, A-99; Reaffirmation I-07; Modified: CMS Rep. 8, A-08; Reaffirmed in lieu of Res. 813, I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 112, A-09; Reaffirmation A-11; Reaffirmed: Res. 239, A-12; Modified: Speakers Rep., A-14; Reaffirmed: CMS Rep. 09, A-19;

Information Technology Standards and Costs D-478.996

1. Our AMA will:(a) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems;(b) work with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate when they implement these technologies in their offices;(c) review the following issues when participating in or commenting on initiatives to create a NHII: (i) cost to physicians at the office-based level; (ii) security of electronic records; and (iii) the standardization of electronic systems;(d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and(e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems.

2. Our AMA advocates that physicians: (a) are offered flexibility related to the adoption and use of new certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of

certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of EHR products that meet the specified certification standards; and (b) not be financially penalized for certified EHR technology not meeting current standards.

Citation: Res. 717, A-04; Reaffirmation, A-05; Appended: Sub. Res. 707, A-06; Reaffirmation A-07;

Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08; Reaffirmation I-09; Reaffirmation A-10; Reaffirmation I-10; Reaffirmed: Res. 205, A-11; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed in lieu of Res. 724, A-13; Reaffirmation I-13; Reaffirmation A-14; Reaffirmed: BOT Rep. 03, I-16; Reaffirmed: BOT Rep. 05, I-16; Appended: Res. 204, I-17; Reaffirmation: I-17; Reaffirmed: BOT Rep. 45, A-18; Reaffirmed: BOT Rep. 19, A-18; Reaffirmation: A-19;

Resolution: 209

(1-19)

Introduced by: American Society of Transplant Surgeons

Federal Government Regulation and Promoting Patient Access to Kidney Subject:

Transplantation

Referred to: Reference Committee B

1 Whereas, Kidney transplantation is the best and most cost-effective treatment for many patients with End Stage Renal Disease (ESRD); and 2

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Whereas, Executive Order on Advancing American Kidney Health¹, issued on July 10, 2019, seeks to increase patient choice through affordable ESRD therapy by encouraging higher value care; and

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Whereas, The Executive Order intent is to increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations; and

10 11 12

Whereas. There exist comprehensive patient-oriented care models² designed with physician input to promote access to transplantation; and

13 14 15

Whereas, Dialysis and transplant professional³⁻⁵ as well as patient-centered groups^{5,6} favor physician-advised patient choice of kidney transplantation in ESRD treatment; and

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Whereas. Payment models creating incentives for greater use of kidney transplants for ESRD Medicare beneficiaries have been proposed; therefore be it

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RESOLVED, That our American Medical Association engage US government regulatory and professional organ transplant organizations to advance patient and physician-directed care for End Stage Renal Disease (ESRD) patients (Directive to Take Action); and be it further

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RESOLVED, That our AMA actively promote regulatory efforts to assure physician and patient involvement in the design of any ESRD federal demonstration program (Directive to Take Action); and be it further

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RESOLVED, That our AMA actively advocate for legislative and regulatory efforts which create incentives for dialysis providers, transplant centers, organ donors, and ESRD patients to increase organ donation and improve access to kidney transplantation in the United States.

(Directive to Take Action). 32

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/02/19

Resolution: 209 (I-19)

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- 3. American Society of Transplant Surgeons: The ASTS-AST-AOPO-AAKP Joint Letter on Dialysis PATIENTS Demonstration Act of 2017: https://asts.org/docs/default-source/legislative/joint-letter-on-the-house-patients-act-december-1-2017.pdf?sfvrsn=94227ed3 2
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RELEVANT AMA POLICY

Equal Access to Organ Transplantation for Medicaid Beneficiaries H-370.962

Our AMA supports federal funding of organ transplants for Medicaid patients.

Citation: (BOT Rep. 15, A-13)

Ethical Procurement of Organs for Transplantation H-370.967

Our AMA will continue to monitor ethical issues related to organ transplantation and develop additional policy as necessary.

Citation: BOT Rep. 13, A-08; Reaffirmed: CEJA Rep. 06, A-18;

UNOS Kidney Paired Donation Program H-370.960

Our AMA: (1) encourages the continued expansion of the United Network for Organ Sharing's (UNOS) Kidney Paired Donation program which provides a national registry of living donors, carries out ongoing data collection on key issues of concern in transplantation from living donors, and through its operational guidelines provides consistent, national standards for the transplant community; and (2) encourages voluntary coordination among private donor registries and UNOS to enhance the availability of organs for transplantation. Citation: (BOT Action in response to referred for decision Res. 2, A-13)

Cost-Saving Public Coverage for Renal Transplant Patients H-370.963

- 1. Our AMA supports private and public mechanisms that would extend insurance coverage for evidence-based treatment of renal transplant care for the life of the transplanted organ.
- 2. Our AMA will continue to offer technical assistance to individual state and specialty societies when those societies lobby state or federal legislative or executive bodies to implement evidence-based cost-saving policies within public health insurance programs. Citation: (Res. 104, A-13)

Resolution: 210

(I-19)

Introduced by: American Society of Transplant Surgeons

Subject: Federal Government Regulation and Promoting Renal Transplantation

Referred to: Reference Committee B

Whereas, Kidney transplantation is the best and most cost-effective treatment for many patients with End Stage Renal Disease (ESRD); and

Whereas, The Executive Order on Advancing American Kidney Health¹, issued on July 10, 2019, seeks to increase patient choice through affordable ESRD therapy by encouraging higher value care; and

Whereas, The Executive Order intent is to increase access to kidney transplants by modernizing the organ recovery and transplantation systems while updating outmoded and counterproductive regulations²; and

Whereas, Factors leading to deceased donor kidney discard in the US have been identified to include donors who are older and or have co morbidities such as diabetes and hypertension³; and

Whereas, Recent studies have shown that more than 2500 kidneys (>17% of those recovered from deceased donors) were discarded in 2013 despite evidence that many of these kidneys would provide a survival benefit to certain wait-listed patients⁴; and

Whereas, Studies have documented that excessive regulation and oversight have led transplant centers to risk-aversion donor criteria which exclude kidneys which could benefit many patients⁵⁻⁷; therefore be it

RESOLVED, That our American Medical Association actively advocate for US organ transplant legislative and regulatory policies that would advance kidney transplantation by modifying or eliminating arbitrary transplant center outcomes measures that currently discourage sound clinical judgment by physicians and surgeons to accept and transplant kidneys suitable for many patients. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/02/19

Resolution: 210 (I-19)

Page 2 of 3

References:

- 1. Executive Order on Advancing American Kidney Health, Issued on July 10, 2019
- 2. American Society of Transplant Surgeons: The ASTS Letter re: CMS-3346-P; Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (Proposed Rule); RIN 0938-https://asts.org/docs/default-source/regulatory/asts-comments-on-pfs-qpp-2019-proposed-rule-september-10-2018.pdf?sfvrsn=14b040d3_
- 3. Mohan S, Chiles MC, Patzer RE, Pastan SO, Husain SA, Carpenter DJ, Dube GK, Crew RJ, Ratner LE, Cohen DJ. Factors leading to the discard of deceased donor kidneys in the United States. Kidney Int. 2018 Jul;94(1):187-198.
- 4. Reese PP, Harhay MN, Abt PL, Levine MH, Halpern SD. New Solutions to Reduce Discard of Kidneys Donated for Transplantation. J Am Soc Nephrol. 2016 Apr;27(4):973-80.
- 5. Stewart DE, Garcia VC, Rosendale JD, Klassen DK, Carrico BJ. Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. Transplantation. 2017 Mar;101(3):575-587
- 6. Kadatz M, Gill JS. Compelling Evidence of the Need for Policy Change to Decrease Deceased Donor Kidney Discard in the United States: Waste Not Want Less. Clin J Am Soc Nephrol. 2018 Jan 6;13(1):13-15
- 7. Ouayogodé MH. Quality-based ratings in Medicare and trends in kidney transplantation. Health Serv Res. 2019 Feb;54(1):106-116

RELEVANT AMA POLICY

Equal Access to Organ Transplantation for Medicaid Beneficiaries H-370.962

Our AMA supports federal funding of organ transplants for Medicaid patients. Citation: (BOT Rep. 15, A-13)

Ethical Procurement of Organs for Transplantation H-370.967

Our AMA will continue to monitor ethical issues related to organ transplantation and develop additional policy as necessary.

Citation: BOT Rep. 13, A-08; Reaffirmed: CEJA Rep. 06, A-18;

Removing Disincentives and Studying the Use of Incentives to Increase the National Organ Donor Pool H-370.958

- 1. Our AMA supports the efforts of the National Living Donor Assistance Center, Health Resources Services Administration, American Society of Transplantation, American Society of Transplant Surgeons, and other relevant organizations in their efforts to eliminate disincentives serving as barriers to living and deceased organ donation.
- 2. Our AMA supports well-designed studies investigating the use of incentives, including valuable considerations, to increase living and deceased organ donation rates.
- 3. Our AMA will seek legislation necessary to remove legal barriers to research investigating the use of incentives, including valuable considerations, to increase rates of living and deceased organ donation.

Citation: (Res. 7, I-15)

6.2.1 Guidelines for Organ Transplantation from Deceased Donors

Transplantation offers hope to patients with organ failure. As in all patient-physician relationships, the physicians primary concern must be the well-being of the patient. However, organ transplantation is also unique in that it involves two patients, donor and recipient, both of whose interests must be protected. Concern for the patient should always take precedence over advancing scientific knowledge.

Physicians who participate in transplantation of organs from deceased donors should:

- (a) Avoid actual or perceived conflicts of interest by ensuring that:
- (i) to the greatest extent possible that the health care professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor. Physicians should encourage health care institutions to distinguish the roles of health care professionals who solicit or coordinate organ transplantation from those who provide care at the time of death:
- (ii) no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.

Resolution: 210 (I-19)

Page 3 of 3

- (b) Ensure that death is determined by a physician not associated with the transplant team and in accordance with accepted clinical and ethical standards.
- (c) Ensure that transplant procedures are undertaken only by physicians who have the requisite medical knowledge and expertise and are carried out in adequately equipped medical facilities.
- (d) Ensure that the prospective recipient (or the recipients authorized surrogate if the individual lacks decision-making capacity) is fully informed about the procedure and has given voluntary consent in keeping with ethics guidance.
- (e) Except in situations of directed donation, ensure that organs for transplantation are allocated to recipients on the basis of ethically sound criteria, including but not limited to likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in certain cases, amount of resources required for successful treatment.
- (f) Ensure that organs for transplantation are treated as a national, rather than a local or regional, resource.
- (g) Refrain from placing transplant candidates on the waiting lists of multiple local transplant centers, but rather place candidates on a single waiting list for each type of organ.

AMA Principles of Medical Ethics: I,III,V

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

Methods to Increase the US Organ Donor Pool H-370.959

In order to encourage increased levels of organ donation in the United States, our American Medical Association: (1) supports studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; (2) urges development of effective methods for meaningful exchange of information to educate the public and support well-informed consent about donating organs, including educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates; and (3) encourages continued study of ways to enhance the allocation of donated organs and tissues.

Citation: BOT Rep. 13, A-15; Reaffirmed in lieu of: Res. 002, I-16; Modified: CSAPH Rep. 02, I-17;

Organ Donation D-370.985

Our AMA will study potential models for increasing the United States organ donor pool. Citation: Res. 1, A-14; Reaffirmed in lieu of Res. 5, I-14; Reaffirmed in lieu of: Res. 002, I-16;

Resolution: 211

(I-19)

Introduced by: Michigan

Subject: Effects of Net Neutrality on Public Health

Referred to: Reference Committee B

Whereas, "Net neutrality" is the principle that, "all traffic on the Internet should be treated the same," by preventing interference of the flow of content, services, and applications by internet service providers (ISPs); and

Whereas, ISPs are business entities who provide internet services and host websites; and

Whereas, Federal Communications Commission (FCC) Order 15-24 (2015) classified ISPs as Title II information providers per the Telecommunications Act of 1996, thereby subsuming ISPs to "common carrier" categorization; and

Whereas, A "common carrier" is a private entity that facilitates the free flow of commerce by transportation, communications, and other services, with the legal obligation of doing so in a non-discriminatory and censorship free manner; and

Whereas, Recent repeal of comprehensive net neutrality rules now removes Title II regulations on ISPs, and by extension, their "common carrier" classification; and

Whereas, ISPs are now able to block content from websites or apps, throttle--slow---bandwidth, and prioritize hosting sites, i.e. "fast lane" programs, for entities willing to pay premiums; and

Whereas, Throttling and regulating quality of service (QoS) would alter end user choice of service, thereby increasing discrimination and segmentation of internet access for consumers; and

Whereas, "Health" loosely describes a compendium of disparate themes (e.g., myriad health, commerce, and technology such as internet services); and

Whereas, Individuals with greater internet access are more likely to use eHealth and eHealth users are more likely to visit a doctor, use preventative health measures, have shorter hospital stays, and have overall better health outcome; and

Whereas, Net neutrality, in facilitating "health," potentially improves patient services, reduces health care costs, and improves population health; and

 Whereas, Individual pricing of internet access could lead to the favorability of certain services and contents, including but not limited to, health insurance options, telehealth services, and electronic health record services; and

Resolution: 211 (I-19) Page 2 of 3

Whereas, Telehealth has been shown to improve health care for those with limited access to health care through services such as remote rehabilitation and maternal and child health; and

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Whereas, ISPs such as Verizon and Comcast are heavily invested in health care companies such as Oncare and Onpatient respectively; and

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Whereas, Net neutrality repeal may decrease consumer access to health care and insurance providers, and further contribute to the increasing prices of pharmaceutical products via the prioritization of certain drug providers; and

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Whereas, Net neutrality repeal may lead to deficits in medical training, insofar as net neutrality promotes open access resources to which physicians-in-training turn; therefore be it

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RESOLVED, That our American Medical Association amend current policy H-478.980, "Increasing Access to Broadband Internet to Reduce Health Disparities," by addition and deletion as follows:

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Increasing Access to Broadband Internet Access to Reduce Health Disparities Our AMA: (1) will advocate for net neutrality; and (2) will advocate for the expansion of broadband and wireless connectivity to all rural and underserved areas of the United States while at all times taking care to protecting existing federally licensed radio services from harmful interference that can be caused by broadband and wireless services. (Modify Current HOD Policy)

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Fiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Sources

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- 3. Report and Order on Remand, Declaratory Ruling, and Order, 30 FCC Rcd 5601 (7). 2015
- 4. Nunziato, D. By Any Means Necessary? the Fcc's Implementation of Net Neutrality. 8 First Amendment Law Review 138-175; GWU Law School Public Law Research Paper No. 2017-39; GWU Legal Studies Research Paper No. 2017-39.
- 5. Declaratory Ruling, Report and Order, and Order, 33 FCC Rcd. 311. 2018
- Marsden, C. T. Net Neutrality and Consumer Access to Content. SCRIPTed: A Journal of Law, Technology and Society, 2007; 4, 407-435
- Macher, J. T., Mayo, J. W., & Ukhaneva, O. Does the Internet Improve Health Behaviors and Health Outcomes? Evidence From the National Health Interview Survey. The 44th Research Conference on Communication, Information, and Internet policy 2016
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- 12. Kang, C. FCC Repeals Net Neutrality Rules. New York Times. December 14, 2017.
- Cuk, N., Robinson, CL., Net Neutrality Repeal and the Potential Harm to Medical Education. JAMA. 2018; 319(16):1655-1656. Doi:10.1001/jama.2018.1683

Resolution: 211 (I-19)

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RELEVANT AMA POLICY

Increasing Access to Broadband Internet to Reduce Health Disparities H-478.980

Our AMA will advocate for the expansion of broadband and wireless connectivity to all rural and underserved areas of the United States while at all times taking care to protecting existing federally licensed radio services from harmful interference that can be caused by broadband and wireless services.

Citation: Res. 208, I-18;

Promoting Internet-Based Electronic Health Records and Personal Health Records D-478.979

Our American Medical Association will advocate for the Centers for Medicare & Medicaid Services (CMS) to evaluate the barriers and best practices for those physicians who elect to use a patient portal or interface to a personal health record (PHR) and will work with CMS to educate physicians about the barriers to PHR implementation, how to best minimize risks associated with PHR use and implementation, and best practices for physician use of a patient portal or interface to a PHR.

Citation: (BOT Rep. 11, I-11)

Resolution: 212

(I-19)

Introduced by: Michigan

Subject: Centers for Medicare and Medicaid Services Open Payments Program

Referred to: Reference Committee B

Whereas, The Physician Payments Sunshine Act (Sunshine Act) was enacted along with the 2010 Patient Protection and Affordable Care Act; and

Whereas, The Sunshine Act is a law that was designed to increase transparency of financial relationships between physicians, teaching hospitals, and manufacturers of drugs, medical devices, biologics, and medical supplies and to uncover potential conflicts of interest by disclosing this information to the public; and

 Whereas, The Sunshine Act requires manufacturers of drugs, medical devices, biologics, and medical supplies covered by the three federal health care programs, Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP), to collect and track all financial relationships with physicians and teaching hospitals and to report these data to the Centers for Medicare and Medicaid Services (CMS); and

Whereas, The Centers for Medicare and Medicaid Services (CMS) fulfills the law's mandate through the CMS Open Payments Program as a national disclosure program; and

Whereas, On September 30, 2014, CMS reported payment information on its Open Payments Program website for the first time, reporting attribution of payments data from 2012; and

Whereas, The CMS Open Payments Program data may be inaccurate due to erroneous reporting of the payment amount, payment reason, and/or name of the physician receiving the payment; and

Whereas, Inaccurate reporting may reflect unfairly on a physician's reputation and/or employment arrangement, including inaccurate reporting of potential conflicts of interest; and

Whereas, Understanding how payments are attributed and what may be legally recorded by the pharmaceutical companies is important to protect physicians; and

Whereas, In 2013, the American Medical Association (AMA) offered physicians training to understand the Sunshine Act and its implications; and

Whereas, Many physicians are unaware of the potential need to check the CMS Open Payments Program website and review any attributed payments to avoid any inaccurate potential conflicts of interest; and

Whereas, The available time frame to review and dispute these payments is limited to the calendar year in which the attributed payment is reported; and

Resolution: 212 (I-19) Page 2 of 3

1 Whereas, The process for disputing payments is time consuming to complete; and

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Whereas, The pharmaceutical companies are listed on the site with only payments to physicians or teaching hospitals listed; and

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Whereas, Some states are allowing pharmacists to prescribe some medications, either as a direct legal change in the laws of that state or as a potential delegated option by physicians, and

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Whereas, The prescribing of medications and/or the prior authorization process may increasingly be directly influenced by pharmacists and Pharmacy Benefit Managers (PBMs); and

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Whereas, Pharmacists and PBMs are not reported for the attribution of any payments within the CMS Open Payments Program in spite of the increasing influence of pharmacists and/or PBMs on the prescribing habits of physicians and teaching hospitals; therefore be it

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RESOLVED, That our American Medical Association amend current policy H-140.848, "Physician Payments Sunshine Act," by addition and deletion to read as follows:

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Our AMA will: (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by the Centers for Medicare & Medicaid Services (CMS) and will recommend to the CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database; (2) lobby Congress to amend the Sunshine Act to limit transfer of value reporting to items with a value of greater than \$100; (3) advocate that: (a) (i) any payment or transfer of value reported as part of the Physician Payments Sunshine Act should include whether the physician acknowledged receipt of said payment or transfer of value, and (ii) each payment or transfer of value on the Open Payments website indicates whether the physician verified the payment or transfer of value; and (b) a contested reported payment or transfer of value should be removed immediately from the Open Payments website until the reporting company validates the compensation with verifiable documentation; and (4) support significant modifications to the Sunshine Act, such as substantially increasing the monetary threshold for reporting. that will decrease the regulatory and administrative burden on physicians, protect physician rights to challenge false and misleading reports, change the dispute process so that successfully disputed charges are not included publicly on the Open Payments database, and provide a meaningful, accurate picture of the physician-industry relationship; (5) urge the Centers for Medicare and Medicaid Services to expand the definition of "covered recipients" to include pharmacists and Pharmacy Benefit Managers; and (6) continue to educate physicians about the Sunshine Act and its implications in light of publicly available data on the Centers of Medicare and Medicaid (CMS) Open Payments Program website. (Modify Current HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/03/19

Sources:

^{1.} Sunshine Act: "S.301 - Physician Payments Sunshine Act of 2009 - 111th Congress (2009-2010)". Library of Congress (Congress.gov). 2009. Accessed 02-16-2019.

^{2.} Centers for Medicare and Medicaid Services (CMS) Open Payments Act: https://www.cms.gov/openpayments.

Resolution: 212 (I-19)

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RELEVANT AMA POLICY

Physician Payments Sunshine Act H-140.848

Our AMA will: (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by the Centers for Medicare & Medicaid Services (CMS) and will recommend to the CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database: (2) lobby Congress to amend the Sunshine Act to limit transfer of value reporting to items with a value of greater than \$100; (3) advocate that: (a) (i) any payment or transfer of value reported as part of the Physician Payments Sunshine Act should include whether the physician acknowledged receipt of said payment or transfer of value, and (ii) each payment or transfer of value on the Open Payments website indicates whether the physician verified the payment or transfer of value; and (b) a contested reported payment or transfer of value should be removed immediately from the Open Payments website until the reporting company validates the compensation with verifiable documentation; and (4) support significant modifications to the Sunshine Act, such as substantially increasing the monetary threshold for reporting, that will decrease the regulatory and administrative burden on physicians, protect physician rights to challenge false and misleading reports, change the dispute process so that successfully disputed charges are not included publicly on the Open Payments database, and provide a meaningful, accurate picture of the physician-industry relationship. Citation: Res. 233, A-12; Appended: Res. 222, A-14; Appended: Res. 241, A-18; Appended:

Res. 208, A-19;

Resolution: 213

(1-19)

Introduced by: Colorado

Subject: Data Completeness and the House of Medicine

Referred to: Reference Committee B

Whereas, The AMA, through its founding of the AMA Integrated Health Model Initiative, its creation of the External Advisory Committee for Value-Based Care, and its collaboration with multiple other data projects and initiatives has demonstrated its understanding that use and control of health data by physicians is essential to the profession and to our patients' health; and

Whereas, Our AMA has explicit policy (policy entitled "Price Transparency, D-155.987") endorsing one particular type of health care data organization, All-Payer Claims Databases (APCDs), specifically stating that, "Our AMA will work with states to support and strengthen the development of all-payer claims databases"; and

Whereas, APCDs are rapidly becoming an essential part of health care data infrastructure throughout the US, having been established in 17 states, with 5 other states currently in the process of implementing APCDs, and 5 additional states participating in voluntary claims-based submission efforts¹; and

Whereas, In places where APCDs have examined cost/utilization/quality measures, they have often absolved physicians of primary culpability for the current ills of American healthcare, centered physicians as the solution to such ills, and will likely increase in utilization for, and by, physicians in the future; and

Whereas, The Supreme Court decision in the case *Gobeille v. Liberty Mutual Insurance Company* has limited the ability of APCDs to maintain their comprehensive data completeness, by preventing states from compelling self-funded group health plans defined under the Employee Retirement Income Security Act (ERISA) to submit their data to APCDs, but left open the possibility that the United States Department of Labor (DOL) may fix the loss of data to state APCDs by imposing a federal requirement that ERISA plans submit health care claims data²; and

Whereas, The DOL issued a Notice of Proposed Rulemaking on July 21, 2016 requesting public comments on its proposed reporting requirements for group health plans (called Schedule J) seeking specific comments in light of the *Gobeille* decision, with the National Academy for State Health Policy (NASHP), the All-Payer Claims Database Council (APCD Council), and the National Association of Health Data Organizations (NAHDO) all responding in efforts to encourage a rulemaking process that would allow sharing of data from ERISA plans in a

¹ State-by-State APCD Establishment Analysis. *Interactive State Report Map*, All-Payer Claims Database Council, https://www.apcdcouncil.org/state/map.

² Riley, Trish. *Gobeille v. Liberty Mutual: Decision*, National Academy for State Health Policy, https://nashp.org/gobeille-vs-liberty-mutual-decision/.

Resolution: 213 (I-19) Page 2 of 3

1 consistent manner with consistent definitions as defined by a methodology called the Common Data Layout³; and

Whereas, Despite efforts by multiple organizations to advance the rule making process as regards Schedule J by the DOL in matters related to the *Gobeille v. Liberty Mutual Insurance Company* decision, such is currently "stalled out" at the federal level secondary to current federal departmental vacancies and work backlogs due to current political gridlock as regards filling such vacancies within cabinet departments; and

Whereas, A "squeaky wheel phenomenon" currently exists in Washington, D.C., where only those federal initiatives deemed most critical to government and stakeholders are likely to be prioritized within cabinet departments; and

Whereas, The AMA, by lending its voice to an already extant effort to improve the capacity of APCDs, could achieve maximal impact for its physician members with a very small and finite outlay of personnel, resources, and political capital to ensure that a rapidly growing piece of health care infrastructure, that might potentially benefit physicians, will be as complete and comprehensive as possible; therefore be it

RESOLVED, That our American Medical Association amend section 4 of policy D-155.987, "Price Transparency," by addition to read as follows:

4. Our AMA will work with states <u>and the federal government</u> to support and strengthen the development of all-payer claims databases. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with the National Academy for State Health Policy (NASHP), the All-Payer Claims Database Council (APCD Council), the National Association of Health Data Organizations (NAHDO), and other interested organizations to speed promulgation of final rule making as regards Schedule J by the United States Department of Labor (DOL) in matters related to the *Gobeille v. Liberty Mutual Insurance Company* decision (Directive to Take Action); and be it further

RESOLVED, That, in supporting a rule making process by the DOL in matters related to the *Gobeille v. Liberty Mutual Insurance Company* decision, our AMA support the adoption of a standardized set of health care claims data such as the Common Data Layout, support that any DOL requirement for plans to submit health care claims data must be tied to current rule making processes (such as its proposed Schedule J), and support that the DOL implement a pilot program to collect health care claims data in cooperation with state APCDs. (Directive to Take Action)

Figoral Note

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/04/19

³NASHP Staff. Next Steps for APCDs: US Department of Labor (DOL) Rulemaking, National Academy for State Health Policy, https://nashp.org/next-steps-for-apcds-us-department-of-labor-dol-rulemaking/.

Resolution: 213 (I-19)

Page 3 of 3

RELEVANT AMA POLICY

Price Transparency D-155.987

- 1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible.
- 2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
- 3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide.
- 4. Our AMA will work with states to support and strengthen the development of all-payer claims databases.
- 5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients.
- 6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
- 7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments. Citation: CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed in lieu of: Res. 213, I-17; Reaffirmed: BOT Rep. 14, A-18; Reaffirmed in lieu of: Res. 112, A-19;

Resolution: 214

(I-19)

Introduced by: New York

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Subject: AMA Should Provide a Summary of Its Advocacy Efforts on Surprise Medical

Bills

Referred to: Reference Committee B

Whereas, There has recently been very significant legislative activity in regards to surprise medical bills and balance billing, critically important issues for physicians; and

Whereas, Insurance companies have tried to use the issue of surprise medical bills to essentially outlaw all physician billing, which would be devastating to the medical profession; and

Whereas, The AMA goal of improved physician satisfaction with professional activity is enhanced by supporting various modes of practice; and

Whereas, Coordination of messaging and engagement of various organizations is critical to success in our advocacy efforts on behalf of our members, patients, and profession; and

Whereas Member and non-member engagement should be improved by a better understanding of our efforts; therefore be it

Resolution: 214 (I-19) Page 2 of 2

RESOLVED, That our American Medical Association Board of Trustees provide a detailed report of its efforts and those of allies and opponents around the issue of surprise medical bills in 2019; this discussion should include the following points comparing the AMA and partners activity vs that of its opponents (the insurance companies):

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- 1) What testimony was provided at various committee meetings?
- 2) What letters were written to various legislators?
- 3) What grass roots efforts were performed?
- 4) What other groups supported the efforts
- 10 5) What other groups were recruited to support the efforts?
 - 6) What media efforts were performed?
 - 7) What television ads were run?
 - 8) What radio ads were run?
 - 9) What print ads were run?
 - 10) What op-ed pieces were run, in national journals, Washington journals, and regional publications?
- 17 11) What meetings occurred with various legislators?
 - 12) What meetings occurred with members of the administration?
 - 13) How much money was spent on the various efforts?
 - 14) What studies were published in insurance journals, medical journals, and other journals on this matter?
 - 15) Which senators and representatives and administration members could either side count on as solid supporters?
 - 16) What level of collaboration was there with other national, state, and specialty societies and how was this carried out? (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/04/19

Resolution: 215

(I-19)

Introduced by: American Academy of Dermatology, American College of Mohs Surgery,

American Society for Dermatologic Surgery Association, Society for

Investigative Dermatology, American Society of Dermatopathology, American Association of Neurological Surgeons, Congress of Neurological Surgeons, American College of Emergency Physicians, Iowa, Maryland, Wisconsin, Virginia, Florida, International Society of Hair Restoration Surgery, Arizona

Subject: Board Certification of Physician Assistants

Referred to: Reference Committee B

Whereas, In 2019, state legislatures considered over 1,000 bills seeking to expand the scope of practice of non-physicians; and

Whereas, Physician assistants sought legislation consistent with elements of the optimal team practice act, which was adopted by the American Academy of Physician Assistants. While many states attempted to remove direct physician supervision or allow PAs to perform certain functions without physician supervision, most of the legislation was defeated or made minimal change in practice; and

Whereas, Physician assistants are a valuable member of the physician-led team; and

Whereas, Physician assistants complete a 26-month physician assistant program followed by 2,000 hours of clinical rotations, which emphasize primary care in ambulatory clinics, physician offices and acute or long-term care facilities; and

Whereas, After finishing a rigorous undergraduate academic curriculum, physicians receive an additional four years of education in medical school, followed by 3-7 years of residency and 12,000-16,000 hours of patient care training; and

Whereas, There are substantial differences in the education of physician assistants and physicians, both in depth of knowledge and length of training; and

Whereas, According to four nationwide surveys, 84% of respondents prefer a physician to have primary responsibility for diagnosing and managing their health care, and 91% of respondents said that a physician's years of medical education and training are vital to optimal patient care, especially in the event of a complication or medical emergency; and

Whereas, A recent survey conducted by the American Medical Association's Scope of Practice Partnership confirms increasing patient confusion regarding the many types of health care providers - including physicians, nurses, physician assistants, technicians and other varied providers. The survey revealed that 55 percent of patients believe it is difficult to identify who is a licensed medical doctor and who is not by reading what services they offer, their title and other licensing credentials in advertising or other marketing materials; and

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Whereas, An organization independent of the National Commission on Certification of 1 2 Physician Assistants is providing board certification exams for physician assistants 3 working within dermatology; and

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Whereas, This certification can deceive the public and allow physician assistants to advertise themselves as being "board certified;" and

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Whereas, This can lead to significant patient safety issues; therefore be it

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RESOLVED, That our American Medical Association amend Policy H-35.965, "Regulation of Physician Assistants," by addition and deletion to read as follows:

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Our AMA: (1) will advocate in support of maintaining the authority of medical licensing and regulatory boards to regulate the practice of medicine through oversight of physicians, physician assistants and related medical personnel; and (2) opposes legislative efforts to establish autonomous regulatory boards meant to license, regulate, and discipline physician assistants outside of the existing state medical licensing and regulatory bodies' authority and purview; and (3) opposes efforts by independent organizations to board certify physician assistants in a manner that misleads the public to believe such certification is equivalent to medical specialty board certification. (Modify Current HOD Policy); and be it further

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RESOLVED, That our AMA amend Policy H-275.926, "Medical Specialty Board Certification Standards," by addition to read as follows

1. Opposes any action, regardless of intent, that appears likely to confuse the public

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Our AMA:

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about the unique credentials of American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS) board certified physicians in any medical specialty, or take advantage of the prestige of any medical specialty for purposes contrary to the public good and safety. 2. Opposes any action, regardless of intent, by independent organizations providing board certification for non-physicians that appears likely to confuse the public about the unique credentials of medical specialty board certification or take advantage of the

prestige of medical specialty board certification for purposes contrary to the public good 35 36 and safety. 37

3. Continues to work with other medical organizations to educate the profession and the public about the ABMS and AOA-BOS board certification process. It is AMA policy that when the equivalency of board certification must be determined, accepted standards, such as those adopted by state medical boards or the Essentials for Approval of Examining Boards in Medical Specialties, be utilized for that determination. (Modify Current HOD Policy)

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Fiscal Note: Minimal - less than \$1,000

Received: 10/16/19

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RELEVANT AMA POLICY

Regulation of Physician Assistants H-35.965

Our AMA: (1) will advocate in support of maintaining the authority of medical licensing and regulatory boards to regulate the practice of medicine through oversight of physicians, physician assistants and related medical personnel; and (2) opposes legislative efforts to establish autonomous regulatory boards meant to license, regulate, and discipline physician assistants outside of the existing state medical licensing and regulatory bodies' authority and purview. Citation: Res. 233. A-17

Physician Assistants H-35.989

- 1. Our AMA opposes legislation to increase public funding for programs to train physician assistants and supports a careful reevaluation of the need for public funding at the time that present legislative authorities expire.
- 2. A physician assistant should provide patient care services only in accord with the medical practice act and other applicable state law, and such law should provide that the physician assistant's utilization by a physician or group of physicians be approved by the medical licensing board. A licensed physician or group of physicians seeking to utilize a physician assistant should submit to the medical licensing board an application for utilization that identifies: the qualifications and experience of the physician assistant, the qualifications and experience of the supervising physician and a description of his or her practice, and a description of the manner and the health care settings in which the assistant will be utilized, and the arrangements for supervision by the responsible physician. Such an application should also specify the number of physician assistants that the physician or group of physicians plans to employ and supervise. A physician assistant should be authorized to provide patient care services only so long as the assistant is functioning under the direction and supervision of a physician or group of physicians whose application for utilization has been approved by the medical licensing board. State medical licensing boards, in their review of applications for utilization of a physician assistant, should take special care to insure that the proposed physician assistant functions not be of a type which: (a) would unreasonably expand the professional scope of practice of the supervising physician, (b) cannot be performed safely and effectively by the physician assistant, or (c) would authorize the unlicensed practice of medicine.
- 3. The physician assistant should function under the direction of and supervision by a duly qualified licensed physician. The physician must always maintain the ultimate responsibility to assure that high quality care is provided to every patient. In discharging that responsibility, the physician should exercise that amount of control or supervision over a physician assistant which is appropriate for the maintenance of quality medical care and in accord with existing state law and the rules and regulations of the medical licensing authority. Such supervision in most settings includes the personal presence or participation of the physician. In certain instances, such as remote practice settings, where the physician assistant may function apart from the supervising physician, such remote function (if permitted by state law) should be approved by the state medical licensing board on an individual basis. Such approval should include requirements for regular reporting to the supervising physician, frequent site visits by that physician, and arrangements for immediate communication with the supervising physician for consultation at all times. The physician assistant may serve the patients of the supervising physician in all types of health care settings, including but not limited to: physician's office, ambulatory or outpatient facility, clinic, hospital, patient's home, long-term care facility or nursing home. The state medical licensing board should determine on an individual basis the number of physician assistants that a particular physician may supervise or a group of physicians may employ.
- 4. While it is preferable and desirable that the physician assistant be employed by a physician or group of physicians so as to ensure appropriate physician supervision in the interests of the

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patient, where a physician assistant is employed by a hospital, the physician assistant must provide patient care services in accordance with the rules and procedures established by the organized medical staff for utilization of physician-employed physician assistants functioning in that institution, and under the direction and supervision of a designated physician who has been approved by the state medical licensing board to supervise that physician assistant in accordance with a specific utilization plan and who shall be directly responsible as the attending physician for the patient care services delegated to his physician assistant.

5. The AMA opposes legislation or proposed regulations authorizing physician assistants to make independent medical judgments as to the drug of choice for an individual patient.
6.In view of an announced interest by HHS in considering national legislation which would override state regulatory systems for health manpower, the AMA recommends that present Association policy supporting state prerogatives in this area be strongly reaffirmed.
7.Our AMA opposes legislation or regulation that allows physician assistant independent practice.

Citation: BOT/CME/CMS Joint Rep., I-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmation A-99; Reaffirmed: CME Rep. 2, A-09; Reaffirmed: BOT Rep. 9, I-11; Appended: Res. 230, I-17

Medical Specialty Board Certification Standards H-275.926Our AMA:

- 1. Opposes any action, regardless of intent, that appears likely to confuse the public about the unique credentials of American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS) board certified physicians in any medical specialty, or take advantage of the prestige of any medical specialty for purposes contrary to the public good and safety.
- 2. Continues to work with other medical organizations to educate the profession and the public about the ABMS and AOA-BOS board certification process. It is AMA policy that when the equivalency of board certification must be determined, accepted standards, such as those adopted by state medical boards or the Essentials for Approval of Examining Boards in Medical Specialties, be utilized for that determination.
- 3. Opposes discrimination against physicians based solely on lack of ABMS or equivalent AOA-BOS board certification, or where board certification is one of the criteria considered for purposes of measuring quality of care, determining eligibility to contract with managed care entities, eligibility to receive hospital staff or other clinical privileges, ascertaining competence to practice medicine, or for other purposes. Our AMA also opposes discrimination that may occur against physicians involved in the board certification process, including those who are in a clinical practice period for the specified minimum period of time that must be completed prior to taking the board certifying examination.
- 4. Advocates for nomenclature to better distinguish those physicians who are in the board certification pathway from those who are not.
- 5. Encourages member boards of the ABMS to adopt measures aimed at mitigating the financial burden on residents related to specialty board fees and fee procedures, including shorter preregistration periods, lower fees and easier payment terms.

Citation: Res. 318, A-07; Reaffirmation A-11; Modified: CME Rep. 2, I-15

Resolution: 216

(I-19)

Introduced by: American Association of Public Health Physicians

Subject: Legislation to Facilitate Corrections-to-Community Healthcare Continuity via

Medicaid

Referred to: Reference Committee B

Whereas, Our AMA has established policy in item 6 of Policy H-430.986, "Health Care While Incarcerated," to "urge the Center for Medicare and Medicaid Services (CMS) and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities"; and

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Whereas, Medicare and Medicaid are legally prohibited by the inmate exclusion provision, section 1905(a)(29)of the Social Security Act¹, from paying for expenses incurred while a beneficiary is incarcerated, thus requiring Congressional action before CMS and states can implement the policy that our AMA supports in H-430.986; and

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Whereas, A bipartisan Congressional bill, H.R. 1329, introduced to the 116th Congress by Rep. Paul Tonko (D-NY) & Rep. Michael Turner (R-OH)² and known as the Medicaid Reentry Act, would amend the inmate exclusion provision to grant states flexibility to restart benefits for Medicaid-eligible incarcerated individuals during the 30 day period preceding the date of release; and

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Whereas, The AMA has not yet announced support for the Medicaid Reentry Act as of October 13, 2019; therefore be it

RESOLVED That our American Medical Association amend item #6 of HOD Policy H-430.986, "Health Care While Incarcerated," by addition of the word "Congress" to read as follows:

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6. Our AMA urges <u>Congress</u>, the Centers for Medicare & Medicaid Services (CMS), and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/17/19

¹ https://www.ssa.gov/OP_Home/ssact/title19/1905.htm, accessed October 14, 2019.

² H.R. 1329, The Medicaid Reentry Act, https://www.congress.gov/bill/116th-congress/house-bill/1329, accessed October 14, 2019.

Resolution: 216 (I-19)

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RELEVANT AMA POLICY

Health Care While Incarcerated H-430.986

- 1. Our AMA advocates for adequate payment to health care providers, including primary care and mental health, and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.
- 2. Our AMA supports partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of health care services for juveniles and adults in the correctional system.
- 3. Our AMA encourages state Medicaid agencies to accept and process Medicaid applications from juveniles and adults who are incarcerated.
- 4. That our AMA encourage state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid.
- 5. Our AMA encourages states to suspend rather than terminate Medicaid eligibility of juveniles and adults upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community.
- 6. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism.
- 7. Our AMA advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum women.
- 8. Our AMA will collaborate with state medical societies and federal regulators to emphasize the importance of hygiene and health literacy information sessions for both inmates and staff in correctional facilities.
- 9. Our AMA supports: (a) linkage of those incarcerated to community clinics upon release in order to accelerate access to comprehensive health care, including mental health and substance abuse disorder services, and improve health outcomes among this vulnerable patient population, as well as adequate funding; and (b) the collaboration of correctional health workers and community health care providers for those transitioning from a correctional institution to the community.

Citation: CMS Rep. 02, I-16; Appended: Res. 417, A-19; Appended: Res. 420, A-19

Resolution: 217

(I-19)

Introduced by: Women Physicians Section

Subject: Promoting Salary Transparency Among Veterans Health Administration

Employed Physicians

Referred to: Reference Committee B

Whereas, Gender inequities among health care providers exist and are receiving increasing scrutiny; and

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Whereas, Inequities may be associated with a lack of mentors, discrimination, gender bias, imposter syndrome, and difficulties with work-life balance; and

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Whereas, Pay disparities exists as an example of gender inequity; and

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Whereas, Pay disparity impacts women's morale and their ability to attain economic stability; and

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Whereas, Pay disparity also creates barriers to workforce participation for women, slowing the growth of the U.S. economy, according to a Brookings Institute study;¹ and

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Whereas, Following a steady increase between 1950-1999, female U.S. labor force participation rates began to decline in the next decade;² and

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Whereas, Most recent data demonstrate male physicians earn 9 to 40 percent more than female physicians, controlling for age, experience, specialty, faculty rank, and clinical revenue;³ and

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Whereas, This leads to an estimated \$36K-\$95K annual difference in earnings; and

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Whereas, Pay scales should be easily quantifiable metrics and therefore ready targets for intervention to improve equity; and

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Whereas, There are no published data regarding Veterans Health Administration physician pay differences; therefore be it

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RESOLVED, That our American Medical Association encourage physician salary transparency within the Veterans Health Administration. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/08/19

Resolution: 217 (I-19)

Page 2 of 3

References:

1. Dews, F. Charts of the Week: The gender wage gap. *Brookings Now.* March 22, 2019. Available at www.brookings.edu/blog/brookings-now/2019/03/22/charts-of-the-week-the-gender-wage-gap/.

2. Toossi M. and Morisi TL. Women in the Workforce Before, During, and After the Great Recession. Available at https://www.bls.gov/spotlight/2017/women-in-the-workforce-before-during-and-after-the-great-recession.pdf.

3. Kacik, Alex. Large gap remains between male, female physician pay. *Modern Healthcare*. March 26, 2019. Available at www.modernhealthcare.com/finance/large-gap-remains-between-male-female-physician-pay.

RELEVANT AMA POLICY

Principles for Advancing Gender Equity in Medicine H-65.961 Our AMA:

- 1. declares it is opposed to any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender);
- 2. affirms the concept of equal rights for all physicians and that the concept of equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender;
- 3. endorses the principle of equal opportunity of employment and practice in the medical field;
- 4. affirms its commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine;
- 5. acknowledges that mentorship and sponsorship are integral components of one's career advancement, and encourages physicians to engage in such activities;
- 6. declares that compensation should be equitable and based on demonstrated competencies/expertise and not based on personal characteristics;
- 7. recognizes the importance of part-time work options, job sharing, flexible scheduling, re-entry, and contract negotiations as options for physicians to support work-life balance;
- 8. affirms that transparency in pay scale and promotion criteria is necessary to promote gender equity, and as such academic medical centers, medical schools, hospitals, group practices and other physician employers should conduct periodic reviews of compensation and promotion rates by gender and evaluate protocols for advancement to determine whether the criteria are discriminatory; and
- 9. affirms that medical schools, institutions and professional associations should provide training on leadership development, contract and salary negotiations and career advancement strategies that include an analysis of the influence of gender in these skill areas.

Our AMA encourages: (1) state and specialty societies, academic medical centers, medical schools, hospitals, group practices and other physician employers to adopt the AMA Principles for Advancing Gender Equity in Medicine; and (2) academic medical centers, medical schools, hospitals, group practices and other physician employers to: (a) adopt policies that prohibit harassment, discrimination and retaliation; (b) provide anti-harassment training; and (c) prescribe disciplinary and/or corrective action should violation of such policies occur. Citation: BOT Rep. 27, A-19;

Advancing Gender Equity in Medicine D-65.989

1. Our AMA will: (a) advocate for institutional, departmental and practice policies that promote transparency in defining the criteria for initial and subsequent physician compensation; (b) advocate for pay structures based on objective, gender-neutral criteria; (c) encourage a specified approach, sufficient to identify gender disparity, to oversight of compensation models, metrics, and actual total compensation for all employed physicians; and (d) advocate for training to identify and mitigate implicit bias in compensation determination for those in positions to determine salary and bonuses, with a focus on how subtle differences in the further evaluation of physicians of different genders may impede compensation and career advancement.

Resolution: 217 (I-19)

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2. Our AMA will recommend as immediate actions to reduce gender bias: (a) elimination of the question of prior salary information from job applications for physician recruitment in academic and private practice; (b) create an awareness campaign to inform physicians about their rights under the Lilly Ledbetter Fair Pay Act and Equal Pay Act; (c) establish educational programs to help empower all genders to negotiate equitable compensation; (d) work with relevant stakeholders to host a workshop on the role of medical societies in advancing women in medicine, with co-development and broad dissemination of a report based on workshop findings; and (e) create guidance for medical schools and health care facilities for institutional transparency of compensation, and regular gender-based pay audits.

- 3. Our AMA will collect and analyze comprehensive demographic data and produce a study on the inclusion of women members including, but not limited to, membership, representation in the House of Delegates, reference committee makeup, and leadership positions within our AMA, including the Board of Trustees, Councils and Section governance, plenary speaker invitations, recognition awards, and grant funding, and disseminate such findings in regular reports to the House of Delegates and making recommendations to support gender equity.
- 4. Our AMA will commit to pay equity across the organization by asking our Board of Trustees to undertake routine assessments of salaries within and across the organization, while making the necessary adjustments to ensure equal pay for equal work.

Citation: Res. 010, A-18; Modified: BOT Rep. 27, A-19;

Inequity in Military Pay for Physicians D-40.993

Our AMA will work, as appropriate, with other interested organizations, to support immediate reintroduction of a bill based on H.R. 5353 (107th Congress) in this Congress. Citation: (BOT Action in response to referred for decision Res. 901, I-03; Reaffirmed: BOT Rep. 28, A-13)

Resolution: 218

(I-19)

Introduced by: American College of Rheumatology, American Academy of Neurology,

American Association of Clinical Endocrinologists, Endocrine Society,

North American Neuro-Ophthalmology Society

Subject: Private Payers and Office Visit Policies

Referred to: Reference Committee B

Whereas, Recently commercial payers have implemented polices for evaluation and management (E/M) services that discontinue payments for consultations, in that they will deny claims billed with CPT codes for consultation services as not valid; and

Whereas, Consultation is requested by primary care and other referring physicians to address patients' most challenging and complex medical problems, and this work often includes extensive review of prior records as well as communication and coordination with referring providers. The expertise of the consulting physician is often cost-saving to the insurance carrier, as these specialists can often diagnose and treat the condition without ordering unnecessary tests or treatments; and

Whereas, Failing to acknowledge the difference in work between a consultation and the relative simplicity of assuming the care of a patient with a known diagnosis is misguided and will predictably limit the ability of providers to consult on complex cases; and

Whereas, When the Centers for Medicare and Medicaid Services discontinued payment for consultation codes in 2010, the medical community raised significant concerns because in its decision the agency failed to recognize the expertise and additional collaboration that is reflected in the use of consultation codes; and

 Whereas, In its CY 2020 Medicare physician fee schedule proposed rule the Centers for Medicare and Medicaid services proposed adopting the American Medical Association RVS Update Committee (RUC) recommended values for the office and outpatient evaluation and management (E/M) visit codes for CY 2021, which would more appropriately value complex E/M services; and

Whereas, Given that healthcare policy makers are moving toward a more appropriate valuation of office visits and E/M services, it is alarming that commercial payers would move to stop recognizing consultation services at this time; therefore be it

RESOLVED, That our American Medical Association with all haste directly engage and advocate with commercial insurance companies that discontinue payment for consultation codes or that are proposing to or considering eliminating payment for such codes, requesting that the companies reverse or delay such policy changes while the Centers for Medicare and Medicaid Services (CMS) updates its approach to valuation of office visits (Directive to Take Action); and be it further

Resolution: 218 (I-19)

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- 1 RESOLVED, That if in the CY 2020 Medicare physician fee schedule final rule CMS finalizes its
- 2 proposal to increase payments for evaluation and management services, then our American
- 3 Medical Association will advocate publicly and with all private payers that those private payers
- mirror and follow CMS' lead in more appropriately valuing office visits, by increasing payments
- 5 for evaluation and management services in their reimbursement schedules. (Directive to Take

Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

RELEVANT AMA POLICY

Consultation Codes and Private Payers D-385.955

- 1. Our AMA will proactively engage and advocate with any commercial insurance company that discontinues payment for consultation codes or that is proposing to or considering eliminating payment for such codes, requesting that the company reconsider the policy change.
- 2. Where a reason given by an insurance company for policy change to discontinue payment of consultation codes includes purported coding errors or abuses, our AMA will request the company carry out coding education and outreach to physicians on consultation codes rather than discontinue payment for the codes, and call for release of de-identified data from the company related to purported coding issues in order to help facilitate potential education by physician societies.

Citation: Res. 819, I-17

Medicare's Proposal to Eliminate Payments for Consultation Service Codes D-70.953

1. Our American Medical Association opposes all public and private payer efforts to eliminate payments for inpatient and outpatient consultation service codes, and supports legislation to overturn recent Center for Medicare & Medicaid Services (CMS) action to eliminate consultation codes, 2, Our AMA will work with CMS and interested physician groups through the CPT Editorial Panel to address all concerns with billing consultation services either through revision or replacement of the current code sets or by some other means. 3. Our AMA will, at the conclusion of the CPT Editorial Panel's work to address concerns with billing consultation services, work with CMS and interested physician groups to engage in an extensive education campaign regarding appropriate billing for consultation services. 4. Our AMA will: (a) work with the Centers for Medicare & Medicaid Services to consider a two-year moratorium on RAC audit claims based on three-year rule violations for E/M services previously paid for as consultations; and (b) pursue Congressional action through legislation to reinstate payment for consultation codes within the Medicare Program and all other governmental programs. 5. Our AMA will petition the CMS to limit RAC reviews to less than one year from payment of claims. Citation: Res. 807, I-09; Appended: Sub. Res. 212, I-10; Reaffirmation A-12; Appended: Res.

216, A-12; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation: A-17

Resolution: 219

(I-19)

Introduced by: American Society of Clinical Oncology

Subject: QPP and the Immediate Availability of Results in CEHRTs

Referred to: Reference Committee B

Whereas, The Centers for Medicare and Medicaid Services (CMS), through the Promoting Interoperability Program for hospitals and MIPS eligible clinicians, currently requires health care providers to share patient health data (including laboratory and pathology data) through an application programming interface (API) within four days of its availability; and

Whereas, CMS recently issued an Advanced Notice of Proposed Rulemaking (ANPRM) that seeks comment on whether Merit-based Incentive Payment System (MIPS) eligible clinicians should be required to make patient health information available immediately through an API no later than one day after it is available to the clinicians in the certified electronic health record technology (CEHRT); and

Whereas, This, if implemented, would be part of the Quality Payment Program's (QPP) Promoting Interoperability (PI) performance category and therefore directly impacts MIPS participants and their reimbursement; and

Whereas, Generally, feasibility of information exchange is driven by improvements in technology and the health information technology (HIT) infrastructure is led by vendors and developers, not physicians; and

Whereas, EHR prompts do not give physicians the ability to publish notes into just the practice-facing chart then separately into the patient-facing portal; and

Whereas, Patient access to their protected health information (PHI) should be supported, there are concerns relating to immediate availability of certain laboratory and pathology test results because patients would have access to pathology reports prior to a consultation with their physician to aid in the understanding of the results; and

Whereas, This situation could cause significant patient and family distress so it is important to equip patients with the necessary contextual information and clinical expertise provided by their physicians when reviewing test results; therefore be it

RESOLVED, That our American Medical Association urge the Centers for Medicare & Medicaid Services to create guardrails around the "immediate" availability of laboratory, pathology, and radiology results, factoring in an allowance for physician judgement and discretion regarding the timing of release of certain results (Directive to Take Action); and be it further

Resolution: 219 (I-19)

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1 RESOLVED, That our AMA encourage vendors to implement prompts that give physicians the

2 ability to either approve notes to just the chart or approve and publish them in both the chart and

3 patient portal. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

RELEVANT AMA POLICY

Information Technology Standards and Costs D-478.996

1. Our AMA will:(a) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems;(b) work with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate when they implement these technologies in their offices;(c) review the following issues when participating in or commenting on initiatives to create a NHII: (i) cost to physicians at the office-based level; (ii) security of electronic records; and (iii) the standardization of electronic systems;(d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and(e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems.

2.Our AMA advocates that physicians: (a) are offered flexibility related to the adoption and use of new certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of EHR products that meet the specified certification standards; and (b) not be financially penalized for certified EHR technology not meeting current standards. Citation: Res. 717, A-04; Reaffirmation, A-05; Appended: Sub. Res. 707, A-06; Reaffirmation A-07; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08; Reaffirmation I-09; Reaffirmation A-10; Reaffirmed in lieu of Res. 205, A-11; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed in lieu of Res. 724, A-13; Reaffirmation I-13; Reaffirmation A-14; Reaffirmed: BOT Rep. 03, I-16; Reaffirmed: BOT Rep. 05, I-16; Appended: Res. 204, I-17; Reaffirmation: I-17; Reaffirmed: BOT Rep. 45, A-18; Reaffirmed: BOT Rep. 19, A-18; Reaffirmation: A-19

Reference Committee C

CME Report(s)

- 02 Healthcare Finance in the Medical School Curriculum
- 03 Standardization of Medical Licensing Time Limits Across States
- 04 Board Certification Changes Impact Access to Addiction Medicine Specialists
- 06 Veterans Health Administration Funding of Graduate Medical Education

Resolution(s)

- 301 Engaging Stakeholders for Establishment of a Two-Interval, or Pass/Fail, Grading System of Non-Clinical Curriculum in U.S. Medical Schools
- 302 Strengthening Standards for LGBTQ Medical Education
- 303 Investigation of Existing Application Barriers for Osteopathic Medical Students Applying for Away Rotations
- 304 Issues with the Match, The National Residency Matching Program (NRMP)
- 305 Ensuring Access to Safe and Quality Care for our Veterans
- 306 Financial Burden of USMLE Step 2 CS on Medical Students
- 307 Implementation of Financial Education Curriculum for Medical Students and Physicians in Training
- 308 Study Expediting Entry of Qualified IMG Physicians to US Medical Practice

^{*} Contained in Handbook Addendum

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 2-I-19

Subject: Healthcare Finance in the Medical School Curriculum (Resolution 307-A-18)

Presented by: Jacqueline A. Bello, MD, Chair

Referred to: Reference Committee C

INTRODUCTION

Resolution 307-A-18, "Healthcare Finance in the Medical School Curriculum," introduced by the Missouri Delegation and referred by the American Medical Association (AMA) House of Delegates (HOD), asks that the AMA "study the extent to which medical schools and residency programs are teaching topics of healthcare finance and medical economics" and "make a formal suggestion to the Liaison Committee on Medical Education encouraging the addition of a new Element, 7.10, under Standard 7, 'Curricular Content,' that would specifically address the role of healthcare finance and medical economics in undergraduate medical education."

During the 2018 Annual Meeting, Reference Committee C heard mixed testimony on this item. It was noted that health care finance is already being taught in some medical schools, but an overall understanding of the breadth, depth, and frequency of these offerings is unknown. Furthermore, concern was expressed that the second Resolve implied a curricular mandate in an already distended medical education curriculum. The reference committee believed that additional study was warranted; the HOD agreed, and this item was referred. This report addresses that referral.

BACKGROUND AND DATA

The United States spends more on health care than any other nation in the world, with health care expenditures at 17.9 percent of gross domestic product in 2017, and national health care spending is projected to increase at a rate of 5.5 percent per year for the next 10 years under current law. Multiple factors contribute to the high cost of health care in the United States, including costs for labor and goods, pharmaceutical costs, administrative costs. 1,2,3 Numerous studies have found that while cost of care in the U.S. is often double that of other industrialized countries, outcome measures are essentially the same. In recognition of this concern, reducing cost of care is one of the Triple Aims of the Institute for Health Care Improvement and one of the three core aims of health care reform. 4

The medical education system has been shown to favorably impact cost of care by medical school graduates who have had cost, financing, and medical economics topics integrated into their respective program curricula. Chen et al.⁵ found that the spending pattern of the training location was positively associated with care expenditures when the residents entered practice, implying that interventions in training may have the potential to reduce health care spending after completion of training. Phillips et al.⁶ similarly found that family physician and general internist spending was influenced by location of training in low, average, or high-cost locations, and concluded, "The 'imprint' of training spending patterns on physicians is strong and enduring, without discernible

quality effects..." Stammen et al. in a published systematic review on the effectiveness of medical education on high-value, cost-conscious care, reached the following conclusion:

... learning by practicing physicians, resident physicians, and medical students is promoted by combining specific knowledge transmission, reflective practice, and a supportive environment. These factors should be considered when educational interventions are being developed.

Curriculum content in health care financing is currently required by the accrediting body for allopathic medical schools in the United States, the Liaison Committee on Medical Education (LCME). The LCME's accreditation *Standard 7: Curricular Content* requires that "the medical school curriculum provides content of sufficient breadth and depth to prepare medical students for entry into any residency program and for the subsequent contemporary practice of medicine." This requirement is expressed through *Element 7.1: Biomedical, Behavioral, and Social Sciences* by ensuring that "the medical curriculum includes content from biomedical, behavioral, and socioeconomic sciences to support medical students' mastery of contemporary scientific knowledge and concepts and the methods fundamental to applying them to the health of individuals and populations." As part of their accreditation documents, schools are asked to document where in the curriculum health care financing is taught (preclinical or clinical phases), but schools are not asked to comment on the content or quantity of the subject matter. The quality of instruction and educational materials is not evaluated. No inquiries are made regarding medical economics. "

Unrelated to the accreditation process, each year the LCME requests that schools complete a voluntary survey, the LCME Annual Medical School Questionnaire Part II. The questionnaire includes queries on where in the curriculum certain topics are taught. Data relevant to this report from academic years 2013-14 through 2017-18 are provided in the tables below.

Health Care Financing*/Cost of Care#						
Survey	Total number of schools	Location in curriculum				
year	surveyed	Required	Elective	Pre-	Clerkships	
		Course		clerkship	_	
2017-18*	147	131	63	120	89	
2016-17#	145	140	72	128	97	
2015-16#	142	137	67	120	125	
2014-15*	141	140	61	127	112	
2014-15#	141	139	84	120	112	
2013-14*	140	133	64	120	108	
2013-14#	140	129	53	112	103	

^{*} Survey item was "health care financing"

²⁰¹³⁻¹⁴ and 2014-15 surveys included both terms

Medical Socioeconomics*/Medical Economics#						
Survey	Total number of schools	Location in curriculum				
year	surveyed	Required	Elective	Pre-	Clerkships	
		Course		clerkship		
2017-18*	147	143	79	141	117	
2017-18#	147	135	85	132	105	
2016-17*	145	136	84	129	105	
2016-17#	145	141	77	136	112	
2015-16#	142	132	71	123	107	

[#] Survey question was "cost of care"

2015-	16*	142	138	72	131	110
2014-	15*	141	137	96	128	116
2013-	14*	140	133	60	125	106

^{*} Survey item was "medical socioeconomics"

For 2016-17 and 2017-18, schools were also asked where in the curriculum the specific topics were covered to prepare students for entry into residency training.

Health system content (e.g., health care financing, billing, coding)							
Survey	Total number of	Location in curriculum					
year	schools	4 th year	Required	Required 3 rd	Intersession		
	surveyed	transition to	sub-	year clinical			
		residency	internship	clerkship			
		course					
2017-18	147	67	42	80	42		
2016-17	145	82	51	93	52		

The accreditation standards of the Commission on Accreditation of Osteopathic Colleges (COCA) do not explicitly state a requirement for curriculum related to medical economics or health care financing.¹⁰

The Accreditation Council for Graduate Medical Education common program requirements IV.B.1.f).(1).(f) and (g) require residents to demonstrate competence in "incorporating considerations of value, cost awareness, delivery and payment..." and "understanding health care finances and its impact on individual patients' health decisions." ¹¹ A limited review of specialty-specific milestones, the mechanism by which residents are assessed for achievement of competency, revealed that family medicine, internal medicine, emergency medicine, and diagnostic radiology have milestones that assess residents' competency in delivering cost-conscious care, cost-effective care, or consideration of health care costs. ¹²

CURRENT INITIATIVES

Despite the UME and GME requirements noted above, there has been a growing realization of the need for additional training in health systems, including health care financing and medical economics during UME. To address this concern, the concept of health systems science (HSS) has recently taken hold as a "third pillar" of medical education¹³ (basic science and clinical science being the traditional two pillars). In recognition of the need to change the medical education system to train physicians in HSS, the AMA funded the Accelerating Change in Medical Education initiative, with the goal of enhancing medical school curricula to better train future physicians in the competencies needed to provide high quality care in health systems. HSS curriculum, which includes medical economics content, is a focus of the initiative. A tangible outcome from the consortium was the publication of the first HSS textbook. The initial 11-school consortium has grown to 37 schools. The AMA also supports a learning module, "Health Care Delivery Systems - AMA Health Systems Science Learning Series," through the AMA Ed Hub. In addition, through its GME Competency Education Program (GCEP), the AMA offers a series of online educational modules designed to complement teachings in residency and fellowship programs, with a library of more than 30 individualized courses designed for self-paced learning. One content area of the

[#] Survey question was "medical economics"

^{2015-16, 2016-17,} and 2017-18 surveys included both terms

module is how payment models affect patient care and costs. A study of consortium schools found that health care economics and value-based care are core domains of their HSS curricula.¹⁶

 The inclusion of UME curricular content on HSS in general, and health care financing specifically, has been advanced by the inclusion of these topics on standardized examinations. The United States Medical Licensing Examination (USMLE) Content Outline website lists health care economics, health care financing, high value/cost-conscious care, and relevant subtopics as content areas across all USMLE examinations. A case-based review book on HSS has been developed by the ACE consortium as a review tool on HSS topics covered on the USMLE examinations. The review book includes a chapter of cases and questions on health care economics. To further support HSS assessment at the UME level, a pilot subject examination in HSS has been developed by a consortium of medical schools in collaboration with the National Board of Medical

H-295.924, "Future Directions for Socioeconomic Education" (Modified and reaffirmed 2017)

by a consortium 13 Examiners.²⁰

RELEVANT AMA POLICY

The AMA: (1) asks medical schools and residencies to encourage that basic content related to the structure and financing of the current health care system, including the organization of health care delivery, modes of practice, practice settings, cost effective use of diagnostic and treatment services, practice management, risk management, and utilization review/quality assurance, is included in the curriculum; (2) asks medical schools to ensure that content related to the environment and economics of medical practice in fee-for-service, managed care and other financing systems is presented in didactic sessions and reinforced during clinical experiences, in both inpatient and ambulatory care settings, at educationally appropriate times during undergraduate and graduate medical education; and (3) will encourage representatives to the Liaison Committee on Medical Education (LCME) to ensure that survey teams pay close attention during the accreditation process to the degree to which "socioeconomic" subjects are covered in the medical curriculum.

D-295.321, "Health Care Economics Education" (Modified and reaffirmed 2015)

Our AMA, along with the Association of American Medical Colleges, Accreditation Council for Graduate Medical Education, and other entities, will work to encourage education in health care economics during the continuum of a physician's professional life, starting in undergraduate medical education, graduate medical education and continuing medical education.

H-295.977, "Socioeconomic Education for Medical Students" (Modified 2010)

- 1. The AMA favors (a) continued monitoring of U.S. medical school curricula and (b) providing encouragement and assistance to medical school administrators to include or maintain material on health care economics in medical school curricula.
- 2. Our AMA will advocate that the medical school curriculum include an optional course on coding and billing structure, RBRVS, RUC, CPT and ICD-9.

H-295.864, "Systems-Based Practice Education for Medical Students and Resident/Fellow Physicians" (Modified and reaffirmed 2017)

Our AMA: (1) supports the availability of educational resources and elective rotations for medical students and resident/fellow physicians on all aspects of systems-based practice, to improve awareness of and responsiveness to the larger context and system of health care and to aid in developing our next generation of physician leaders; (2) encourages development of model guidelines and curricular goals for elective courses and rotations and fellowships in systems-based practice, to be used by state and specialty societies, and explore developing an educational module on this topic as part of its Introduction to the Practice of Medicine (IPM) product; and (3) will request that undergraduate and graduate medical education accrediting bodies consider incorporation into their requirements for systems-based practice education such topics as health care policy and patient care advocacy; insurance, especially pertaining to policy coverage, claim processes, reimbursement, basic private insurance packages, Medicare, and Medicaid; the physician's role in obtaining affordable care for patients; cost awareness and risk benefit analysis in patient care; inter-professional teamwork in a physician-led team to enhance patient safety and improve patient care quality; and identification of system errors and implementation of potential systems solutions for enhanced patient safety and improved patient outcomes.

SUMMARY AND RECOMMENDATIONS

 The academic literature suggests that education and role-modeling have an effect on the cost-effectiveness of care provided by graduates of programs that emphasize cost considerations in education of physicians. Curriculum content on health care financing/medical economics is required by the accrediting bodies for allopathic medical schools and GME programs. With few exceptions, allopathic medical schools report the inclusion of the topics of health care financing, health care costs, medical socioeconomics, and medical economics in their respective curricula. Several of the larger GME specialty milestones require cost considerations in the training curricula. The exact content and amount of curricular time devoted to these topics at individual schools and GME programs is unknown. The AMA provides online educational resources on HSS topics, including the effect of payment models on health outcomes and cost of care, and the AMA-supported Accelerating Change in Medical Education initiative includes medical economics in the focus area of HSS. USMLE Step exams include questions on health care economics, and a subject exam focusing on HSS has been developed. The AMA has existing policy encouraging medical schools and residency programs to include health care finance and medical economics in their respective curricula while avoiding curricular mandates.

Related to Resolution 307-A-18, its first directive (that the AMA "study the extent to which medical schools and residency programs are teaching topics of healthcare finance and medical economics") has been addressed through this report.

The resolution also asks that the AMA "make a formal suggestion to the Liaison Committee on Medical Education encouraging the addition of a new Element, 7.10, under Standard 7, 'Curricular Content,' that would specifically address the role of healthcare finance and medical economics in undergraduate medical education." To address this aspect, amendments to Policy H-295.924, "Future Directions for Socioeconomic Education," are proposed below. The rationale for each edit is as follows:

• GME programs, not medical schools, are responsible for graduate medical education. Most GME programs are not under the direct authority of medical schools. Adding "and

residencies" to item 2 of this policy clarifies the responsibility and authority for oversight of graduate medical education and curricular content.

Historically, the AMA has refrained from curricular mandates, especially mandates with this degree of specificity. Similarly, the LCME has been disinclined to accept recommendations with curricular mandates. Eliminating the phrase "in didactic sessions and reinforced during clinical experiences, in both inpatient and ambulatory care settings" allows for more flexibility to medical schools and residency programs in implementation of this curricular content.

• The AMA does not have "representatives" on the LCME. Some LCME members are nominated by the AMA for consideration as professional members of the LCME, but, if elected by the LCME, they do not represent the AMA. Their fiduciary responsibility while serving as a member of the LCME is to the LCME. DOE regulations require separation of the accrediting agency from direct sponsor influence.

The Council on Medical Education therefore recommends that the following recommendation be adopted in lieu of Resolution 307-A-18 and the remainder of the report be filed.

1. That our American Medical Association (AMA) amend Policy H-295.924, "Future Directions for Socioeconomic Education," by addition and deletion to read as follows:

"The AMA: (1) asks medical schools and residencies to encourage that basic content related to the structure and financing of the current health care system, including the organization of health care delivery, modes of practice, practice settings, cost effective use of diagnostic and treatment services, practice management, risk management, and utilization review/quality assurance, is included in the curriculum; (2) asks medical schools and residencies to ensure that content related to the environment and economics of medical practice in fee-for-service, managed care and other financing systems is presented in didactic sessions and reinforced during clinical experiences, in both inpatient and ambulatory care settings, at educationally appropriate times during undergraduate and graduate medical education; and (3) will encourage representatives to the Liaison Committee on Medical Education (LCME) to ensure that survey teams pay close attention during the accreditation process to the degree to which 'socioeconomic' subjects are covered in the medical curriculum." (Modify Current HOD Policy)

Fiscal note: \$500.

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 3-I-19

Subject: Standardization of Medical Licensing Time Limits Across States

(Resolution 305-A-18)

Presented by: Jacqueline A. Bello, MD, Chair

Referred to: Reference Committee C

.....

INTRODUCTION

Resolution 305-A-18, introduced by the American Medical Association Medical Student Section (AMA-MSS), asked that our AMA:

Amend Policy H-275.978, "Medical Licensure," by addition to read as follows

The AMA... (23) urges the state medical and osteopathic licensing boards which maintain a time limit on complete licensing examination sequences to adopt a time limit of no less than 10 years for completion of a licensing examination sequence for either USMLE or COMLEX.

Testimony before Reference Committee C at the 2018 Annual Meeting was in favor of referring this complex item for further study. Some states have no time limit for completion of the licensing examination sequence; some set a time limit of seven years; and some cap eligibility at 10 years (to accommodate the longer timeline for dual-degree individuals, e.g., those seeking to hold MD and PhD credentials). Testimony was heard concerning the perception that physicians who have academic troubles will take longer to complete the sequence, such that the time limit becomes a mechanism through which to ensure patient safety by eliminating these individuals from the practice of medicine. This belief, however, does not take into account the legitimate health or personal issues that may affect a given physician's ability to complete all exams within a prescribed timeframe, or the challenges faced by those pursuing dual degrees. Testimony in favor of a time limit was that this would ensure that examinees are being assessed based on their current medical knowledge. Accordingly, the AMA House of Delegates referred this item, to ensure a comprehensive, holistic review and study of all the relevant factors and consideration of potential unintended consequences, with the involvement of all relevant stakeholders, such as the Federation of State Medical Boards (FSMB) and the 70 state medical and osteopathic regulatory boards it represents.

BACKGROUND

State medical boards are entrusted to protect the public from unprofessional, unlawful or incompetent physician behavior. To ensure that physicians practicing in a state or jurisdiction are minimally competent to provide patient care, physicians under the board's purview are required to complete either the United States Medical Licensing Examination (USMLE), for allopathic medical school graduates, or the Comprehensive Osteopathic Medical Licensing Examination (COMLEX-USA), if a graduate of an osteopathic medical college. Passage of the USMLE or the COMLEX-USA is necessary to be eligible for a full and unrestricted license to practice medicine. Both the USMLE and COMLEX-USA are composed of a series of exams. Most students studying medicine

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in the U.S. take the first three exams while in medical school; the final exam is typically taken while the physician is in residency training.

Current U.S. Licensing Completion Requirements

 States may have different requirements as to the number of attempts to pass the exams, as well as different limits that cap the length of time for completion. Furthermore, many states allow for more time if the physician is pursuing a dual-degree (e.g., MD-PhD), and may also waive the time limit in the event of extenuating circumstances. Although many states have similar requirements, there is no universal standard, and there is great variability between MD and DO boards within states (for USMLE and COMLEX-USA, respectively) and between states. Table 1 presents data from the FSMB on the 66 licensing boards in the states, District of Columbia, and Puerto Rico. Some states' responses regarding extenuating circumstances are omitted due to lack of clarity. ¹

Table 1. U.S. medical boards' USMLE or COMLEX-USA completion time limits

	No limit	/ years	<u>8 years</u>	9 years	10 years	12 years
USMLE	10	28	•	•	13	•
COMLEX-USA	22	14			8	
MD/DO-PhD/dual degree	4		1	1	14	1

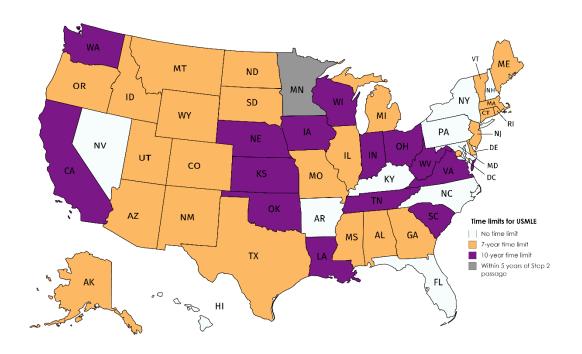
Although 23 of reporting boards with a time limit for completion will waive the limit depending on extenuating circumstances, 12 will not; these 12 have the time limits as shown in Table 2.

Table 2.

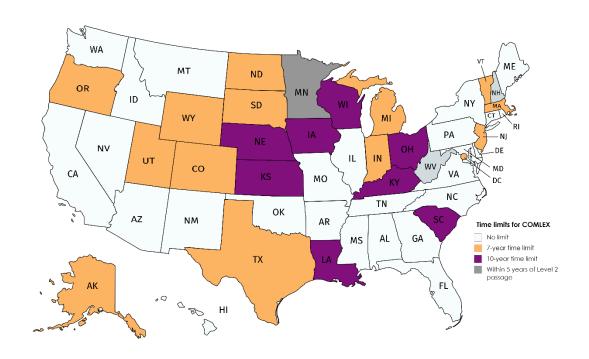
USMLE or COMLEX-USA completion and dual-degree time limits of U.S. medical boards that do not waive time limits

30	Number of boards	mber of boards USMLE/COMLEX-USA limit	
31	6	7 years	_
32	2	10 years	
33	1	7 years	8 years
34	1	7 years	10 years
35	1	10 years	10 years
36	1	10 years	12 years

The two maps present time limits for USMLE and COMLEX-USA completion. Although some contiguous states have identical requirements, many do not. For example, four of the five states bordering New York—which has no time limit for completion of USMLE—require completion within seven years.



Created with mapchart.net \otimes



Data from the National Board of Medical Examiners (NBME), the organization that administers the USMLE, suggests that most physicians pass the three steps of the USMLE within seven years of starting the process (91 percent); 99 percent complete the USMLE within 10 years. These data are for U.S. medical school graduates of schools accredited by the Liaison Committee on Medical Education (LCME) and do not include graduates of foreign medical schools or graduates of osteopathic medical schools.² Similarly, the National Board of Osteopathic Medical Examiners (NBOME), which administers the COMLEX-USA, has found the average time from the initial attempt of the Level 1 examination to completion of COMLEX-USA with passage of Level 3 to be 2.81 years. In addition, less than 0.2% of candidates who passed Level 3 between 2015 and 2019 took longer than seven years.3

In a study examining the performance of over 40,000 Step 3 examinees, Feinberg et al. reported that 55 percent of examinees took the Step 3 exam within six to 18 months of starting residency, 93 percent tested within 36 months of training, and 99 percent had tested within 60 months of starting training.⁴

Patient Safety and Workforce Issues

 The purpose of passing the USMLE and the COMLEX-USA is to ensure the public that a physician has met a standard of medical knowledge and clinical skills to provide safe and effective patient care. There have been studies examining the association between USMLE performance and 1) demographic characteristics of physicians⁵ and 2) academic performance, remediation, and referral to a competency committee while in medical school,^{6,7} among other studies. Much is unknown, however, about USMLE/COMLEX-USA performance and state medical licensure. In a study that found an association between physicians' unprofessional behavior noted during medical school and subsequent disciplinary actions by state medical licensing boards, there was no statistical association with Step 1 score and subsequent disciplinary action.⁸ A study by Cuddy et al. that included Step 1, Step 2 CK scores, and state medical licensure data on over 164,000 physicians found that higher Step 2 CK scores were associated with a decreased chance of disciplinary action.⁹

Actions taken by state medical licensure boards are, by default, taken against physicians who have completed the medical licensure process. As Cuddy et al. point out: "Physicians who fail the USMLE are unable to obtain a license to practice medicine in the United States, thus precluding the possibility of establishing whether or not physicians who have met USMLE standards provide better patient care than those who have failed to meet these standards." It is not known if physicians who do not become licensed as a result of not completing the licensure process within the time required, or ever, would pose a risk to patient safety—linkages have been made between poor performance on exams and academic performance in medical school and state disciplinary actions. It can be assumed that *failing* the exams is an indicator of compromised physician competency.

 Physician-scientists, or physicians who pursue PhDs as well as clinical training, are an important workforce in biomedical research; however, they likely take longer to become licensed, an accommodation recognized by 21 state licensing boards. Typically, around 550 physicians graduate each year with an MD-PhD, taking approximately eight years to receive both degrees. ¹⁰

When considering time-limit exceptions for completing the USMLE sequence in the case of dualdegree physicians, the NBME recommends state licensing boards waive the time limit for candidates meeting the following requirements:

• The candidate has obtained both degrees from an institution or program accredited by the LCME and a regional university accrediting body.

- The PhD should reflect an area of study which ensures the candidate a continuous involvement with medicine and/or issues related, or applicable to, medicine.
- A candidate seeking an exception to the seven-year rule should be required to present a verifiable and rational explanation for the fact that he or she was unable to meet the seven-year limit. These explanations will vary, and each licensing jurisdiction will need to decide on its own which explanation justifies an exception. Students who pursue both degrees should understand that while many states' regulations provide specific exceptions to the seven-year rule for dual-degree candidates, others do not. Students pursuing a dual degree are advised to check the state-specific requirements for licensure listed by the FSMB.

The NBME has had discussions with its Advisory Committee for Medical School Programs concerning dual-degree candidates and their potential need for more time to complete the licensure sequence than some states may permit. Within those discussions, however, the committee was not able to identify a qualified dual-degree candidate who was denied state licensure based on exceeding a state time-limited rule for passing USMLE.²

What is not known is how many physicians are delayed in completing the USMLE or COMLEX-USA sequence due to life circumstances, including taking a leave of absence to care for a family member or for other personal situations. Physicians who do not become licensed can pursue careers in health-related fields but will not be able to practice medicine. At a time when physician workforce shortages are predicted, lack of state licensure resulting solely from circumstances that did not permit a physician to complete the USMLE or COMLEX-USA sequence within a given time limit seems improvident.

Advantages to Nationwide Uniformity

Medical licensing boards vary greatly in their regulations concerning the number of times physicians can take the different Step or Level exams, the length of time to complete the sequence for single- or dual-degree physicians, and whether exceptions can be made for qualifying extenuating circumstances. States that are contiguous can have very different requirements. Yet, once a physician is licensed in one jurisdiction, and is in good standing, another licensing board is not likely to weigh the length of time the physician required to complete the exam sequence in the initial location against the physician if he or she is seeking a license to practice in a new state. Without data suggesting qualitative differences in the competency of physicians who become licensed in seven versus 10 years, or even longer, there may be few valid arguments for time limits except as an external source for motivation to complete the task—although the ability to independently practice medicine should be the most compelling motivation.

RELEVANT AMA POLICY

The appendix shows relevant AMA policy, including H-275.955, "Physician Licensure Legislation" and D-275.994, "Facilitating Credentialing for State Licensure."

SUMMARY AND RECOMMENDATIONS

There is geographic mobility among physicians, particularly soon after completing residency or in pursuing a fellowship, and crossing state lines is likely. Ensuring uniformity in the time requirement in which to become fully licensed would remove one regulatory burden for young physicians when mapping out their career and future practice location. Furthermore, an acknowledgement of, and accommodation for, the many life events that can affect the ability to study for and take the required

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exams may potentially allow for greater diversity among the physician workforce. Lastly, providing the extra time that dual-degree physicians need in order to complete both degrees and become fully licensed will ensure that this vital workforce is fully integrated into both research and clinical realms.

The Council on Medical Education therefore recommends that the following recommendations be adopted in lieu of Resolution 305-A-18 and the remainder of this report be filed:

 1. That our American Medical Association (AMA) urge the state medical and osteopathic boards that maintain a time limit for completing licensing examination sequences for either USMLE or COMLEX to adopt a time limit of no less than 10 years for completion of the licensing exams to allow sufficient time for individuals who are pursuing combined degrees (e.g, MD/PhD). (New HOD Policy)

2. That our AMA urge that state medical and osteopathic licensing boards with time limits for completing the licensing examination sequence provide for exceptions that may involve personal health/family circumstances. (New HOD Policy)

That our AMA encourage uniformity in the time limit for completing the licensing examination sequence across states, allowing for improved inter-state mobility for physicians. (New HOD Policy)

Fiscal note: \$1,000.

APPENDIX: RELEVANT AMA POLICY

H-275.955, "Physician Licensure Legislation"

Our AMA reaffirms earlier policy urging licensing jurisdictions to adopt laws and rules facilitating the movement of physicians between states, to move toward uniformity in requirements for the endorsement of licenses to practice medicine, and to base endorsement of medical licenses on an assessment of competence rather than on passing a written examination of cognitive knowledge.

D-275.994, "Facilitating Credentialing for State Licensure"

Our AMA: (1) encourages the Federation of State Medical Boards to urge its Portability Committee to complete its work on developing mechanisms for greater reciprocity between state licensing jurisdictions as soon as possible; (2) will work with the Federation of State Medical Boards (FSMB) and the Association of State Medical Board Executive Directors to encourage the increased standardization of credentials requirements for licensure, and to increase the number of reciprocal relationships among all licensing jurisdictions; (3) encourages the Federation of State Medical Boards and its licensing jurisdictions to widely disseminate information about the Federation's Credentials Verification Service, especially when physicians apply for a new medical license; and (4) supports the FSMB Interstate Compact for Medical Licensure and will work with interested medical associations, the FSMB and other interested stakeholders to ensure expeditious adoption by the states of the Interstate Compact for Medical Licensure and creation of the Interstate Medical Licensure Compact Commission.

CME Rep. 3-I-19 -- page 8 of 8

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 4-I-19

Subject: Board Certification Changes Impact Access to Addiction Medicine Specialists

(Resolution 314-A-18)

Presented by: Jacqueline A. Bello, MD, Chair

Referred to: Reference Committee C

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Resolution 314-A-18, "Board Certification Changes Impact Access to Addiction Medicine Specialists," introduced by the Michigan Delegation and referred by the American Medical Association (AMA) House of Delegates (HOD), asks:

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That our American Medical Association work with the American Board of Addiction Medicine (ABAM) and American Board of Medical Specialties (ABMS) to accept ABAM board certification as equivalent to any other ABMS-recognized Member Board specialty as a requirement to enroll in the transitional maintenance of certification program and to qualify for the ABMS Addiction Medicine board certification examination.

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15 16 This resolution was referred due to mixed testimony about the new requirements for ABMS subspecialty board certification in addiction medicine and concerns centered around the equivalency of ABAM and ABMS board certifications. Although a number of physicians have held ABAM certification, they do not meet the requirements for ABMS subspecialty certification in addiction medicine if they do not hold current ABMS certification in a primary specialty. Although specialty board certification is not required to practice medicine, it may be needed to meet the credentialing requirements of hospitals.

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This report calls attention to the urgent need to train physicians in addiction medicine, provides background information on the process for obtaining subspecialty board certification in addiction medicine, and provides an update on the time-limited pathway for subspecialty certification in addiction medicine for ABAM diplomates.

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BACKGROUND

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More than 20 million Americans need treatment for substance use disorder, and 2 million Americans have an opioid use disorder. However, only 3,500 U.S. physicians (approximately) are trained in addiction medicine to meet this need. Although medical schools and teaching hospitals are actively working to address the crisis in their communities, more physicians need to be trained in addiction medicine to address this public health challenge.

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Since 2008, the ABAM, a non-ABMS member board, has offered certification and recertification in addiction medicine. ABAM certification is valid as long as ABAM diplomates maintain

enrollment in the ABAM Maintenance of Certification program.³ In October 2015, the new

35 subspecialty of addiction medicine, sponsored by the American Board of Preventive Medicine

(ABPM), was recognized by the ABMS.⁴ In June 2016, fellowship training in addiction medicine

37 was approved by the Accreditation Council for Graduate Medical Education (ACGME).

In 2017, the ABPM began offering physicians the opportunity to become certified in the subspecialty of addiction medicine, and physicians certified by any of the ABMS member boards have been eligible to apply. During the first five years (2017-2021) the addiction medicine examination is given, individuals may become qualified by the Practice Pathway (through which physicians can meet eligibility requirements for certification in addiction medicine without completing an addiction medicine fellowship). In order to meet the requirements for ABPM subspecialty certification in addiction medicine, physicians who do not hold ABAM certification must also hold a current ABMS certification in any primary specialty to meet the requirements for ABPM subspecialty certification in addiction medicine.

ABPM PATHWAYS AVAILABLE TO ACHIEVE SUBSPECIALTY CERTIFICATION IN ADDICTION MEDICINE

There are multiple pathways to achieve subspecialty certification in addiction medicine through the ABPM, as described below.⁵

Practice Pathway

• Time in Practice

Applicants must submit documentation of a minimum of 1,920 hours in which they were engaged in the practice of addiction medicine at the subspecialty level; this minimum of 1,920 hours must have occurred over at least 24 of the previous 60 months prior to application. The minimum of 24 months of practice time need not be continuous; however, all practice time must have occurred in the five-year period preceding June 30 of the application year. Practice must consist of broad-based professional activity with significant addiction medicine responsibility. Applicants must also demonstrate a minimum of 25 percent (or 480 hours) as direct patient care. Addiction medicine practice outside of direct patient care, such as research, administration, and teaching activities, may count for a combined maximum of 75 percent (or 1,440 hours). Only 25 percent (480 hours) of general practice can count towards the required hours for the Practice Pathway, and the remaining 75 percent must be specific addiction medicine practice. Fellowship activity that is less than 12 months in duration or non-ACGME accredited may be applied toward the practice activity requirement. The actual training must be described for any fellowship activity.

Documentation of addiction medicine teaching, research, and administration activities, as well as clinical care or prevention of, or treatment of, individuals who are at risk for or have a substance use disorder may be considered.

Non-accredited fellowship training

Credit for completion of training in a non-ACGME-accredited fellowship program may be substituted for the Time in Practice hour requirements of the Practice Pathway. To qualify, the applicant must have successfully completed a non-ACGME-accredited addiction medicine fellowship of at least 12 months that is acceptable to the ABPM. The fellowship training curriculum as well as a description of the actual training experience must also be submitted to the ABPM for its review and consideration.

Fellowship training of less than 12 months in a non-ACGME accredited program may be applied towards the Time in Practice hour requirements of the Practice Pathway.

ABAM Diplomate Pathway (available through 2021)

Applicants holding certification by ABAM must meet the medical licensure and ABPM certification requirements to be considered for the addiction medicine subspecialty examination. Documentation of current ABAM diplomate status may be submitted in place of practice time documentation and required attestation of clinical competence. (ABAM diplomates are required to maintain certification through ABAM's Transitional Continuous Certification [TraCC] Program. Diplomates who passed ABAM's certifying exam in 2015 or who recertified by passing ABAM's recertifying exam in 2015 may be qualified to expedite the certification process with the ABPM.)

ABAM diplomates certified, or recertified, in 2015 must submit formal application through the ABAM diplomate pathway and be accepted by the ABPM. Only then may their ABPM certifying exam be waived and certification conferred following usual procedures, with an effective date of January 1 of the year following the ABPM's approval of the formal application.

The Addiction Medicine ABAM Diplomate Pathway will expire in 2021. Beginning in 2022, all applicants for ABPM certification in addiction medicine must successfully complete an ACGME-accredited addiction medicine fellowship program.

ACGME-accredited Fellowship Pathway

Applicants must successfully complete a minimum of 12 months in an ACGME-accredited addiction medicine fellowship program. If the program is longer than 12 months, the physician must successfully complete all years of training for which the program is accredited in order to meet the eligibility criteria for certification in addiction medicine.

THE ABMS COMMITTEE ON CERTIFICATION (COCERT) APPROVED SPECIFIC, TIME-LIMITED PATHWAY FOR SUBSPECIALTY CERTIFICATION IN ADDICTION MEDICINE FOR ABAM DIPLOMATES

In 2018, the ABPM, in collaboration with the American Society of Addiction Medicine, submitted a request to ABMS to expand the eligibility requirements for the ABPM's Addiction Medicine subspecialty. The ABPM's request was limited in time to include a period beginning on January 1, 2019 and ending at the conclusion of the 2021 exam cycle on December 31, 2021. In March 2019, the ABMS Committee on Certification (COCERT) approved the ABPM's request to expand eligibility to include physicians certified by ABAM, current with the ABAM's TraCC Program, and who previously possessed underlying primary certification from an ABMS member board but allowed that certification to lapse because addiction medicine became the primary area of the physician's practice.

The proposed expansion excluded physicians who never obtained primary ABMS member board certification, who lost ABMS member board certification as a result of a disciplinary action, or who may have surrendered a medical license in lieu of or otherwise to avoid the possibility of disciplinary action.

DIPLOMATES CERTIFIED BY THE ABPM IN ADDICTION MEDICINE NO LONGER REQUIRED TO MAINTAIN PRIMARY CERTIFICATION TO RECERTIFY IN ADDICTION MEDICINE

Previously, the ABMS approved ABPM's request that diplomates certified by the ABPM in addiction medicine will no longer be required to maintain primary ABMS member board

certification in order to recertify. With this policy change, diplomates certified by the ABPM in addiction medicine may recertify their ABPM subspecialty certificate in addiction medicine without the need to maintain primary ABMS member board certification.

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RELEVANT AMA POLICY

It is the policy of the AMA to encourage all physicians, particularly those in primary care fields, to undertake education in treatment of substance use disorder. The AMA also supports the new ABMS-approved multispecialty subspecialty of addiction medicine, which offers certification to qualified physicians who are diplomates of any of the 24 ABMS member boards and the ABPM certification examination in addiction medicine. AMA policies related to addiction medicine and specialty board certification are shown in the Appendix.

DISCUSSION

There is a significant shortage of qualified addiction physicians in the United States, and physicians from a variety of disciplines (e.g., internal medicine, family medicine, pediatrics) are needed.⁷ Expanding the ABPM pathway will assist in growing the addiction medicine workforce at a time when the treatment of opioid addiction is a national public health crisis and there is a spectrum of medical problems associated with substance use disorders.⁷

The ABPM pathway runs through an examination and not through any "deeming" or general recognition of equivalency of any board outside the ABMS member board community. Thus, individuals will be required to demonstrate to the ABPM that they possess the "knowledge, clinical skills, and professionalism" to practice safely in the discipline of addiction medicine in order to be granted a certificate from this ABMS member board. Physicians who choose to become certified in the new subspecialty may qualify to take the addiction medicine exam by meeting time-in-practice and other eligibility requirements, but will not be required to complete specialized fellowship training at this time. However, in 2022 the ABPM will require physicians to complete an ACGME-accredited program. The ACGME has accredited 62 twelve-month addiction medicine fellowship programs, with plans to increase the number of programs to 125.8 Education in addiction medicine is also becoming a viable choice for medical students and residents.9

The American Osteopathic Association (AOA) has also created a mechanism to allow osteopathic physicians (DOs) with an active primary AOA board certification and ABAM certification to be granted AOA subspecialty certification in addiction medicine. Osteopathic physicians will be required to maintain such certification through the AOA's addiction medicine osteopathic continuous certification process. Osteopathic continuous certification process.

SUMMARY AND RECOMMENDATIONS

The Council on Medical Education has been committed to working with the ABMS and the ABPM to ensure that all qualified physicians are offered pathways to obtain ABMS-approved certification in the new ABPM subspecialty of addiction medicine in order to improve access to care for patients with substance use disorder.

The Council on Medical Education therefore recommends that the following recommendations be adopted in lieu of Resolution 314-A-18 and the remainder of the report be filed.

CME Rep. 4-I-19 -- page 5 of 8

- That our American Medical Association (AMA) recognize the American Board of Preventive
 Medicine (ABPM) for developing and providing pathways for all qualified physicians to obtain
 ABMS-approved certification in the new ABPM subspecialty of addiction medicine, in order
 to improve access to care for patients with substance use disorder. (Directive to Take Action)
- That our AMA rescind Policy H-300.962 (3) "Recognition of Those Who Practice Addiction Medicine," since the ABPM certification examination in addiction medicine is now offered.
 (Rescind HOD Policy)

Fiscal Note: \$500.

APPENDIX

H-300.962, "Recognition of Those Who Practice Addiction Medicine"

- 1. It is the policy of the AMA to: (a) encourage all physicians, particularly those in primary care fields, to undertake education in treatment of substance abuse; (b) direct its representatives to appropriate Residency Review Committees (RRCs) to ask the committees on which they serve to consider requiring instruction in the recognition and management of substance abuse. Those RRCs that already require such instruction should consider greater emphasis for this subject. (c) encourage treatment of substance abuse as a subject for continuing medical education; and (d) affirm that many physicians in fields other than psychiatry have graduate education and experience appropriate for the treatment of substance abuse, and for utilization review, and for other evaluation of such treatment, and should be entitled to compensation.
- 2. Our AMA commends the American Board of Preventive Medicine (ABPM) for its successful application to the American Board of Medical Specialties (ABMS) to establish the new ABMS-approved multispecialty subspecialty of addiction medicine, which will be able to offer certification to qualified physicians who are diplomates of any of the 24 ABMS member boards.
- 3. Our AMA encourages the ABPM to offer the first ABMS-approved certification examination in addiction medicine expeditiously in order to improve access to care to treat addiction.
- (CME Rep. I-93-5 Reaffirmed: CME Rep. 10, I-98 Reaffirmed: CME Rep. 11, A-07 Appended: Res. 314, A-16)

Policy H-275.924 (15), "Continuing Board Certification"

15. The MOC program should not be a mandated requirement for licensure, credentialing, recredentialing, privileging, reimbursement, network participation, employment, or insurance panel participation.

H-275.926, "Medical Specialty Board Certification Standards" Our AMA:

- 1. Opposes any action, regardless of intent, that appears likely to confuse the public about the unique credentials of American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS) board certified physicians in any medical specialty, or take advantage of the prestige of any medical specialty for purposes contrary to the public good and safety.
- 2. Continues to work with other medical organizations to educate the profession and the public about the ABMS and AOA-BOS board certification process. It is AMA policy that when the equivalency of board certification must be determined, accepted standards, such as those adopted by state medical boards or the Essentials for Approval of Examining Boards in Medical Specialties, be utilized for that determination.
- 3. Opposes discrimination against physicians based solely on lack of ABMS or equivalent AOA-BOS board certification, or where board certification is one of the criteria considered for purposes of measuring quality of care, determining eligibility to contract with managed care entities, eligibility to receive hospital staff or other clinical privileges, ascertaining competence to practice medicine, or for other purposes. Our AMA also opposes discrimination that may occur against physicians involved in the board certification process, including those who are in a clinical practice period for the specified minimum period of time that must be completed prior to taking the board certifying examination.
- 4. Advocates for nomenclature to better distinguish those physicians who are in the board certification pathway from those who are not.
- 5. Encourages member boards of the ABMS to adopt measures aimed at mitigating the financial burden on residents related to specialty board fees and fee procedures, including shorter preregistration periods, lower fees and easier payment terms.

(Res. 318, A-07 Reaffirmation A-11 Modified: CME Rep. 2, I-15)

D-120.985, "Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone"

- 1. Our AMA will incorporate into its web site a directory consolidating available information on the safe and effective use of opioid analysesics in clinical practice.
- 2. Our AMA, in collaboration with Federation partners, will collate and disseminate available educational and training resources on the use of methadone for pain management.
- 3. Our AMA will work in conjunction with the Association of American Medical Colleges, American Osteopathic Association, Commission on Osteopathic College Accreditation, Accreditation Council for

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Graduate Medical Education, and other interested professional organizations to develop opioid education resources for medical students, physicians in training, and practicing physicians. (Sub. Res. 508, A-03 Reaffirmed: CSAPH Rep. 1, A-13 Appended: Res. 515, A-14 Reaffirmed: BOT Rep. 14, A-15 Appended: Res. 311, A-18 Reaffirmation: A-19)

H-310.906, "Improving Residency Training in the Treatment of Opioid Dependence"

Our AMA: (1) encourages the expansion of residency and fellowship training opportunities to provide clinical experience in the treatment of opioid use disorders, under the supervision of an appropriately trained physician; and (2) supports additional funding to overcome the financial barriers that exist for trainees seeking clinical experience in the treatment of opioid use disorders.

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 6-I-19

Subject: Veterans Health Administration Funding of Graduate Medical Education

(Resolution 954-I-18)

Presented by: Jacqueline A. Bello, MD, Chair

Referred to: Reference Committee C

INTRODUCTION

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Resolution 954-I-18, introduced by the American Academy of Dermatology, American Society for Dermatologic Surgery Association, and American Society of Dermatopathology, asked that our American Medical Association (AMA):

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1. Continue to support the mission of the Department of Veterans Affairs Office of Academic Affiliations for expansion of graduate medical education (GME) residency positions;

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2. Collaborate with appropriate stakeholder organizations to advocate for preservation of Veterans Health Administration (VHA) funding for GME and support its efforts to expand GME residency positions in the federal budget and appropriations process; and

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3. Oppose service obligations linked to VHA GME residency or fellowship positions, particularly for resident physicians rotating through the VA for only a portion of their GME training.

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The AMA House of Delegates adopted Resolves 1 and 2; these were appended to Policy D-510.990, "Fixing the VA Physician Shortage with Physicians." Resolve 3, which was referred, is the topic of this report.

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- Testimony before the reference committee on this resolution was mixed. The AMA has long been an advocate for preservation and expansion of GME funding to mitigate projected physician shortages and ensure that positions are available for medical school graduates applying to residency programs. Currently, there are no residency completion service obligations for Veterans Administration (VA) residency programs. Furthermore, it was noted that all funding for
- Administration (VA) residency programs. Furthermore, it was noted that all funding for residency/fellowship positions, whether from private, VA, and/or Centers for Medicare &
- Medicaid Services (CMS) sources, carries with it the expectation that residents/fellows perform
- service for patients during their years in the training program. In addition, the VA sponsors very
- few residency programs; most residents who train in a VA facility do so as part of their training,
- 31 with other sites and institutions responsible for components of the residency or fellowship. Due to
- 32 the complicated rules at institutions that sponsor residency programs related to full funding for a
- resident full-time employee, it was recommended that Resolve 3 be referred for further study.

BACKGROUND

The Department of Veterans Affairs (VA) has long supported the training of health care professionals as part of its mission. With very few exceptions, the VA does not sponsor and operate its own GME programs, but instead partners with teaching hospitals to provide rotations in VA medical facilities, sharing the costs of faculty and residents when residents are training in VA facilities. When a resident is training at a VA facility, that resident is not counted as part of the Medicare GME cap for the sponsoring institution (and so is not paid via Medicare). This allows the sponsoring institution to train additional residents above its Medicare cap. Over 43,000 residents and fellows rotate through roughly 11,000 VA-funded full-time-equivalent residency positions in VA medical facilities each year; while rotating through the VA, residents remain employees of the sponsoring institution and are not employees of the VA, nor are they subject to service obligations upon completion of the rotation or training program. Approximately one third of the entire GME workforce per year receives training in VA facilities and provides care to veterans.

VA GME Expansion

The Veterans Access, Choice, and Accountability Act (VACAA) of 2014 included a requirement that the VA expand the number of residents and fellows it trains by up to 1,500 positions by 2024, in selected specialties and/or geographic areas, as well as specialties designated as critical need specialties located within health professional shortage areas (as defined by the Health Resources and Services Administration), having a shortage of physicians, rural locations, or in a program/area where there are significant delays in veteran access to care.³ After five rounds, the VA has approved 1,055 positions, from 2015 through 2019 (443.2 in primary care, 229.1 in mental health, and 383.0 in critical need specialties).⁴

Subsequent legislation introduced in 2017, but not passed, also increased the number of GME positions funded by the VA by 1,500, but required a service obligation post-GME equal to the number of years of residency stipend and benefit support.^{5,6}

The VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 builds upon VACAA in that one of its aims is to increase GME in rural locations, an area in which VACAA has had limited success. The MISSION Act will enable the VA to place at least 100 residents (through positions created by VACAA) in "covered" federal facilities, that may not be on a traditional VA campus. Indian Health Service facilities, Federally Qualified Health Centers, Department of Defense medical centers, or other underserved VA areas are included as sites for potential GME expansion. The MISSION Act also provides the VA authority to assist in the development costs of starting new GME programs in VA-designated underserved areas. Finally, the MISSION Act includes provisions to enable the VA to recruit physicians and dentists into rural and underserved areas through two scholarship opportunities and a loan repayment program. The Health Professions Scholarship Program (HPSP) will offer scholarships to medical and dental students in exchange for VA service, with a repayment period of 18 months per year of support. Upon completion of training, the participants will be assigned by the VA to areas experiencing a critical need in the specialty of training. The number of scholarships to be funded will be based on VA-determined provider shortages.

A second scholarship opportunity provides four years of tuition, fees and stipend support to two veterans at nine medical schools:

- Charles R. Drew University of Medicine and Science (California)
- Howard University College of Medicine (District of Columbia)

- 1 Morehouse School of Medicine (Georgia)
 - Wright State University Boonshoft School of Medicine (Ohio)
 - University of South Carolina School of Medicine
 - East Tennessee State University James H. Quillen College of Medicine
 - Meharry Medical College (Tennessee)
 - Texas A&M Health Science Center College of Medicine
 - Joan C. Edwards School of Medicine at Marshall University (West Virginia)

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After completion of residency or fellowship, the recipient of the scholarship is required to practice in a VA facility for four years.⁷

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The Specialty Education Loan Repayment program offers \$40,000 in loan repayment to residents (who have at least two or more years left of training) in exchange for 12 months' service post-GME in a VA medical center or site, with a maximum of \$160,000 loan repayment. Preferences will be given to veterans, residents training in rural areas or in the Indian Health Services, or in sites in underserved areas. Rather than an assignment by the VA, recipients in the loan repayment program can select from a list of approved sites the location of the VA site for their service obligation.⁷

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To date, the Specialty Education Loan Repayment program has been enacted. The scholarship opportunity for recently separated military veterans attending selected medical schools will be offered to the medical school class of 2020, as a trial, with hope of its continuation. The language for the HPSP scholarship opportunity is currently in development and not yet published for public comment. It is anticipated that the GME expansion in "covered" facilities, as well as the creation of new GME programs in Indian Health Service (IHS) and tribal facilities, will not be underway until at least 2022.8

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RELEVANT AMA POLICY

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D-510.990, "Fixing the VA Physician Shortage with Physicians"

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Our AMA will: (1) work with the VA to enhance its loan forgiveness efforts to further incentivize physician recruiting and retention and improve patient access in the Veterans Administration facilities; (2) Call for an immediate change in the Public Service Loan Forgiveness Program to allow physicians to receive immediate loan forgiveness when they practice in a Veterans Administration facility; (3) Work with the Veterans Administration to minimize the administrative burdens that discourage or prevent non-VA physicians without compensation (WOCs) from volunteering their time to care for veterans; (4) (a) continue to support the mission of the Department of Veterans Affairs Office of Academic Affiliations for expansion of graduate medical education (GME) residency positions; and (b) collaborate with appropriate stakeholder organizations to advocate for preservation of Veterans Health Administration funding for GME and support its efforts to expand GME residency positions in the federal budget and appropriations process.

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SUMMARY AND RECOMMENDATIONS

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The health care system of the VA is the largest system in the U.S. Not only does the VA provide training opportunities for over 43,000 residents and fellows, it also has collaborative agreements with 178 allopathic and osteopathic medical schools, providing educational opportunities for nearly 25,000 medical students and other health professions trainees⁷ (who are not subject to service obligations upon completion of the rotation or training program). As such, the importance and

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value of the VA to the nation's health care workforce cannot be overstated.

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While other sources of financing for more GME positions have been limited, the VA's ability to expand may reduce the effects of a forecasted physician shortage. Recently passed legislation that enables the VA to expand opportunities for physician training within the VA, and to provide financial assistance to eligible physicians who will then repay that assistance through service obligation to VA and other underserved populations, will further one of the statutory missions of the VA, which is to assist in the training of health professionals for its own needs and those of the nation.

The Council on Medical Education therefore recommends that the following recommendations be adopted in lieu of Resolution 954-I-18 and the remainder of this report be filed:

1. That our AMA support postgraduate medical education service obligations through any program where the expectation for service is explicitly delineated in the contract with the trainee. (New HOD Policy)

2. That our American Medical Association (AMA) oppose the blanket imposition of service obligations through any program where physician trainees rotate through the facility as one of many sites for their training. (New HOD Policy)

Fiscal note: \$500.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 301

(I-19)

Introduced by: Medical Student Section

Subject: Engaging Stakeholders for Establishment of a Two-Interval, or Pass/Fail,

Grading System of Non-Clinical Curriculum in U.S. Medical Schools

Referred to: Reference Committee C

Whereas, Students in two-interval, or pass/fail, grading systems have better mental well-being compared to students in multi-tiered grading systems, including experiencing less emotional exhaustion, fewer feelings of depersonalization, less consideration for dropping out of school, decreased perceived stress, and greater satisfaction with their medical education and personal lives^{1,2,3,4}; and

Whereas, Students in a pass/fail grading system experienced increased group cohesion, collaboration, and cooperation compared to students in a multi-tiered grading system^{4,5}; and

Whereas, Students in a pass/fail grading system had more time to devote to extracurricular activities, student organizations, and volunteer/service activities compared to students in a multi-tiered grading system⁶; and

Whereas, Multiple medical schools that changed to a pass/fail grading system did not have a statistical difference in United States Medical Licensing Examination (USMLE) Step 1 scores and USMLE Step 2 scores^{3,4,6,7,8}; and

Whereas, Even though there is no study on osteopathic schools with two-interval grading systems and Comprehensive Osteopathic Medical Licensing Examination of the United States (COMLEX-USA) Level 1 Scores, the previous literature suggests that COMLEX-USA Level 1 scores will not be affected, since the correlation between COMLEX-USA Level 1 and USMLE Step 1 scores is statistically significant⁹; and

Whereas, Non-clinical, or preclinical, grades were ranked 12th out of 14 academic criteria when selecting for residency according to the 2006 National Program Director Survey, and as of 2016, residency program directors are no longer surveyed to rank the importance of preclinical grades¹⁰; and

Whereas, There is a growing trend for allopathic and osteopathic medical schools to adopt a pass/fail grading system for preclinical courses, from 87 to 108 allopathic schools from 2013 to 2017, and 21 to 27 osteopathic schools from 2012 to 2016^{11,12,13}; and

Whereas, U.S. medical students want a pass/fail grading system; in 2011, pass/fail was the most requested form of preclinical grading, as exhibited by the responses of 52 medical schools to the American Association of Medical Colleges (AAMC) Organization of Student

36 Representatives (OSR) Preclinical Grading Questionnaire¹⁴; and

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Whereas, Existing AMA policy recognizes that burnout, defined as emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness, is a problem among residents, and fellows, and medical students (H-295.866); and

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Whereas, Existing AMA policy acknowledges the importance of physician health and the need for ongoing education of all physicians and medical students regarding physician health and wellness (H-405.961); and

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Whereas, Existing AMA policy acknowledges the benefits of a pass/fail grading system in medical colleges and universities in the United States for the non-clinical curriculum (H-295.866); and

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Whereas, AMA policy could use stronger wording in support of pass/fail grading systems; and

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Whereas, Existing AMA policy states that AMA will encourage the Accreditation Council for Graduate Medical Education (ACGME) and the AAMC to address the recognition, treatment, and prevention of burnout among residents, fellows, and medical students (H-295.866); and

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Whereas, The Liaison Committee on Medical Education (LCME) currently does not take a position on a pass/fail grading system for preclinical courses; and

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Whereas, Existing AMA policy insufficiently addresses the importance of pass/fail grading systems, as there remain medical schools that have multi-tiered grading systems⁵; therefore be it

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RESOLVED, That our American Medical Association amend Policy H-295.866 by addition and deletion to read as follows:

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Supporting Two-Interval Grading Systems for Medical Education, H-295.866

Our AMA will work with stakeholders to encourage the establishment of acknowledges the benefits of a two-interval grading system in medical colleges and universities in the United States for the non-clinical curriculum. (Modify Current HOD Policy)

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Fiscal Note: Minimal - less than \$1,000

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Received: 08/28/19

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RELEVANT AMA POLICY

Supporting Two-Interval Grading Systems for Medical Education H-295.866

Our AMA acknowledges the benefits of a two-interval grading system in medical colleges and universities in the United States for the non-clinical curriculum.

Physician and Medical Student Burnout D-310.968

- 1. Our AMA recognizes that burnout, defined as emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness, is a problem among residents, fellows, and medical students.
- 2. Our AMA will work with other interested groups to regularly inform the appropriate designated institutional officials, program directors, resident physicians, and attending faculty about resident, fellow, and medical student burnout (including recognition, treatment, and prevention of burnout) through appropriate media outlets.
- 3. Our AMA will encourage partnerships and collaborations with accrediting bodies (e.g., the Accreditation Council for Graduate Medical Education and the Liaison Committee on Medical Education) and other major medical organizations to address the recognition, treatment, and prevention of burnout among residents, fellows, and medical students and faculty.
- 4. Our AMA will encourage further studies and disseminate the results of studies on physician and medical student burnout to the medical education and physician community.
- 5. Our AMA will continue to monitor this issue and track its progress, including publication of peer-reviewed research and changes in accreditation requirements.
- 6. Our AMA encourages the utilization of mindfulness education as an effective intervention to address the problem of medical student and physician burnout.
- 7. Our AMA will encourage medical staffs and/or organizational leadership to anonymously survey physicians to identify local factors that may lead to physician demoralization.
- 8. Our AMA will continue to offer burnout assessment resources and develop guidance to help organizations and medical staffs implement organizational strategies that will help reduce the sources of physician demoralization and promote overall medical staff well-being.
- 9. Our AMA will continue to: (a) address the institutional causes of physician demoralization and burnout, such as the burden of documentation requirements, inefficient work flows and regulatory oversight; and (b) develop and promote mechanisms by which physicians in all practices settings can reduce the risk and effects of demoralization and burnout, including implementing targeted practice transformation interventions, validated assessment tools and promoting a culture of well-being.

Citation: CME Rep. 8, A-07; Modified: Res. 919, I-11; Modified: BOT Rep. 15, A-19

Physician Health Programs H-405.961

- 1. Our AMA affirms the importance of physician health and the need for ongoing education of all physicians and medical students regarding physician health and wellness.
- 2. Our AMA encourages state medical societies to collaborate with the state medical boards to: (a) develop strategies to destigmatize physician burnout; and (b) encourage physicians to participate in the state's physician health program without fear of loss of license or employment. Citation: CSAPH Rep. 2, A-11; Reaffirmed in lieu of Res. 412, A-12; Reaffirmed: BOT action in response to referred for decision Res. 403, A-12; Modified: BOT Rep. 15, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 302

(I-19)

Introduced by: Medical Student Section

Subject: Strengthening Standards for LGBTQ Medical Education

Referred to: Reference Committee C

Whereas, Approximately 8 million adults in the United States identify as lesbian, gay, or bisexual, and 700,000 U.S. adults identify as transgender¹; and

Whereas, Individuals with disorders/differences of sex development (DSD) have "congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical," as defined by the 2006 Consensus Statement²; and

Whereas, Individuals with DSD comprise approximately 1% of the population and are at increased risk of cancer, infertility, psychosocial distress, and other issues²; and

 Whereas, Research has shown significant disparities between sexual and gender minorities and the general public, with poorer health outcomes in areas including: 1) modifiable risk factors for cardiovascular disease such as mental distress, obesity, hypertension, and average blood glucose levels³; 2) risk of mortality from breast cancer⁴; 3) substance use disorders, including use of tobacco and electronic nicotine vapor devices⁵; 4) sexually transmitted infections such as human immunodeficiency virus and syphilis⁶; and 5) mental health disorders, including suicidal behavior⁷; and

Whereas, The Association of American Medical Colleges recommends comprehensive coverage of the specific health care needs of lesbian, gay, bisexual, transgender, and queer (LGBTQ) patients in medical school curricula⁸ but these recommendations are not reflected in Liaison Committee for Medical Education (LCME) or American Osteopathic Association (AOA) accreditation requirements for medical schools, nor are they reflected in the Accreditation Council for Graduate Medical Education (ACGME) accreditation requirements for medical residency programs; and

Whereas, A survey of American and Canadian medical school deans found that medical schools allocate five hours of instruction to LGBTQ health care on average⁹; and

Whereas, Most medical students rate their LGBTQ curriculum as "fair" or worse but feel more prepared and comfortable caring for LGBTQ patients after additional LGBTQ-focused medical education¹⁰; and

Whereas, LGBTQ medical education has been demonstrated to improve knowledge, behavior, and beliefs regarding this patient population among medical students¹¹⁻¹³; and

Whereas, Pursuant to existing AMA policy H-160.991, our AMA believes in educating physicians on the current state of research in and knowledge of LGBTQ health; and

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Whereas, Numerous health disparities and unique risk factors experienced by LGBTQ people are not limited to children and adolescents³⁻⁷; and

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Whereas, The screening, diagnosis, and treatment of conditions affecting LGBTQ patients are not fully encompassed by a cultural competency curriculum; therefore be it

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RESOLVED, That our American Medical Association amend policy H-295.878, "Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Health Issues in Medical Education," by addition and deletion to read as follows:

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Eliminating Health Disparities – Promoting Awareness and Education of Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Health Issues, H-295.878

Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender, gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian. Gay, Bisexual, Transgender and Queer communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include Lesbian, Gay, Bisexual, Transgender and Queer health issues in the basic science, clinical care, and cultural competency curriculum curricula for both undergraduate and graduate medical education; and (4) encourages the Liaison Committee on Medical Education (LCME), American Osteopathic Association (AOA), and Accreditation Council for Graduate Medical Education (ACGME) to periodically reassess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent Lesbian, Gay, Bisexual, Transgender and Queer patients. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Health Issues in Medical Education H-295.878

Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender, gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian, Gay, Bisexual, Transgender and Queer communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include LGBTQ health issues in the cultural competency curriculum for both undergraduate and graduate medical education; and (4) encourages the LCME, AOA, and ACGME to assess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent LGBTQ patients.

Citation: Res. 323, A-05; Modified in lieu of Res. 906, I-10; Reaffirmation A-11; Reaffirmation A-12; Reaffirmation A-16; Modified: Res. 16, A-18

Health Care Needs of Lesbian, Gay, Bisexual and Transgender Populations H-160.991

- 1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
- 2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.
- 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
- 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people. Citation: CSA Rep. C, I-81; Reaffirmed: CLRPD Rep. F, I-91; CSA Rep. 8 I-94; Appended: Res. 506, A-00; Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18; Reaffirmed: CSAPH Rep. 01, I-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 303

(I-19)

Introduced by: Medical Student Section

Subject: Investigation of Existing Application Barriers for Osteopathic Medical

Students Applying for Away Rotations

Referred to: Reference Committee C

Whereas, By June 30, 2020, all U.S. osteopathic and allopathic residencies will be accredited under a single graduate medical education (GME) system that is managed under a single National Resident Matching Program (NRMP)¹; and

Whereas, The Accreditation Council for Graduate Medical Education (ACGME) states that the benefits of the single GME accreditation system include offering all U.S. medical graduates a uniform education pathway, increasing collaboration among the medical education community, providing consistency across all residency and fellowship programs, reducing costs and increasing opportunities for osteopathic graduate medical education¹; and

Whereas, Undergraduate medical education will continue to be accredited by the two separate accreditation bodies of the Liaison Committee of Medical Education (LCME) for allopathic schools and the Commission on Osteopathic College Accreditation (COCA) for osteopathic schools^{2,3}; and

Whereas, The Executive Summary of the Agreement among ACGME, American Osteopathic Association (AOA), and American Association of Colleges of Osteopathic Medicine (AACOM) specifically outlines that graduates of osteopathic medical schools will be eligible for all ACGME-accredited programs⁴; and

 Whereas, Both osteopathic and allopathic physicians practice medicine across all specialties, in all 50 US states and are licensed under the same state licensing boards, as well as have completed similar undergraduate paths, medical school, clinical rotations and a residency program⁵; and

Whereas, Elective visiting clinical rotations -- also known as 'Sub-Internships' or 'Away Rotations' -- are beneficial to fourth year medical students by providing additional clinical experiences in varying specialties, often at their residencies of interest, promoting networking opportunities, and allowing students to obtain letters of recommendations to submit with their residency program application⁶; and

Whereas, The majority of U.S. medical schools offering visiting medical student clinical rotations participate in the Visiting Student Application Services program (VSAS), serviced by the Association of American Medical Colleges (AAMC), which enables students to browse and apply to electives offered by host institutions⁷; and

Whereas, The AAMC strives "to assure that all medical students possess equal freedom and opportunity to pursue the career directions of their choice"⁸; and

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Page 2 of 4

- 1 Whereas, Despite AMA policy Equal Fees for Osteopathic and Allopathic Medical Students
- 2 H-295.876 that states: "Our AMA, in collaboration with the American Osteopathic Association,
- 3 discourages discrimination against medical students by institutions and programs based on
- 4 osteopathic or allopathic training. Our AMA encourages equitable fees for allopathic and
- 5 osteopathic medical students in access to clinical electives, while respecting the rights of
- 6 individual allopathic and osteopathic medical schools to set their own policies related to visiting 7 students," other programs participating in VSAS have differing rotation fees between allopathic 8

and osteopathic medical students^{13, 25, 29}; and

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Whereas, Despite having such policy in place, osteopathic medical students continue to face financial barriers in applying for away rotations^{25,29} and

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Whereas, An osteopathic student upon finding such language while searching for potential rotation sites, would likely be deterred from pursuing the away rotation and thus would not possess equal freedom of opportunity to pursue their desired career direction; and

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Whereas, In our primary research, including contacting aforementioned programs, we were not able to determine a cause for the discrepancies between accepting osteopathic students for away rotations at specific programs; therefore be it

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RESOLVED, That our American Medical Association work with relevant stakeholders to explore reasons behind application barriers that result in discrimination against osteopathic medical students when applying to elective visiting clinical rotations, and generate a report with the findings by the 2020 Interim Meeting. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 08/28/19

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RELEVANT AMA POLICY

AMA Membership Strategy: Osteopathic Medicine G-635.053

Our AMA's membership strategy on osteopathic physicians (DOs) includes the following: Our AMA:

- (1) encourages all state societies to accept DOs as members at every level of the Federation;
- (2) encourages state societies with schools of osteopathic medicine to support development of Medical Student Sections at those schools; Both the MSS Governing Council and existing MSS chapters in states with osteopathic schools should assist in this effort;
- (3) encourages that DO members of our AMA continue to participate in the Membership Outreach program;
- (4) will provide recruiters with targeted lists of DO non-members upon request;
- (5) will include DOs, as appropriate, in direct nonmember mailings; and
- (6) will expand its database of information on osteopathic students and doctors.

Citation: BOT Rep. I-93-11 Consolidated: CLRPD Rep. 3, I-01 Reaffirmed: Res. 809, I-05 Reaffirmed: BOT Rep. 35, A-08 Modified: CCB/CLRPD Rep. 3, A-12

Equal Fees for Osteopathic and Allopathic Medical Students H-295.876

Our AMA, in collaboration with the American Osteopathic Association, discourages discrimination against medical students by institutions and programs based on osteopathic or allopathic training. 2. Our AMA encourages equitable fees for allopathic and osteopathic medical students in access to clinical electives, while respecting the rights of individual allopathic and osteopathic medical schools to set their own policies related to visiting students. Citation: Res. 809, I-05 Appended: CME Rep. 6, A-07 Modified: CCB/CLRPD Rep. 2, A-14

Resolution: 303 (I-19)

Page 4 of 4

Expanding the Visiting Students Application Service for Visiting Student Electives in the Fourth Year H-295.867

- 1. Our American Medical Association strongly encourages the Association of American Medical Colleges (AAMC) to expand eligibility for the Visiting Students Application Service (VSAS) to medical students from Commission on Osteopathic College Accreditation (COCA)-accredited medical schools.
- 2. Our AMA supports and encourages the AAMC in its efforts to increase the number of members and non-member programs in the VSAS, such as medical schools accredited by COCA and teaching institutions not affiliated with a medical school.
- 3. Our AMA encourages the AAMC to ensure that member institutions that previously accepted both allopathic and osteopathic applications for fourth year clerkships prior to VSAS implementation continue to have a mechanism for accepting such applications of osteopathic medical students.

Citation: Res. 910, I-09 Reaffirmed: CME Rep. 01, A-19

ACGME Residency Program Entry Requirements H-310.909

Our AMA supports entry into Accreditation Council on Graduate Medical Education (ACGME) accredited residency and fellowship programs from either ACGME-accredited programs or American Osteopathic Association-accredited programs.

Citation: Res. 920, I-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 304

(I-19)

Introduced by: Indiana

Subject: Issues with the Match, the National Residency Matching Program (NRMP)

Referred to: Reference Committee C

Whereas, A record number of physicians applied for residency programs through the National Residency Matching Program (NRMP) in 2019. The total was 44,603 with ultimately 2,718 withdrawing and 3,509 not fully completing the application process. Of the remainder who completed the Match program, only 79.6% of 38,376 matched, with 7,826 unmatched; and

Whereas, Applicants who do not match quickly the first time go through a secondary match called the SOAP (Supplemental Offer and Acceptance Program); and

Whereas, A growing discrepancy exists between the number of medical school graduates and available residency slots, causing the number of applicants who do not match each year to grow at a time when there is also a growing shortage of physicians, with a large number over age 60 who will be retiring within 10 years; and

Whereas, Medical school graduates typically incur a significant burden of academic loans through their years of education that is worsened by the fees charged to go through The Match process. (Costs ranging from \$85 up to thousands of dollars.) The residency programs also pay the NRMP for their services, which range from \$370 up to many thousands of dollars. Income generated by the match has become quite lucrative as the number of applicants grows from year to year. The Board of the NRMP has an obligation to be good stewards of these funds and to ensure that are spent wisely and frugally; and

Whereas, The SOAP gives applicants who fail to match in the first round an opportunity to find a position in a second-round matching process. This year, the SOAP website crashed on the first day it came online, preventing participants from entering their program of choice and the programs from seeing the list of those interested in positions. While the board extended the SOAP one additional day, this system failure undoubtedly affected the outcome of the secondary match for some individuals in both negative and positive ways. In other words, changing the procedure and process produced a different outcome than if the SOAP system had not failed; and

Whereas, Failure to match initially is an extremely stressful and difficult time, as applicants try to learn about residencies that have remaining slots. Applicants who do not match must scramble to sort out what they will do during the next year, when they typically apply again after discerning what contributed to their failure to match; and

Whereas, Failure to match for one year is serious, but the bigger tragedy is to have expended resources to become a physician and yet never match. This is also a waste of taxpayer dollars, since these individuals can never independently practice as physicians, and yet the state and nation have invested hundreds of thousands of dollars in their education; therefore be it

Resolution: 304 (I-19) Page 2 of 2

RESOLVED, That our American Medical Association redouble its efforts to promote an increase in residency program positions in the U.S. (Directive to Take Action); and be it further

RESOLVED, That our AMA assign an appropriate AMA committee or committees to:

- Study the issue of why residency positions have not kept pace with the changing physician supply and investigate what novel residency programs have been successful across the country in expanding positions both traditionally and nontraditionally.

- Seek to determine what causes a failure to match and better understand what strategies are most effective in increasing the chances of a successful match, especially after a prior failure. The committee(s) would rely upon the BNRMP (Board of the National Residency Matching Program) to provide some of this information through surveys, questionnaires and other means. Valid data would be valuable to medical students who seek to improve their chances of success in The Match.

 Report back to the AMA HOD with findings and recommendations (Directive to Take Action); and be it further

RESOLVED, Because SOAP (Supplemental Offer and Acceptance Program) failed to adequately serve some physicians seeking to match this year, that our AMA support the option to allow individuals participating in one future Match at no cost (Directive to Take Action); and be it further

RESOLVED, That in order to understand the cost of The Match and identify possible savings, our AMA encourage the Board of the National Residency Matching Program to:

1. Conduct an independent and fully transparent audit of SOAP (Supplemental Offer and Acceptance Program) to identify opportunities for savings, with the goal of lowering the financial burden on medical students and new physicians

2. Actively promote success for those participating in The Match by better explaining and identifying those issues that interfere with the successful match and to offer strategies to mitigate those issues. This information can be disseminated through the program website and through services such as its "Help" and "Q&A" links, and also through the AMA. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/27/19

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/Resident%20Match%20/relevant/1.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 305

(I-19)

Introduced by: Young Physicians Section

Subject: Ensuring Access to Safe and Quality Care for our Veterans

Referred to: Reference Committee C

Whereas, Studies have identified barriers related to physicians not employed by the Veterans Administration (VA) and their ability to care for veterans as patients in addressing veterans' status and addressing the military associated needs of this population^{1,2}; and

Whereas, Training of VA physicians require completion of educational modules for addressing specific veteran needs³⁻⁶; and

Whereas, Recognition and treatment of these needs can be taught through the Talent Management System 2.0 modules such as Veterans Health Administration Mandatory Training for Trainees, Military Sexual Trauma, Traumatic Brain Injury, and Suicide Awareness Voices of Education (SAVE)-Suicide³⁻⁶; and

Whereas, The availability of similar training resources could help physicians not employed by the VA provide better care for veterans; therefore be it

RESOLVED, That our American Medical Association amend AMA Policy H-510.986, "Ensuring Access to Care for our Veterans," by addition to read as follows:

Ensuring Access to Safe and Quality Care for our Veterans H-510.986

- 1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans.
- 2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner.
- 3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
- 4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the registry be made available to the veterans in their community and the local Veterans Administration.
- 5. Our AMA supports access to similar clinical educational resources for all health care professionals involved in the care of veterans as those provided by the U.S. Department of Veterans Affairs to their employees with the goal of providing better care for all veterans.
- <u>6.</u> Our AMA will strongly advocate that the Veterans Health Administration and Congress develop and implement necessary resources, protocols, and accountability to ensure the Veterans Health Administration recruits, hires and retains physicians and other health care

professionals to deliver the safe, effective and high-quality care that our veterans have been promised and are owed. (Modify Current HOD Policy)

40 promised and are owed. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 09/26/19

RELEVANT AMA POLICY:

Ensuring Access to Care for our Veterans H-510.986

- 1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans
- 2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner
- 3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
- 4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the registry be made available to the veterans in their community and the local Veterans Administration.
- 5. Our AMA will strongly advocate that the Veterans Health Administration and Congress develop and implement necessary resources, protocols, and accountability to ensure the Veterans Health Administration recruits, hires and retains physicians and other health care professionals to deliver the safe, effective and high-quality care that our veterans have been promised and are owed.

Citation: Res. 231, A-14; Reaffirmation A-15; Reaffirmed: Sub. Res. 709, A-15; Modified: Res. 820, I-18

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- 5. Traumatic Brain Injury, Suicide Awareness Voices of Education (SAVE)-Suicide. US Department of veterans Affairs Talent Management System 2.0. Available at https://www.tms.va.gov.
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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 306

(I-19)

Introduced by: Indiana

Subject: Financial Burden of USMLE Step 2 CS on Medical Students

Referred to: Reference Committee C

Whereas, The cost of medical education and testing is rising, with no relief in sight for medical students; and

3 4

Whereas, The cost of USMLE Step 2 CS Exam will be \$1,300 in 2020 and most medical students will have to travel and stay near one of the five national testing centers; and

5 6 7

Whereas, The USMLE Step 2 CS Exam costs approximately \$27.5 million annually and nationally to medical students, not including travel expenses; and

8 9 10

Whereas, It should be noted that there is no good correlation between Board certification and physician competency; and

11 12

- Whereas, There are no data to support a link between the USMLE Step 2 CS Exam and improved patient outcomes, and 95% of U.S. medical students pass on their first attempt;
- 15 therefore be it

16

- 17 RESOLVED, That our American Medical Association work with the Federation of State Medical
- 18 Boards/United States Medical Licensing Examination (USMLE) to reduce the cost of the
- 19 USMLE Step 2 CS exam and allow medical students to take this exam locally to defray
- 20 unnecessary expenses. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/27/19

RELEVANT AMA POLICY

https://policysearch.ama-

<u>assn.org/policyfinder/detail/USMLE%20Step%202%20CS%20exam%20?uri=%2FAMADoc%2Fdirectives.xml-0-876.xml.</u>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 307

(I-19)

Introduced by: International Medical Graduates Section

Subject: Implementation of Financial Education Curriculum for Medical Students and

Physicians in Training

Referred to: Reference Committee C

Whereas, Burnout is a crisis affecting the physician community in the United States. Burnout is reported to have a deleterious influence on more than half of the practicing physicians¹⁻⁷, up to 70% of medical students^{8,9} and up to 75% of the physicians in training^{5,10-15}; and

Whereas, The causes of burnout are multifactorial, but severity of burnout has been reported to increase with increase in financial debt^{6,14,16-18}. Financial pressures had been found to increase resident burnout and negatively impact professionalism¹⁹. The residents with higher debt were found to have lower Quality of Life (QOL), lower satisfaction with work-life balance, higher emotional exhaustion and depersonalization¹⁶; and

Whereas, Medical students have high amounts of debt^{14,20-24} contributed by a rapid increase both undergraduate²⁵ and medical education expenses^{23,26}. African American medical students are reported to have more debt compared to others.²⁷ The high amount of student loan debt has a big impact on medical student's decision to choose a higher paying specialty²⁸⁻³². This results in decreased interest in primary care specialties as the pay is low resulting in shortage of primary care providers^{28-30,32}. There has been many proposals and initiatives to improve the crisis of medical school debt, but are not implemented widely^{23,33}; and

Whereas, Debt grows significantly during the residency and fellowship period, up to 20 - 50% by the end of the training¹⁴. Once the residents graduate, the physicians will have to pay off the student loans which will take up 9-12% of their post-tax income²³, which will add a significant amount of financial stress on an early career physician; and

Whereas, Physicians are found to have poor financial literacy^{14,34-40}. From a survey of orthopedic residents, it was reported that only 4% of the residents had a formal financial education, but 85% are interested in learning⁴¹; and

Whereas, There have been few attempts to improve the financial literacy by implementing a curriculum in personal finance during medical school and residency, but these opportunities are not widely available 14,34,36,41-48; therefore be it

RESOLVED, That our American Medical Association work with relevant stakeholders to study the development of a curriculum during medical school and residency/fellowship training to educate them about the financial and business aspect of medicine. (Directive to Take Action)

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Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/01/19

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RELEVANT AMA POLICY

Cost and Financing of Medical Education and Availability of First-Year Residency Positions - H-305.988

Our AMA:

- 1. believes that medical schools should further develop an information system based on common definitions to display the costs associated with undergraduate medical education;
- 2. in studying the financing of medical schools, supports identification of those elements that have implications for the supply of physicians in the future:
- 3. believes that the primary goal of medical school is to educate students to become physicians and that despite the economies necessary to survive in an era of decreased funding, teaching functions must be maintained even if other commitments need to be reduced:
- 4. believes that a decrease in student enrollment in medical schools may not result in proportionate reduction of expenditures by the school if quality of education is to be maintained;
- 5. supports continued improvement of the AMA information system on expenditures of medical students to determine which items are included, and what the ranges of costs are;
- 6. supports continued study of the relationship between medical student indebtedness and career choice;
- 7. believes medical schools should avoid counterbalancing reductions in revenues from other sources through tuition and student fee increases that compromise their ability to attract students from diverse backgrounds;
- 8. supports expansion of the number of affiliations with appropriate hospitals by institutions with accredited residency programs;
- 9. encourages for profit-hospitals to participate in medical education and training;
- 10. supports AMA monitoring of trends that may lead to a reduction in compensation and benefits provided to resident physicians;
- 11. encourages all sponsoring institutions to make financial information available to help residents manage their educational indebtedness; and
- 12. will advocate that resident and fellow trainees should not be financially responsible for their training.

CME Rep. A, I-83 Reaffirmed: CLRPD Rep. 1, I-93Res. 313, I-95Reaffirmed by CME Rep. 13, A-97Modified: CME Rep. 7, A-05Modified: CME Rep. 13, A-06Appended: Res. 321, A-15Reaffirmed: CME Rep. 05, A-16Modified: CME Rep. 04, A-16

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Principles of and Actions to Address Medical Education Costs and Student Debt- H-305.925

The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue, our American Medical Association (AMA) will:

- 1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.
- 2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs--such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector--to promote practice in underserved areas, the military, and academic medicine or clinical research.
- 3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.
- 4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.
- 5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
- 6. Work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of trainees with educational debt.
- 7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.
- 8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.
- 9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).
- 10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.
- 11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.
- 12. Encourage medical schools to (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education; (b) Engage in fundraising activities to increase the availability of scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, low-interest loan programs; (c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students; (d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students; (e) Counsel

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individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation; (f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen; (g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees; (h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; (i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.

- 13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.
- 14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals: (a) Eliminating the single holder rule; (b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training; (c) Retaining the option of loan forbearance for residents ineligible for loan deferment; (d) Including, explicitly, dependent care expenses in the definition of the "cost of attendance"; (e) Including room and board expenses in the definition of tax-exempt scholarship income; (f) Continuing the federal Direct Loan Consolidation program, including the ability to "lock in" a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs: (g) Adding the ability to refinance Federal Consolidation Loans: (h) Eliminating the cap on the student loan interest deduction; (i) Increasing the income limits for taking the interest deduction; (j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001; (k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating; (I) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.
- 15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.
- 16. Continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.
- 17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.
- 18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.
- 19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.
- 20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will: (a) Advocate that all resident/fellow physicians have access to PSLF during their training years; (b) Advocate against a monetary cap on PSLF and other federal loan forgiveness programs; (c) Work with the United

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States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed; (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note; (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer; (f) Advocate that the profit status of a physicians training institution not be a factor for PSLF eligibility; (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed; (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas; (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.

- 21. Advocate for continued funding of programs including Income-Driven Repayment plans for the benefit of reducing medical student load burden.
- 22. Formulate a task force to look at undergraduate medical education training as it relates to career choice, and develop new polices and novel approaches to prevent debt from influencing specialty and subspecialty choice.

CME Report 05, I-18 Appended: Res. 953, I-18 Reaffirmation: A-19 Appended: Res. 316, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 308

(I-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Study Expediting Entry of Qualified IMG Physicians to US Medical Practice

Referred to: Reference Committee C

Whereas, There continues to be a steady influx of immigrants from strife-torn regions of the world; and

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Whereas, Some of these immigrants are highly trained physicians fleeing their country because of political or religious persecution; and

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Whereas, In order to be able to practice in the United States these physicians often have to repeat complete cycles of training including medical school, residency, and subspecialty training; and

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Whereas, There is projected to be a shortage of physicians¹ given the aging of the present physician and general civilian populations; and

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Whereas, The immigrant physician may have beneficial skills such as language proficiency; and

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Whereas, It is possible to retrain immigrant physicians in 18–24 months to be able to practice medicine in their host country after they have demonstrated proficiency in language, medicine, and the culture of the host country as demonstrated by a program of the National Health Service of Scotland² profiled in a recent BBC America program; and

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Whereas, Immigrant physicians in Scotland who have been retrained on an accelerated path and who have demonstrated proficiency in language, medicine, and Scottish culture are obligated by the NHS of Scotland to practice in the NHS in specific areas of need.³ and

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Whereas, Minnesota's International Medical Graduate Assistance Program was established in 2015 and is the first program of its kind in the United States and may serve as a model for other states; and

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Whereas, The Minnesota program was created by state statute and the program has achieved considerable successes, including: developing a roster of IMG physicians in the state, forming grant agreements with nonprofits to provide career support to IMGs, working with residency directors to carve out pathways for IMGs to demonstrate the clinical expertise required to enter into residency programs, funding dedicated residency slots for IMGs, and studying the licensure

https://www.aamc.org/download/426242/data/ihsreportdownload.pdf?cm_mmc=AAMC-_-ScientificAffairs-_-PDF-_-ihsreport. Accessed on October 25, 2017.

¹ IHS Inc. The *Complexities of Physician Supply and Demand*: Projections from *2013 to 2025*. Final Report. Prepared for the Association of American Medical Colleges. March 2015.

² Scottish Government. Refugee Doctors Programme, February 8, 2017. https://www.youtube.com/watch?v=mufT33JdVQQ. Accessed on October 25, 2017.

³ Ibid.

⁵MN Dept. of Health: International Medical Graduate Assistance Program Report to the Minnesota Legislature August 1, 2018

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changes that would be needed to facilitate full IMG integration into the Minnesota physician workforce⁵; therefore be it

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- 4 RESOLVED, That our American Medical Association study and make recommendations for the
- 5 best means for evaluating, credentialing and expediting entry of competently trained
- 6 international medical graduate (IMG) physicians of all specialties into medical practice in the
- 7 USA. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/02/19

Reference Committee F

BOT Report(s)

- 06 Physician Health Policy Opportunity
- 08 Implementing AMA Climate Change Principles Through JAMA Paper Consumption Reduction and Green Health Care Leadership

CLRPD Report(s)

01 Academic Physicians Section Five-Year Review

HOD Comm on Compensation of the Officers

01* Report of the HOD Committee on Compensation of the Officers

^{*} Contained in Handbook Addendum

REPORT OF THE BOARD OF TRUSTEES

B of T Report 6-I-19

Subject: Physician Health Policy Opportunity

(Resolution 604-I-18)

Request to AMA for Training in Health Policy and Health Law

(Resolution 612-A-19)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

Referred to: Reference Committee F

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At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) considered Resolution 604-I-18, "Physician Health Policy Opportunity," introduced by Washington State, which included the following three resolves:

That our AMA, working with the state and specialty societies, make it a priority to give physicians the opportunity to serve in federal and state health care agency positions by providing the training and transitional opportunities to move from clinical practice to health policy; and

That our AMA study and report back to the House of Delegates at the 2019 Interim Meeting with findings and recommendations for action on how best to increase opportunities to train physicians in transitioning from clinical practice to health policy; and

That our AMA explore the creation of an AMA health policy fellowship, or work with the Robert Wood Johnson Foundation to ensure that there are designated physician fellowship positions with their Health Policy Fellowship program to train physicians in transitioning from clinical practice to health policy.

The reference committee heard conflicting testimony on Resolution 604 and recommended its referral. Testimony agreed that it is critical to have physicians with clinical experience serve in government regulatory agencies to help shape health policy, and favored the AMA studying how best to increase opportunities to train physicians in transitioning from clinical practice to health policy. Testimony recommended broadening partnerships beyond the Robert Wood Johnson Foundation (RWJF), and also noted that developing a health policy fellowship program can be an intricate process, that should be carefully evaluated.

At the 2019 Annual Meeting, the HOD considered a second resolution on a similar topic, Resolution 612-A-19, "Request to AMA for Training in Health Policy and Health Law," introduced by New Mexico, which asked that the AMA "offer its members training in health policy and health law, and develop a fellowship in health policy and health law." Testimony on Resolution 612 was also mixed and the reference committee recommended its referral. Those testifying supported the AMA sharing resources and opportunities to serve its members but were uncertain whether the AMA should introduced by New Mexico, which was also mixed and the reference committee recommended its referral. Those testifying supported the AMA should introduced by New Mexico, which was also mixed and the reference committee recommended its referral. Those testifying supported the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked that the AMA should introduced by New Mexico, which asked the AMA should introduced by New Mexico, which asked the AMA should introduced by New Mexico, which asked the AMA should introduced by New Mexico, which asked the AMA should introduced by New Mexico, which asked the AMA should be not the AMA

32 implement its own fellowship program.

- This report responds to both referred resolutions. It reviews the currently available health policy
- 34 fellowship programs for physicians and recommends that, in lieu of Resolutions 604-I-18 and

612-A-19, the AMA: significantly increase its collaborative efforts with the National Academy of Medicine (NAM) to make physicians aware of existing health policy fellowship opportunities and help them to apply for and participate in them; engage with alumni of the existing programs and provide opportunities for them to share their health policy fellowship experiences with medical students, residents, fellows, and practicing physicians; and disseminate information to medical students and physicians about opportunities to join the Commissioned Corps of the U.S. Public Health Service.

EXISTING HEALTH POLICY OPPORTUNITIES FOR PHYSICIANS

The RWJF Health Policy Fellows program is funded by the RWJF but is administered by NAM. Initiated in 1973, the RWJF program is for mid-career health professionals, behavioral and social scientists, and others with an interest in health and health care. Fellows reside for 12 months in Washington, DC, beginning in September of each year. The AMA is one of the organizations that meets with the RWJF fellows during a 3.5-month orientation period at the beginning of their year during which they meet with national health policy leaders, think tanks, executive branch officials, and members of Congress and their staffs. Afterward, the fellows are placed in full-time positions with members of Congress, a congressional committee, or the executive branch. Under the supervision of the office in which they are placed, fellows:

- Help develop legislative or regulatory proposals;
- Organize hearings, briefings, and stakeholder meetings;
- Meet with constituents; and
- Brief legislators or administration officials on various health issues.

RWJF Fellows receive a stipend of \$104,000 for the year of their Washington residency. Fellows who are affiliated with a sponsoring institution may have their stipends supplemented by the sponsoring institution.

 Testimony on Resolution 604 indicated concern that the number of slots for physicians in the RWJF program has been declining, but NAM data show otherwise. Physicians have always been an important part of this fellowship, and 58 percent of the nearly 300 program alumni are physicians. It is true that the percentage of physician *applicants* for the fellowship has been declining, but nonetheless 50 percent of the 2019-20 fellows will be physicians. Physicians who apply for the RWJF program fare extremely well in the selection process, so if more physicians apply, more are likely to be selected.

At the same time, there are some barriers to greater physician participation. It is very difficult for practicing physicians to participate in a year-long, full-time, residence program in Washington, DC. Academic medical centers have become less willing over time to let their medical staff members leave for a year, and many physicians face pressure to continue providing billable services. The \$104,000 stipend represents a payment reduction for most practicing physicians, as does the transition to a policy role if they continue in health policy after their fellowship has ended.

In addition to the RWJF program, NAM administers seven endowed fellowships for professionals who are early in their careers, of which five are only for physicians:

- Norman F. Gant/American Board of Obstetrics and Gynecology Fellowship;
- James C. Puffer, MD/American Board of Family Medicine Fellowship;
 - Gilbert S. Omenn Fellowship (combining biomedical science and population health);
 - American Board of Emergency Medicine Fellowship;

- Greenwall Fellowship in Bioethics;
 - NAM Fellowship in Pharmacy; and
 - NAM Fellowship in Osteopathic Medicine.

Also, NAM's Emerging Leaders in Health and Medicine (ELHM) Scholars program annually selects up to 10 early- and mid-career professionals with demonstrated leadership and professional achievement in biomedical science, population health, health care and related fields for three-year terms as ELHM scholars. Unlike the full-time residency required in the RWJF program, the ELHM scholars continue to work at their primary institution while also participating in this NAM program. Participants provide input and feedback to help shape NAM's priorities and advance its work in science, medicine, policy, and health equity. Five of the 10 current ELHM scholars are physicians.

Another pathway that many physicians take to become involved in public service careers in the executive branch is joining the <u>Commissioned Corps</u> of the U.S. Public Health Service. Physicians serving as Commissioned Corps officers may be found throughout the federal government, including the Food and Drug Administration, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, National Institutes of Health, and the other agencies within the U.S. Department of Health and Human Services, as well as the U.S. Department of Homeland Security, Federal Bureau of Prisons, and the U.S. Department of Defense. The women and men of the Commissioned Corps fill essential public health, clinical, and leadership roles throughout the nation's federal departments and agencies, particularly those supporting care to underserved and vulnerable populations. The U.S. Surgeon General oversees the Commissioned Corps.

For medical students, according to the Association of American Medical Colleges, more than 80 medical schools provide opportunities to pursue a master's degree in public health. Some physicians also obtain their MPH degree separately from their MD degree, either before or after medical school. Adding an MPH degree can be an effective means for physicians to pursue health policy careers. Some medical schools with health policy departments or schools of public health also welcome participation by practicing physicians in their educational programs and activities. Also, the AMA Government Relations Advocacy Fellow (GRAF) program provides medical students with the opportunity to be a full-time member of the AMA federal advocacy team for one year. A key goal of this program is to educate medical student, resident and young physician AMA members about health policy and encourage activism and leadership in local communities. To date, 15 students have participated in the GRAF program.

HEALTH LAW OPPORTUNITIES FOR PHYSICIANS

 In addition to training and experience in health policy, Resolution 612-A-19 also called for the AMA to offer members training and develop a fellowship in health law. It would probably be considerably more difficult for a mid-career practicing physician to transition to health law than health policy, as the practice of health law would likely require the individual to obtain a law degree. There are many physicians who pursue dual degree programs, and several universities offer joint MD/JD degree programs, including the University of Pennsylvania, Duke University, University of Miami, Boston University, Stanford University, and University of Virginia. Graduates of joint MD/JD programs may often be found in leadership positions in federal government regulatory agencies where they can use their expertise in both law and medicine.

Unlike medicine's specialty board certification process, the legal profession is dominated by state boards and does not offer legal specialty board certification in health law or similar topics. There are interest groups for professionals who focus in this area, such as the American Health Lawyers

Association. There do not appear to be fellowship opportunities that would allow physicians to transition to health law without obtaining a law degree.

AMA POLICY

AMA policy supports educating medical students, residents, and fellows in health policy. Policy H-310.911, "ACGME Allotted Time off for Health Care Advocacy and Health Policy Activities," encourages the Accreditation Council for Graduate Medical Education and other regulatory bodies to adopt policy that resident and fellow physicians be allotted additional time, beyond scheduled vacation, for scholarship and activities of organized medicine, including but not limited to health care advocacy and health policy. Policy H-295.953, "Medical Student, Resident and Fellow Legislative Awareness," advocates that elective political science classes be offered in the medical school curriculum, establishes health policy and advocacy rotations in Washington, DC for medical students and residents, and states that the AMA will support and encourage institutional, state, and specialty organizations to offer health policy and advocacy opportunities for medical students, residents, and fellows. Policy H-440.969, "Meeting Public Health Care Needs Through Health Professions Education," also states that courses in health policy are appropriate for health professions education. Current AMA policies focus on training medical students, residents and fellows in health policy, but the AMA does not currently have policy on mid-career physicians transitioning to health policy careers.

RECOMMENDATIONS

Based upon its review of existing opportunities for practicing physicians to pursue training and careers in health policy, the Board of Trustees does not believe it is necessary or desirable for the AMA to offer its own training and transitional opportunities for physicians to move from clinical practice to health policy. There are multiple avenues already available for physicians who wish to pursue careers in health policy, whether they choose to begin down this path during medical school, residency, or after some years in clinical practice. The Board does agree that the AMA should take a more active role in informing physicians of these opportunities; however, and in helping them to make these career choices. The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolutions 604-I-18 and 612-A-19 and the remainder of the report be filed.

1. That our American Medical Association encourage and support efforts to educate interested medical students, residents, fellows, and practicing physicians about health policy and assist them in starting or transitioning to careers that involve health policy. (New HOD Policy)

2. That our AMA significantly increase its collaborative efforts with the National Academy of Medicine (NAM) to make physicians aware of existing health policy fellowship opportunities and help them to apply for and participate in them. (Directive to Take Action)

3. That our AMA engage with alumni of health policy fellowship programs and joint degree programs and provide opportunities for them to share their health policy experiences with medical students, residents, fellows, and practicing physicians. (Directive to Take Action)

46 4. That our AMA include health policy content in its educational resources for members. (Directive to Take Action)

5. That our AMA work with the Office of the U.S. Surgeon General to disseminate information to medical students, residents, fellows, and practicing physicians about opportunities to join the Commissioned Corps of the U.S. Public Health Service. (Directive to Take Action)

Fiscal Note: Less than \$5000

REPORT OF THE BOARD OF TRUSTEES

B of T Report 8-I-19

Subject: Implementing AMA Climate Change Principles Through JAMA Paper

Consumption Reduction and Green Healthcare Leadership (Resolution 615-A-19)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

Referred to: Reference Committee F

At the 2019 Annual Meeting, the House of Delegates referred Resolution 615, "Implementing AMA Climate Change Principles Through *JAMA* Paper Consumption Reduction and Green Healthcare Leadership," to the Board of Trustees. Resolution 615, introduced by the Medical Student Section, asked:

That our American Medical Association (AMA) change existing automatic paper *JAMA* subscriptions to opt-in paper subscriptions by the year 2020, while preserving the option to receive paper *JAMA*, in order to support broader climate change efforts.

BACKGROUND

The JAMA Network contains a collection of 13 peer-reviewed, clinical research journals published by the American Medical Association, including *JAMA*, 11 specialty titles, and *JAMA Network Open*. The journals publish content online on a weekly basis, as well as in print journals on a periodic schedule (48 times per year for *JAMA*, once a month for specialty titles), except for *JAMA Network Open*, which is online only. The journals are highly prestigious with Impact Factors in the top 10 in their fields, many in the top 3, and acceptance rates for most at 10% or less. The reach of these journals is global, particularly *JAMA*, with countries outside the US accounting for approximately half of the total views. As a benefit of membership, all AMA members receive online access to the entire collection of journals in the JAMA Network. In addition, approximately 55% of members receive a print copy of *JAMA*. The overall business model for the JAMA Network consists of digital site licenses to institutions for access to the content, advertising (primarily print), and licensing/reuse of previously published content. This multifactor business model provides revenue to support the editorial and publishing operations of the JAMA Network, as well as providing funding to support overall AMA initiatives.

DISCUSSION

Over the past 15 years, the business model for Publishing has shifted from one that was previously driven by print advertising to one that is currently driven by institutional site licensing. As a result, the overall revenue mix has shifted from being 90% print to only 40% print in 2018. However, print advertising remains a key leg to the overall business model for Publishing, providing revenue to sustain the publishing and editorial functions of the journals. In addition, this revenue stream has provided funding for the development of new modes of content distribution including a mobile app, podcasts, and video content. Although digital advertising has grown along with online views, it remains a fraction (1/7th) of the existing print revenue as growth in the broader digital ad market is

focused on search advertising, which is dominated by Google and Facebook, while traditional banner ads that run on the JAMA Network have stagnated and/or declined. JAMA's print circulation of 295,000 in 2018 is a strategic benefit both to the JAMA Network as a value proposition for authors regarding the network's ability to communicate critical research as broadly as possible, and for the AMA as a consistently top-cited benefit of membership. Due to US Postal Service regulations, half of the individuals receiving print must be "requesters" in order to mail at periodical rates. Members account for 80% of this requester pool and are a key component to maintaining the overall ratio. A loss of members in print circulation would have a multiplier effect, leading to a 2-for-1 reduction in overall circulation to meet USPS regulations. This would reduce the overall reach of the journals, as well as inhibit the print advertising model, which currently provides a surplus of funds for the JAMA Network and the AMA.

CONCLUSION

 Over the last 5 years, the Publishing group has reduced overall print copies by 33%, saving ~1,500 tons of paper on an annual basis, in efforts to reduce costs and paper waste. The print circulation level is evaluated on an ongoing basis and are exploring opportunities to move to digital printing, a cost-effective option to print at significantly lower quantities. The JAMA Network is now a digital-first portfolio, with most research content published online ahead of print. Along these lines and in deploying environmentally sustainable practices, the recently launched journal, *JAMA Network Open*, is an online-only title with zero print circulation. However, the breadth of circulation for *JAMA* remains a key asset for soliciting the best papers from the author community and supporting the overall business model to fund new digital-focused methods of distributing content.

RECOMMENDATION

JAMA's print circulation is a key asset, best supported by maintaining the current opt-out policy for AMA Members. However, based on the analysis that led to this report, the JAMA Network has accelerated the shift to digital printing for journals in the portfolio and will be moving forward with a pilot program to move JAMA Surgery to digital printing in 2020, which will reduce the overall circulation for that title by over 90%. If successful, this model will be extended as appropriate to other journals in the network to drive an overall reduction in print copies, consistent with reducing the AMA's carbon footprint.

The Board of Trustees recommends that the following be adopted in lieu of Resolution 615-A-19, and the remainder of this report be filed:

That our American Medical Association continue to explore environmentally sustainable practices for *JAMA* distribution.

Fiscal Note: None

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 1-I-19

Subject: Academic Physicians Section Five-Year Review

Presented by: James Goodyear, MD, Chair

Referred to: Reference Committee F

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- 1 AMA Bylaw 7.0.9 states, "A delineated section must reconfirm its qualifications for continued
- 2 delineated section status and associated representation in the House of Delegates by demonstrating
- at least every 5 years that it continues to meet the criteria adopted by the House of Delegates."
- 4 AMA Bylaw 6.6.1.5 states that one function of the Council on Long Range Planning and
- 5 Development (CLRPD) is "to evaluate and make recommendations to the House of Delegates,
- 6 through the Board of Trustees, with respect to the formation and/or change in status of any section.
- 7 The Council will apply criteria adopted by the House of Delegates."

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- 9 The Council analyzed information from a letter of application submitted in June 2018 from the
- 10 Academic Physicians Section (APS) for renewal of delineated section status and representation in
- the AMA House of Delegates (HOD). The letter focuses on activities beginning in June 2014.

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APPLICATION OF CRITERIA

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Criterion 1: Issue of Concern - Focus will relate to concerns that are distinctive to the subset within the broader, general issues that face medicine. A demonstrated need exists to deal with these matters, as they are not currently being addressed through an existing AMA group.

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The APS remains the only AMA constituent group focused specifically on the perspectives of academic physicians. The APS identified the following priority issues/concerns on which the Section has focused over the last five years:

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- 1. Academic physician wellness/burnout
- 2. Graduate medical education funding and sustainability
- 3. Business of medicine
- 4. Health systems science and the work of the Accelerating Change in Medical Education (ACE) Consortium

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The Section listed the following issues/concerns as current priority areas, and ones that the APS will continue to focus on in the coming years, in addition to those previously listed:

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- 1. The transition from undergraduate medical education (UME) to graduate medical education (GME)
- 2. Recent guidance from the Centers for Medicare & Medicaid Services (CMS) on medical student documentation
 - 3. The Match
- Graduate medical education

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The APS provided rationales for increased focus on these issues, and outlined strategies by which the Section has attempted, and will attempt, to address them. As the transition from UME to GME will be a key focus area for the ACE Consortium moving forward, the APS will assist by providing a forum/venue for discussion of this topic and sharing of best practices among all medical schools and teaching hospitals. During the I-17 meeting, the APS held a session on the challenges and ways to improve the residency selection process. At the A-18 meeting, the APS hosted a learning and discussion session on the Accreditation Council on Graduate Medical Education's (ACGME) work to improve GME, and the APS Chair hosted a session, "Implementing the new CMS guidance on medical student evaluation and management (E/M) documentation at your institution." Future APS efforts will include educational sessions, presentations, webinars, forums for discussion and sharing of best practices, and collaboration with other AMA units to develop messaging for physician leaders in academic medical centers.

CLRPD Assessment: The APS is focused on issues that are significant and not currently being addressed through another existing AMA group. The APS is the only section that represents the perspectives of academic physicians.

Criterion 2: Consistency - Objectives and activities of the group are consistent with those of the AMA. Activities make good use of available resources and are not duplicative.

The APS works to increase awareness of the AMA's strategic focus areas, and the priority areas identified by the Section align closely with the AMA strategic direction. APS efforts have included webinars held in collaboration with the ACE Consortium, and a three-part series of educational sessions held at the 2016 Annual Meeting on physician wellness and resiliency throughout the medical education and practice continuum.

Additionally, the APS often collaborates with the AMA Council on Medical Education (CME). The APS Liaison to the CME is a key position for ensuring interchange of news/updates and collaborative work. APS meetings that occur during annual meetings of the HOD are timed to ensure no conflicts with the CME stakeholders forum. At interim meetings, the Section adjourns in sufficient time so that attendees can participate as judges in the AMA Research Symposium.

APS members have also worked to increase AMA membership through outreach to colleagues and promotion of AMA products/services of interest, such as the Academic Leadership Program, GME Competency Education Program, and FREIDA Online.

CLRPD Assessment: The APS has selected areas of focus that align closely with the AMA's strategic direction, particularly Accelerating Change in Medical Education. Additionally, the Section has worked to increase awareness of the strategic focus areas and other AMA efforts/products, and sought opportunities for collaboration on cross-cutting medical education issues and programs with other groups within the AMA.

Criterion 3: Appropriateness - The structure of the group will be consistent with its objectives and activities.

The Section on Medical Schools (SMS) was renamed the APS in June 2015 through action of the HOD. Through strategic planning reviews and nationwide surveys of academic physicians, the Section determined that the former name inhibited interest and involvement of academic physicians outside the leadership and administration of medical schools, including those serving as faculty at non-medical school affiliated medical centers and residency programs. Findings also indicated that the name implied an exclusive focus on undergraduate medical education, even though the SMS

welcomed academic physicians interested in graduate medical education and continuing medical education, as well as those who served in a clinical/research capacity with an academic medical center, community hospital, or other health care setting. Additionally, the focus on the physician's institution (i.e., medical school) rather than the physician's role (i.e., an academic physician) was seen as a barrier to expanded membership in the SMS.

Further, the HOD approved changes put forth by the Section to address membership challenges experienced by the Section and streamline the membership categories and processes of the former SMS to help increase membership and engagement. These new membership categories are now part of APS Bylaws, and are outlined later in this report.

The primary opportunities for APS members to participate in the Section occur during its biannual meetings, held in conjunction with the annual and interim meetings of the HOD. During this time, members may review medical education reports and resolutions, voice opinions, and vote on recommended APS action. Periodic emails to the APS Listserv provide news and updates on key APS and AMA activities, as well as inviting applications for leadership positions on national medical education organizations, and on the Section. Other opportunities for APS involvement include:

- Participating in the APS membership committee, formed in June 2016, with seven regionally based slots throughout the country
- Participating in the CLRPD's annual solicitation of stakeholder input on future health care trends
- Serving on committees to explore special interest topics on behalf of the Section
- Informing Section policies, products and services through participation in surveys and focus groups
- Participating in educational programming tailored to develop the knowledge, skills and attitudes that faculty physicians need to effectively prepare the next generation of physicians
- Networking and interacting with peers who have similar interests at other institutions
- Engaging with the ACE Consortium through participation in consortium-sponsored webinars and online discussions

CLRPD Assessment: The structure of the APS allows members to participate in the deliberations and pursue the objectives of the Section. The APS instituted an orientation and networking session to help new members gain an understanding of the Section's role within the AMA. The APS Listserv provides news and updates on key APS and AMA activities, and provides networking and leadership opportunities for Section members.

 Criterion 4: Representation Threshold - Members of the formal group would be based on identifiable segments of the physician population and AMA membership. The formal group would be a clearly identifiable segment of AMA membership and the general physician population. A substantial number of members would be represented by this formal group. At minimum, this group would be able to represent 1,000 AMA members.

AMA member academic physicians can now seek membership in the APS through three routes:

- 1. Appointment by the dean of their allopathic or osteopathic medical school
- 2. Self-nomination as an academic physician for those with a current faculty appointment at a U.S. medical school

3. Self-nomination as a physician who does not hold a medical school faculty appointment

but has an active role in student (undergraduate), resident/fellow (graduate), and/or

medical center, community hospital, or other health care setting

continuing medical education, or serves in a clinical/research position with an academic

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Data provided by the APS show that the Section had 513 members at the time the letter of application was submitted, with the majority (157 of 176) of allopathic and osteopathic medical schools in the United States represented by at least one member.

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Masterfile data provided by the Section shows the total physician population eligible for APS membership to be 20,786, and the total number of AMA members eligible for APS membership to be 2,561.

Type of	Present Employment	Major Professional	Total	AMA
Practice		Activity		members
Medical	Any	Medical Teaching	12,408	1,368
Teaching				
Administration	Medical School	Administration	960	189
Direct Patient	Medical School	Office Based	7,271	987
Care		Practice		
Non-Patient	Medical School	Other	147	17
Care				
			20,786	2,561

13 CLRPD Assessment: The APS has over 500 members, who represent the majority of medical 14 schools in the country. It is comprised of members from an identifiable segment of AMA membership and the general physician population. The Section's potential membership within the 15 AMA is over 2,500, greater than minimum threshold of 1,000 AMA members. 16

Criterion 5: Stability - The group has a demonstrated history of continuity. This segment can

demonstrate an ongoing and viable group of physicians will be represented by this section and both the segment and the AMA will benefit from an increased voice within the policymaking body.

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The APS (then the SMS) was established in 1976 to "allow more direct participation in the AMA by physician members who are active in medical school administration" (AMA Board of Trustees

Report P C-76). The following table shows the attendance from the last five meetings of the APS; the average number of attendees (61 members) over the last five meetings represents over ten

25 26 percent of APS membership.

Meeting	Attendance			
June 2018	55			
November 2017	34			
June 2017	73			
November 2016	66			
June 2016	79			

- 27 The APS noted that its Listserv is used to provide periodic updates to members on Section
- activities and news/updates, including pre-meeting invitations and post-meeting wrap-up 28
- 29 documents, and invitations to apply for positions on national medical education organizations
- 30 through the CME. This latter effort has led to greater awareness of and a significant increase in

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applications to these positions. From 2016 through 1Q 2018, APS members submitted 44 of 79 applications for positions with nine external organizations.

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- 4 The Section has submitted three resolutions over the last five years that have led to AMA policy.
- 5 At the 2014 Annual Meeting of the HOD, the APS (then the SMS) submitted resolutions 311-A-14,
- 6 "Impact of Competency-Based Medical Education Programs as Opposed to Time-Based
- 7 Programs," and 312-A-14, "Assessing the Impact of Limited GME Residency Positions in the
- 8 Match," which led to amendments to AMA Policies D-295.318, "Competency-Based Portfolio
- 9 Assessment of Medical Students," and D-310.977, "National Resident Matching Program Reform."
- Resolution 312-A-14 and the resulting policy prompted the development of two reports from the
- 11 CME, CME Report 3-A-16, "Addressing the Increasing Number of Unmatched Medical Students,"
- and follow-up CME Report 5-A-17, "Options for Unmatched Medical Students." Additionally, the
- 13 APS submitted Resolution 608-A-17, "Improving Medical Student, Resident/Fellow and Academic
- 14 Physician Engagement in Organized Medicine," which led to the creation of AMA Policy
- 15 G-615.103, "Improving Medical Student, Resident/Fellow and Academic Physician Engagement in
- 16 Organized Medicine and Legislative Advocacy."

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Further, the APS reviews, assesses and provides testimony on a wide variety of reports and resolutions related to academic medicine and medical education that are considered by the HOD during annual and interim meetings.

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24 25 CLRPD Assessment: The APS has a history of more than 40 years at the AMA. In addition to the APS biannual meetings, the Section uses its Listserv to sustain member engagement in APS issues and activities. The Section has introduced or significantly contributed to resolutions and reports that resulted in new policies; therefore, the HOD has benefited from the distinct voice of the APS in its deliberations and policymaking processes.

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Criterion 6: Accessibility - Provides opportunity for members of the constituency who are otherwise under-represented to introduce issues of concern and to be able to participate in the policymaking process within the AMA House of Delegates (HOD).

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The APS is the only AMA component group that specifically represents the perspectives of academic physicians and works to ensure that the interests of academic physicians and medical school administrators are reflected in broader AMA policy.

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38 39 At its meetings on the Fridays prior to the annual and interim meetings of the HOD, the APS Governing Council (GC) reviews all relevant business items and develops a consent calendar for consideration by the entire Section. These recommendations are shared with APS members the following morning during the APS business meeting, which provides sufficient time for review, deliberation, discussion and voting.

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Through the work of the APS Liaison to the CME, as well as APS GC members appointed to serve as ex officio liaisons on various committees of the Council, the APS GC reviews and provides feedback on draft CME reports prior to HOD meetings to ensure a united front on contributions to AMA medical education policy.

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Additionally, the Academic Medicine Caucus, developed by the APS Delegate in 2011, allows a larger group of current and potential APS members (i.e., those who attend the AMA HOD meeting on behalf of their state or specialty delegation and may be less likely to be involved in the activities of AMA sections) to review proposed AMA policy, including the positions of the APS on HOD business items.

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1	CLRPD Assessment: The APS provides numerous ways for its constituents to speak on issues and
2	business items relevant to the work of the Section, and allows more direct participation in the AMA
3	by physician members who are active in medical school administration, and those who serve in a
4	clinical/research position with an academic medical center, community hospital or other health care
5	setting. The APS has introduced or significantly contributed to several resolutions/reports, which
6	resulted in new AMA policies over the past five years. Additionally, the Academic Medicine
7	Caucus, developed in 2011, allows a larger group of academic physicians to participate in the HOD
8	policymaking process.
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10	CONCLUSION
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12	The CLRPD has determined that the APS meets all required criteria, and it is therefore appropriate
13	to renew the delineated section status of the APS.
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15	RECOMMENDATIONS
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17	The Council on Long Range Planning and Development recommends that our American Medical
18	Association renew delineated section status for the Academic Physicians Section through 2024
19	with the next review no later than the 2024 Interim Meeting. (Directive to Take Action)

Fiscal Note: Less than \$500

REPORT OF THE HOUSE OF DELEGATES COMMITTEE ON COMPENSATION OF THE OFFICERS

Report I-19

Subject: Report of the House of Delegates Committee on Compensation of the Officers

Presented by: Richard A. Evans, MD, Chair

Referred to: Reference Committee F

This report by the committee at the 2019 Interim Meeting presents several recommendations. It also documents the compensation paid to Officers for the period July 1, 2018 thru June 30, 2019 and includes the 2018 calendar year IRS reported taxable value of benefits, perquisites, services, and in-kind payments for all Officers.

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BACKGROUND

 At the 1998 Interim Meeting, the House of Delegates (HOD) established a House Committee on Trustee Compensation, currently named the Committee on Compensation of the Officers, (the "Committee"). The Officers are defined in the American Medical Association's (AMA) Constitution and Bylaws. (Note: under changes to the Constitution previously approved by the HOD, Article V refers simply to "Officer," which includes all 21 members of the Board among whom are the President, President-Elect, Immediate Past President, Secretary, Speaker of the HOD and Vice Speaker of the HOD, collectively referred to in this report as Officers.) The composition, appointment, tenure, vacancy process and reporting requirements for the Committee are covered under the AMA Bylaws. Bylaws 2.13.4.5 provides:

The Committee shall present an annual report to the House of Delegates recommending the level of total compensation for the Officers for the following year. The recommendations of the report may be adopted, not adopted, or referred back to the Committee, and may be amended for clarification only with the concurrence of the Committee.

At A-00, the Committee and the Board jointly adopted the American Compensation Association's definition of total compensation which was added to the Glossary of the AMA Constitution and Bylaws. Total compensation is defined as the complete reward/recognition package awarded to an individual for work performance including: (a) all forms of money or cash compensation; (b) benefits; (c) perquisites; (d) services; and (e) in-kind payments.

 Since the inception of this Committee, its reports document the process the Committee follows to ensure that current or recommended Officers compensation is based on sound, fair, cost-effective compensation practices as derived from research and use of independent external consultants, expert in Board compensation. Reports beginning in December 2002 documented the principles the Committee followed in creating its recommendations for Officer compensation.

At A-08, the HOD approved changes that simplified compensation practices with increased transparency and consistency. At A-10, Reference Committee F requested that this Committee recommend that the HOD affirm a codification of the current compensation principle, which

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occurred at I-10. At that time, the HOD affirmed that this Committee has and will continue to base its recommendations for Officer compensation on the principle of the value of the work performed, consistent with IRS guidelines and best practices as recommended by the Committee's external independent consultant, who is expert in Board compensation.

At A-11, the HOD approved the alignment of Medical Student and Resident Officer compensation with that of all other Officers (excluding Presidents and Chair) because these positions perform comparable work.

Immediately following A-11, the Committee retained Mr. Don Delves, founder of the Delves Group, to update his 2007 research by providing the Committee with comprehensive advice and counsel on Officer compensation. The updated compensation structure was presented and approved by the HOD at I-11 with an effective date of July 1, 2012.

The Committee's I-13 report recommended and the HOD approved the Committee's recommendation to provide a travel allowance for each President to be used for upgrades because of the significant volume of travel in representing our AMA.

At I-16, based on results of a comprehensive compensation review conducted by Ms. Becky Glantz Huddleston, an expert in Board Compensation with Willis Towers Watson, the HOD approved the Committee's recommendation of modest increases to the Governance Honorarium and Per Diems for Officer Compensation, excluding the Presidents and Chair, effective July 1, 2017. At A-17 the HOD approved modifying the Governance Honorarium and Per Diem definition so that Internal Representation, greater than eleven days, receives a per diem.

At A-18, based on comprehensive review of Board leadership compensation, the HOD approved the Committee's recommendation to increase the President, President-elect, Immediate Past-President, Chair and Chair-elect honoraria by 4% effective July 1, 2018.

At I-18 and A-19, the House approved the Committee's recommendation to provide a Health Insurance Stipend to President(s) who are under Medicare eligible age when the President(s) and his/her covered dependents, not Medicare eligible, lose the President's employer provided health insurance during his/her term as President. Should the President(s) become Medicare eligible while in office, he/she will receive an adjusted Stipend to provide insurance coverage to his/her dependents not Medicare eligible.

CASH COMPENSATION SUMMARY

The cash compensation of the Officers shown in the following table will not be the same as compensation reported annually on the AMA's IRS Form 990 because Form 990s are based on a calendar year. The total cash compensation in the summary is compensation for the days these officers spent away from home on AMA business approved by the Board Chair. The total cash compensation in the summary includes work as defined by the Governance Honorarium and Per Diem for Representation including conference calls with groups outside of the AMA, totaling 2 hours or more per calendar day as approved by the Board Chair. Detailed definitions are in the Appendix.

The summary covers July 2018 to June 30, 2019.

AMA Officers	Position	Total		Total
			npensation	Days
Grayson W Armstrong, MD, MPH	Resident Officer	\$	-	2.5
Susan R Bailey, MD	Speaker, House of Delegates	\$	89,700	69
David O Barbe, MD, MHA	Immediate Past President	\$	284,960	96.5
Willarda V Edwards, MD, MBA	Officer	\$	65,650	45
Lisa Bohman Egbert, MD	Vice Speaker, House of	\$	-	2
	Delegates			
Jesse M Ehrenfeld, MD, MPH	Chair-Elect & Young	\$	207,480	104.5
	Physician Officer			
Scott Ferguson, MD	Officer	\$	71,500	54.5
Sandra Adamson Fryhofer, MD	Officer	\$	83,200	68
Gerald E Harmon, MD	Immediate Past Chair	\$	86,450	67
Patrice A Harris, MD, MA	President-Elect	\$	288,210	185
William E Kobler, MD	Officer	\$	86,450	62
Russell WH Kridel, MD	Secretary	\$	78,000	66
Barbara L McAneny, MD	President	\$	290,160	189
William A McDade, MD, PhD	Officer	\$	78,000	59.5
Mario E Motta, MD	Officer	\$	66,950	39
Bobby Mukkamala, MD	Officer	\$	74,100	56
Albert J Osbahr, III, MD	Officer	\$	78,000	52.5
Jack Resneck, Jr, MD	Chair	\$	280,280	97.5
Ryan J Ribeira, MD, MPH	Resident Officer	\$	65,000	49
Karthik V Sarma, MS	Medical Student Officer	\$	113,750	91
Bruce A Scott, MD	Vice Speaker, House of	\$	71,500	64
·	Delegates		•	
Sarah Mae Smith	Medical Student Officer	\$	-	6.5
Michael Suk, MD, JD, MPH, MBA	Officer	\$	-	2.5
Georgia A Tuttle, MD	Officer	\$	84,500	58
Willie Underwood, III, MD, MSc,	Officer	\$	-	2
MPH				
Kevin A Williams, MSA	Public Board Member	\$	66,950	50

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President, President-Elect, Immediate Past President, and Chair

In 2018 – 2019, each of these positions received an annual Governance Honorarium which was paid in monthly increments. These four positions spent a total of 568.5 days on approved Assignment and Travel, or 142 days each on average.

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Chair-Elect

This position received a Governance Honorarium of approximately 75% of the Governance Honorarium provided to the Chair.

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13 All other Officers

- 14 All other Officers received cash compensation, which included a Governance Honorarium of
- 15 \$65,000 paid in monthly installments. The remaining cash compensation is for Assignment and
- 16 Travel Days that are approved by the Board Chair to externally represent the AMA. These days
- were compensated at a per diem rate of \$1,300.

- 1 Assignment and Travel Days
- 2 The total Assignment and Travel Days for all Officers (excluding the President, President-Elect
- 3 Immediate Past President and Chair) were 1070.5; this includes reimbursement for telephonic
- 4 representation meetings for external organizations that are 30 minutes or longer during a calendar
- day and total 2 or more hours. These are reimbursed at ½ of the current per diem rate. During this
- 6 reporting period, there were 16 reimbursed calls, representing 8 per diem days.

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EXPENSES

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- Total expenses paid for the period, July 1, 2018 June 30, 2019, \$882,074 compared to \$798,212 for the previous period, representing a 10.5% increase. This includes \$3,644 in upgrades for
- Presidents' travel per the approved Presidential Upgrade Allowance of \$2,500 per position per term.

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BENEFITS, PERQUISITES, SERVICES, AND IN-KIND PAYMENTS

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Officers are able to request benefits, perquisites, services, and in-kind payments, as defined in the "AMA Board of Trustees Standing Rules on Travel Expenses." These non-taxable business expense items are provided to assist the Officers in performing their duties:

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- AMA Standard laptop computer or iPad
- iPhone
 - American Express card (for AMA business use)
 - Combination fax/printer/scanner
 - An annual membership to the airline club of choice offered each year during the Board member's tenure
 - Personalized AMA stationary, business cards and biographical data for official use

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Additionally, all Officers are eligible for \$305,000 term life insurance and are covered under the AMA's \$500,000 travel accident policy and \$10,000 individual policy for medical costs arising out of any accident while traveling on official business for the AMA. Life insurance premiums paid by the AMA are reported as taxable income. Also, travel assistance is available to all Officers when traveling more than 100 miles from home or internationally.

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- Secretarial support, other than that provided by the AMA's Board office, is available up to defined annual limits as follows: President, during the Presidential year, \$15,000, \$5,000 each for the President-Elect, Chair, Chair-Elect and Immediate Past President per year. Secretarial expenses incurred by other Officers in connection with their official duties are paid up to \$750 per year per
- 39 Officer. This is reported as taxable income.

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Travel expenses incurred by family members are <u>not</u> reimbursable, except for the family of the incoming President at the Annual Meeting of the HOD.

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- Calendar year taxable life insurance and taxable secretarial fees reported to the IRS totaled \$41,292 and \$26,250 respectively for 2018. An additional \$12,125 was paid to third parties for secretarial
- 46 services during 2018.

METHODOLOGY

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The Committee commissioned a comprehensive review of Officer compensation, excluding leadership, since it has been three years since the last compensation review. The purpose of this review was to refresh the Committee's knowledge of market conditions related to Board compensation, to ensure the Officers are compensated appropriately for the work performed on behalf of the AMA and that the structure of Officer compensation aligned with current trends in for-profit Board compensation. The Committee also continues to be interested in reviewing and refining its compensation practices for increased simplification and transparency.

To complete the compensation review, the Committee retained Becky Glantz Huddleston, of Willis Towers Watson. Ms. Huddleston is an expert in Board compensation and works with both forprofit and not-for-profit organizations. The firm she works for, Willis Towers Watson, is one of the largest, most prestigious and well-respected compensation consulting firms.

The Committee's review and subsequent recommendations for Officer compensation are based on the principle of the value of the work performed, as affirmed by the HOD and the following additional guidelines:

- Compensation should be based on the value expected by the AMA from its Officers.
- Compensation should take into account that the AMA is a complex organization when comparing compensation provided to Board members at for-profit organizations and at complex not-for-profit organizations of similar size and activities.
- Compensation should reflect a balance of volunteerism while also compensating Officers for level of fiduciary responsibilities and time commitment of the role.
- Compensation should be aligned with the long-term interests of AMA members.
- Compensation should reinforce choices and behaviors that enhance effectiveness.
- Compensation should be approached on a comprehensive basis, rather than as an array of separate elements.

The process the Committee followed along with the aforementioned principles is consistent with the guidelines recommended by the IRS for determining reasonable and competitive levels of Officer compensation.

Ms. Huddleston and the Committee developed their recommendations based on:

- The current compensation structure.
- Review and analysis of Officer compensation data for the past three terms.
- Pay practices for Boards of Directors at for-profit and not-for-profit organizations similar to the AMA who pay their Board members.
 - A collaborative, deliberative and objective review process.

FINDINGS

 The Committee notes that Officers continue to make significant time commitments in supporting our AMA in governance and representation functions. Given the amount of time required of Board members, it is important that individuals seeking a position on the Board be aware of the scope of the commitment and the related compensation.

In reviewing the Officer Compensation data for the past three terms, the Committee and its consultant first reviewed the time commitment of the non-leadership Officers. This review showed

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that the time commitment for Board-related work was generally consistent among the non-leadership Officers with the variability in the honorarium days due to travel, committee meetings which vary by Board committee and committee orientation. Internal representation had more variability than Board-related work and External Representation was the most variable.

The Committee and its consultant also reviewed the current structure of Officer compensation to ensure that the structure appropriately compensates the Officers for the number of days worked and the varied time commitment of each Officer. The analysis compared the Officer compensation for the 2018/2019 term under the current definition which compensates Officers via a Per Diem for Internal Representation days above eleven with a hypothetical scenario where all internal representation days were included in the Governance Honorarium. The conclusion of this analysis is that the current structure appropriately compensates the Officers for the varied time commitments in Internal Representation. The analysis further demonstrated that the current structure addresses the variable time commitment of the Immediate Past Chair role.

External compensation data from both for-profit and not-for-profit organizations was reviewed. For-profit Board compensation data was sourced from the National Association of Corporate Directors (NACD) 2018-2019 survey of organizations with revenue between \$50M - \$500M. This data indicated for-profit Board compensation consisted of both a pay and stock component. The Committee's external consultant noted that not-for-profit organizations do not have the ability to grant stock awards and therefore do not necessarily intend to be competitive with the for-profit sector from the perspective of total compensation. While AMA's Governance Honorarium was close to the median cash compensation, it was well below the total Board compensation due to absence of stock awards.

The consultant collected and analyzed data from not-for-profit organizations determined to be of similar size and complexity as the AMA, AMA's not-for-profit peer group. This information was collected from Form 990 filings, generally for 2017. This data showed that AMA non-leadership Officers spend significantly more time on internal Board and representation when compared to the peer group. Further analysis to adjust for the variance in time commitments showed that AMA's Governance Honorarium was significantly lower than the peer group. Since the 2016 assessment, the compensation data of for-profit and not-for-profit organizations showed an average increase of slightly over 7%.

There is no good external comparison for Per Diem pay for External Representation for non-leadership Officers given the unique nature of this function at the AMA. However, the Per Diem amount has not changed since 2016 and the Committee used the data from the not-for-profit peer group Governance Honorarium comparison to directionally inform them.

 The Committee balanced simplicity, transparency and comparability with internal and external compensation data and the total cost of governance to the AMA when recommending the modest increases to the Governance Honorarium and Per Diems. This Committee is recommending an increase of approximately 3%, or approximately 1% per year, to both the Honorarium and Per Diem, effective July 1, 2020.

RECOMMENDATIONS

The Committee on Compensation of the Officers recommends the following recommendations be adopted and the remainder of this report be filed:

1. That there be no change to the current Definitions effective July 1, 2018 as they appear in the Travel and Expenses Standing Rules for AMA Officers for the Governance Honorarium, Per Diem for Representation and Telephonic Per Diem except for the Governance Honorarium and Per Diem amounts as recommended in 2, 3 and 4 below.

• Definition of Governance Honorarium effective July 1, 2017: The purpose of this payment is to compensate Officers, excluding Board Chair, Chair-Elect and Presidents, for all Chair-assigned internal AMA work and related travel. This payment is intended to cover all currently scheduled Board meetings, special Board or Board committee, subcommittee and task force meetings, Board orientation, Board development and media training, and Board conference calls, and any associated review or preparatory work, and all travel days related to all such meetings. The Governance Honorarium also covers Internal Representation, such as section and council liaison meetings (and associated travel) or calls, up to eleven (11) Internal Representation days.

 • Definition of Per Diem for Representation effective July 1, 2017:
The purpose of this payment is to compensate for Board Chair-assigned representation day(s) and related travel for Officers, excluding Board Chair, Chair-Elect and Presidents.
Representation is either external to the AMA, or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating achievement of the respective organization goals such as the AMA Foundation, PCPI, etc., or for Internal Representation days above eleven (11). The Board Chair may also approve a per diem for special circumstances that cannot be anticipated such as weather-related travel delays.

• Definition of Telephonic Per Diem for Representation effective July 1, 2017: Officers, excluding the Board Chair, Chair-Elect and Presidents, who are assigned as the AMA representative to outside groups as one of their specific Board assignments or assigned Internal Representation days above eleven (11), receive a per diem rate for teleconference meetings when the total of all teleconference meetings of 30 minutes or longer during a calendar day equal 2 or more hours. Payment for these meetings would require approval of the Chair of the Board.

2. That the Governance Honorarium for all Board members excluding, Board Chair, Board Chair-elect, President, President-elect, and Immediate Past President be increased effective July 1, 2020 to \$67,000. (Directive to Take Action)

That the Per Diem for Chair-assigned representation for all Board members excluding the
 Board Chair, Chair-Elect and Presidents and related travel be increased effective July 1, 2020 to \$1,400 per day. (Directive to Take Action)

4. That the Per Diem for Chair-assigned Telephonic Per Diem for Representation be increased effective July 1, 2020 to \$700 as defined. (Directive to Take Action)

Fiscal Note: Estimated annual cost of Recommendations 2, 3 and 4 is \$49,950 based on data reported for July 1, 2018 through June 30, 2019. This cost represents the impact of the Governance Honorarium increase (\$2,000 for each of the 16 non-leadership Officers), the Per Diem increase (\$100 per day) and the Telephonic Per Diem increase (\$50 per teleconference meeting as defined).

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APPENDIX

POSITION	GOVERNAN	GOVERNANCE HONORARIUM		
President	\$	290,160		
Immediate Past President & President-Elect	\$	284,960		
Chair	\$	280,280		
Chair-Elect	\$	207,480		

Reference Committee J

CMS Report(s)

- 01 Established Patient Relationships and Telemedicine
- 02 Addressing Financial Incentives to Shop for Lower-Cost Health Care
- 03 Improving Risk Adjustment in Alternative Payment Models
- 04 Mechanisms to Address High and Escalating Pharmaceutical Prices

Resolution(s)

- 801 Reimbursement for Post-Exposure Protocol for Needlestick Injuries
- 802 Ensuring Fair Pricing of Drugs Developed with the United States Government
- 803 Encourage Federal Efforts to Expand Access to Scheduled Dialysis for Undocumented People
- 804 Protecting Seniors from Medicare Advantage Plans
- 805 Fair Medication Pricing for Patients in United States: Advocating for a Global Pricing Standard
- 806 Support for Housing Modification Policies
- 807 Addressing the Need for Low Vision Aid Devices
- 808 Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs
- 809 AMA Principles of Medicaid Reform
- 810 Hospital Medical Staff Policy
- 811 Require Payers to Share Prior Authorization Cost Burden
- 812* Autopsy Standards as Condition of Participation
- 813* Public Reporting of PBM Rebates
- 814* PBM Value-Based Framework for Formulary Design
- 815* Step Therapy

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-19

Subject: Established Patient Relationships and Telemedicine

(Resolution 215-I-18)

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

- 1 At the 2018 Interim Meeting, the House of Delegates referred Resolution 215-I-18, "Extending the
- 2 Medical Home to Meet Families Wherever They Go," which was introduced by the American
- 3 Academy of Pediatrics. The Board of Trustees assigned this item to the Council on Medical
- 4 Service for a report back at the 2019 Interim Meeting. Resolution 215-I-18 asked that our
- 5 American Medical Association (AMA) "develop model legislation to permit primary care
- 6 physicians, who work in medical homes/primary care practices that satisfy the National Committee
- 7 for Quality Assurance Patient-Centered Medical Home Recognition Program guidelines, and who
- 8 have documented a face-to-face patient-care relationship, to provide telehealth services for the

9 patient when the patient travels to any of the fifty states."

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This report provides an overview of state-based medical licensure and telemedicine; describes the Interstate Medical Licensure Compact (the Compact); summarizes relevant AMA policy; and makes recommendations.

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BACKGROUND

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18 19 Telemedicine is a key health care delivery innovation that has the potential to improve access to care and reduce health care costs. The AMA advocates for policies that encourage the adoption of telemedicine, while strongly supporting the current state-based medical licensure structure and the ability of states to enforce their medical practice laws that are in place to protect patients.

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Although technological developments have enabled the application of telemedicine across a range of care settings, including patient-centered medical home practices, barriers to its widespread use remain. The financial burden of implementing telemedicine was cited as one such barrier in a recent study, which found that 15.4 percent of physicians worked in practices utilizing telemedicine to interact with patients, and 11.2 percent worked in practices that used telemedicine for interactions between physicians and health care professionals.¹

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Referred Resolution 215-I-18 highlighted concerns historically raised by physicians that the state-based licensure process has served as an additional barrier for physicians trying to expand telemedicine practices. Unlike some countries that have national oversight of medical practice, states are responsible for regulating the practice of medicine in the US. State authority to protect the health of its citizens was granted in 1791 under the 10th Amendment of the US Constitution, with formal licensing of physicians through state medical boards dating back to the 1800s.² The primary goals of state medical boards are to protect patients, ensure quality health care, and foster the professional practice of medicine. The prevailing standard for state medical licensure found in

the medical practice acts of each state affirms that the practice of medicine is determined to occur

where the patient is located, so that the full resources of the state are available for the protection of that patient. Without such protection, a patient who receives services that fall short of the standard of care would have limited recourse to seek redress and relief under the state's medical practice and patient safety statutes and regulations.

Licensure requirements established by state medical boards vary with respect to telemedicine but, according to the Federation of State Medical Boards (FSMB), 49 state boards—as well as the medical boards of the District of Columbia, Puerto Rico, and the Virgin Islands—require physicians practicing telemedicine to be licensed in the state in which the patient is located, 3 consistent with AMA policy. Fourteen state medical boards issue a special purpose license, telemedicine license or certificate, or license to practice medicine across state lines.⁴

Historically, the process of obtaining licenses to practice medicine in multiple states has been burdensome and time-consuming for physicians, and some states formed interstate agreements to practice medicine across state lines. The AMA has long supported solutions that make it easier for physicians to obtain licenses to practice across multiple states, while preserving the ability of states to protect patient health and oversee the care provided to patients within their borders. For many years, the AMA urged policymakers to address the cost, time and paperwork burdens associated with licensure, which were compounded when a physician sought licensure in more than one state.⁵ Accordingly, the AMA strongly supported development and implementation of the Compact as a licensure solution that would make it easier and faster for physicians to obtain licenses to practice in multiple states.⁶

Interstate Medical Licensure Compact

The Compact, developed over many years and officially launched in 2017, established a new pathway to expedite the licensing of physicians already licensed to practice in one state, who seek to practice medicine in one or more other states. This expedited process helps facilitate license portability and allows physicians to practice medicine—including telemedicine—in a safe and accountable manner that expands access to care without compromising patient protections. At the time this report was prepared, the Compact was an agreement among the following 29 states, the District of Columbia and the Territory of Guam: Alabama, Arizona, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming.⁷

 The Compact provides a licensing option under which qualified physicians seeking to practice in multiple states are eligible for expedited licensure in all states participating in the Compact. Licensing fees vary and remain the purview of each state's medical board. For a state to join the Compact, the state legislature must enact authorizing legislation. A license obtained through the expedited procedure provided for by the Compact provides the same licensing currently provided for physicians by state medical boards—the only difference is that the process of obtaining a license is significantly streamlined. Physicians can apply for licenses through the Compact on the Compact's website.

Importantly, the Compact creates another pathway for licensure and does not otherwise change a state's medical practice act. Of priority to the AMA, facilitating expedited medical licensure through the Compact ensures that states retain their roles in regulating the practice of medicine and protecting patient welfare. The Compact adopts the prevailing standard that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter.

A physician practicing under a license facilitated by the Compact is thus bound to comply with the statutes, rules and regulations of each Compact state wherein he/she chooses to practice medicine. The Compact serves as a leading alternative to proposals to change the site of practice from where the patient is located to where the physician is located for purposes of telemedicine, which would usurp state authority to regulate the practice of medicine.

AMA POLICY AND RESOURCES

The recommendations contained in <u>Council on Medical Service Report 7-A-14</u> established Policy H-480.946, which outlines safeguards and standards to support the appropriate coverage of and payment for telemedicine services. In the report, the Council prioritized the need for AMA policy to support future innovation in the use of telemedicine while ensuring patient safety, quality of care and the privacy of patient information, as well as protecting the patient-physician relationship and promoting improved care coordination and communication with medical homes.

A key safeguard included in Policy H-480.946 stipulates that physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board. In addition, the policy requires physicians and other health practitioners delivering telemedicine services to abide by state licensure laws, state medical practice acts and other requirements in the state where the patient receives services, and maintains that the delivery of telemedicine services must be consistent with state scope of practice laws. The Council included these safeguards in the recommendations of its report because the Council believed that the key tenets in the delivery of in-person services hold true for the delivery of telemedicine services. Policy H-480.946 also states that a valid patient-physician relationship must be established before the provision of telemedicine services, through:

• A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine; or

• A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient's care; or

 Meeting standards of establishing a patient-physician relationship included as part of
evidence-based clinical practice guidelines on telemedicine developed by major medical
specialty societies, such as those of radiology and pathology.

Additionally, the policy maintains that prior to the delivery of any telemedicine service, physicians need to verify that their medical liability insurance covers telemedicine services, including telemedicine services provided across state lines, if applicable.

Long-standing AMA policy also maintains that medical boards of states and territories should require a full and unrestricted license in that state for the practice of telemedicine, unless there are other appropriate state-based licensing methods, with no differentiation by specialty, for physicians who wish to practice telemedicine in that state or territory (Policy H-480.969). The policy also states that this license category should adhere to the following principles:

• Application to situations where there is a telemedical transmission of individual patient data from the patient's state that results in either; (i) provision of a written or otherwise documented medical opinion used for diagnosis or treatment or; (ii) rendering of treatment to a patient within the board's state;

- Exemption from such a licensure requirement for traditional informal physician-tophysician consultations ("curbside consultations") that are provided without expectation of compensation;
- Exemption from such a licensure requirement for telemedicine practiced across state lines in the event of an emergent or urgent circumstance, the definition of which for the purposes of telemedicine should show substantial deference to the judgment of the attending and consulting physicians as well as to the views of the patient; and
- Application requirements that are non-burdensome, issued in an expeditious manner, have fees no higher than necessary to cover the reasonable costs of administering this process, and that utilize principles of reciprocity with the licensure requirements of the state in which the physician in question practices.

Policy D-480.999 opposes a single national federalized system of medical licensure. Policy H-480.974 directs our AMA to work with the FSMB and state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries. Policy D-480.969 states that our AMA will work with the FSMB to draft model state legislation to ensure that telemedicine is appropriately defined in each state's medical practice statutes and its regulation falls under the jurisdiction of the state medical board. Policies H-275.978 and H-275.955 urge licensing jurisdictions to adopt laws and regulations facilitating the movement of licensed physicians between states. Policy D-275.994 supports the Compact and directs the AMA to work with interested medical associations, the FSMB and other interested stakeholders to ensure expeditious adoption by the states of the Interstate Compact for Medical Licensure.

Policies H-480.974, H-480.968 and H-480.969 encourage national medical specialty societies to develop appropriate and comprehensive practice parameters, standards and guidelines addressing the clinical and technological aspects of telemedicine. Policy H-480.968 urges national private accreditation organizations to require that medical care organizations that establish ongoing arrangements for medical care delivery from remote sites require practitioners at those sites to meet no less stringent credentialing standards and participate in quality review procedures that are at least equivalent to those at the site of care delivery.

The AMA has substantial scope of practice policy, including Policies D-160.995, H-270.958, and H-160.949. Principles for the supervision of nonphysician providers when telemedicine is used are outlined in Policy H-160.937. This policy states that in all settings and circumstances, physician supervision is required when nonphysician providers deliver services via telemedicine, and the extent of supervision provided by the physician should conform to the applicable medical practice act in the state where the patient receives services. Policy H-160.937 further states that nonphysician providers who deliver services via telemedicine should do so according to the applicable nonphysician practice acts in the state where the patient receives such services. Code of Medical Ethics Opinion 1.2.12 states that physicians who provide clinical services through telemedicine must uphold the standards of professionalism expected in in-person interactions, follow appropriate ethical guidelines of relevant specialty societies and adhere to applicable law governing the practice of telemedicine.

Consistent with AMA policy, AMA model state legislation ensures that, with certain exceptions (eg, curbside consultations, volunteer emergency medical care), physicians and other health practitioners practicing telemedicine are licensed in the state where the patient receives services or are providing these services as otherwise authorized by that state's medical board. A Continuing Medical Education (CME) module, "Adopting Telemedicine in Practice," outlines steps physicians should take before adopting telemedicine into practice and is available on the AMA Ed Hub.

DISCUSSION

The Council appreciates the intent of referred Resolution 215-I-18 and understands the frustrations of the authors. It is increasingly challenging for physician practices to compete with large commercial entities that are contracting with payers to provide telemedicine services, including primary care services. Commercial direct-to-consumer telemedicine enables patients to receive care from their homes, offices or mobile devices; however, these encounters are provided outside of a patient's medical home and can lead to fragmented care. Where there is an established patient relationship, a physician should be able to use telemedicine to provide quality emergent or urgent care for a patient's existing condition when that patient is traveling in another state.

The Council also discussed potential unintended consequences of the model legislation requested via referred Resolution 215-I-18, which would create an exception for primary care physicians who work in accredited patient-centered medical homes and would ultimately be very disruptive to existing laws and regulations. The Council is concerned that such legislation, if implemented, could result in national oversight of telemedicine provided across state lines, and that any national oversight would be subject to influence by a variety of stakeholders including physicians, but also commercial telemedicine providers and retail health clinics. Additionally, the Council believes it would be difficult to limit the suggested exception to primary care physicians. It is possible that direct-to-consumer telemedicine providers would be able to become medical homes, which could in turn lead to other unintended consequences, such as the overprescribing of antibiotics.⁸

The Council believes that patient safety must remain a primary consideration during discussions of proposals to enhance patient access to care through telemedicine, and that maintaining AMA policy in support of state licensing boards having authority over medical services where patients are located prioritizes patient protections. The Council notes that treating physicians not licensed by the state where a patient is located may not receive public health department alerts, including notice of local outbreaks such as measles or food borne illness.

 The Council discussed the concerns raised by referred Resolution 215-I-18 and believes that the Compact is a sensible and viable approach to facilitating multistate licensure without undermining state jurisdiction over medical practice and patient health. The Council acknowledges that the licensing option available under the Compact is not yet available to all physicians because not all states have become members of the Compact. However, within two years after its official launch, over half of all states joined the Compact and it was used by more than 3,000 physicians to secure more than 5,400 medical licenses in Compact member states. The Council recognizes the importance of persuading remaining states to join the Compact, which will ultimately facilitate multistate licensure for most physicians who want it, and recommends that our AMA work with state medical associations to encourage states that are not part of the Compact to consider joining it as a means of enhancing patient access to and proper regulation of telemedicine services.

With respect to the travel considerations raised in referred Resolution 215-I-18, the Council discussed the ability of physicians to provide telemedicine services to their patients while they are traveling to another state and points to the practical exemptions from state licensure requirements already encompassed in AMA policy—for emergent or urgent circumstances and "curbside consultations." Physicians who wish to provide telemedicine services to patients in a state where they are not licensed are encouraged to direct inquiries to that state's medical board.

Finally, the Council believes that state-based exceptions and carve-outs of not only AMA telemedicine policy, but also state licensure laws, will further complicate oversight and regulation

and could potentially diminish the standards and patient safeguards that are centerpieces of AMA policy. Accordingly, the Council also recommends reaffirming Policies H-480.946 and H-480.969.

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RECOMMENDATIONS

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The Council on Medical Service recommends that the following be adopted in lieu of Resolution 215-A-18, and the remainder of the report be filed:

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10 11 1. That our American Medical Association (AMA) work with state medical associations to encourage states that are not part of the Interstate Medical Licensure Compact to consider joining the Compact as a means of enhancing patient access to and proper regulation of telemedicine services. (Directive to Take Action)

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2. That our AMA reaffirm Policy H-480.946, which delineates standards and safeguards that should be met for the coverage and payment of telemedicine, including that physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services. (Reaffirm HOD Policy)

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That our AMA reaffirm Policy H-480.969, which maintains that state medical boards should require a full and unrestricted license in that state for the practice of telemedicine, with no differentiation by specialty, unless there are other appropriate state-based licensing methods, and with exemptions for emergent or urgent circumstances and "curbside consultations." (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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² Federation of State Medical Boards. Understanding Medical Regulation in the United States. Available online at: https://www.fsmb.org/siteassets/education/pdf/best-module-text-intro-to-medical-regulation.pdf.

³ Federation of State Medical Boards. Telemedicine Policies: Board by Board Overview. Jan. 23, 2018. Available online at: http://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf. ⁴ Ibid.

⁵ American Medical Association. Statement for the Record to the Federal Trade Commission's Economic Liberty Task Force. Streamlining Licensing Across State Lines: Initiatives to Enhance Occupational License Portability. July 20, 2017. Available online at: https://searchlf.ama-

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⁶ American Medical Association. Statement for the Record to the Federal Trade Commission's Economic Liberty Task Force. Streamlining Licensing Across State Lines: Initiatives to Enhance Occupational License Portability. July 20, 2017. Available online at: https://searchlf.ama-

⁷ The Interstate Medical Licensure Compact website: https://imlcc.org/.

⁸ Ray KN, Shi Z, Gidengil CA, Poon SJ, Uscher-Pines L and Mehrotra A. Antibiotic prescribing during pediatric direct-to-consumer telemedicine visits. *Pediatrics* 143, No. 5 (May 2019).

⁹ The Interstate Medical Licensure Compact. Press Release dated April 27, 2019.

REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-19) Addressing Financial Incentives to Shop for Lower-Cost Health Care (Reference Committee J)

EXECUTIVE SUMMARY

The Council on Medical Service presents this report to examine the practice of employers and insurance companies increasingly implementing programs (ie, Financial Incentive Programs or FIPs) that offer patients financial incentives when they use shopping tools to compare prices on health care items and services and choose lower-cost options. This report examines the potential benefits and risks of FIPs, analyzes examples of current FIPs, and offers guidance on how FIPs could be improved.

Virtues of FIPs include promoting price transparency, empowering patients to pursue health care that minimizes financial burden and reducing societal health care costs. At the same time, it is critical that patients be empowered to make fully informed decisions about their health care, that they are never coerced into accepting lower-cost care if it could jeopardize their health, and that programs that influence patient decision-making be equally transparent about quality and cost. To protect patient access to high-quality care, the Council recommends a set of guiding principles that it encourages health care payers (employers, insurance companies, etc.) and third-party vendors to incorporate into the design and implementation of FIPs. These guiding principles focus on protecting physician involvement in FIPs, the patient-physician relationship, quality assurance and transparency, and patient choice. To further promote these ideals, the Council recommends that the American Medical Association (AMA) encourage state medical associations and national medical specialty societies to seek opportunities to collaborate in the design and implementation of FIPs to empower physicians and patients to make high-value referral choices, and to encourage objective studies of the impact of FIPs.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-19

Subject: Addressing Financial Incentives to Shop for Lower-Cost Health Care

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

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While encouraging patients to pursue lower-cost health care, employers and insurance companies are increasingly implementing programs (ie, Financial Incentive Programs or FIPs) that offer patients financial incentives when they use shopping tools to compare prices on health care items and services and choose lower-cost options. The Council on Medical Service presents this Council-initiated report to examine the emergence and impact of FIPs, as well as the potential benefits and risks of FIPs, and to offer guidance on how FIPs could be improved.

BACKGROUND

Care can be deemed "shoppable" when it is a common service that can be researched in advance, multiple providers of that service are available in a market, and sufficient data about the prices and quality of services are available. Estimates vary as to what proportion of health care spending can be deemed "shoppable," with some estimates at 10 percent, and others as high as 33 to 43 percent.

FIPs appeal to employers and insurers because they encourage patients to price shop without exposing them to increased out-of-pocket costs.⁵ Additional virtues of FIPs include promoting price transparency, empowering patients to pursue health care that minimizes financial burden and reducing societal health care costs. While considering these potential benefits of FIPs, it is critical to ensure that patients are empowered to make fully informed decisions about their health care, that they are never coerced into accepting lower-cost care if it could jeopardize their health, and that programs that influence patient decision-making be equally transparent about quality and cost.

FIPs in the private sector can be used by employers as part of employee benefit packages, or health insurance companies can implement FIPs for their enrollees. In the public sector, some states have implemented FIPs as part of state employees' benefits. The Council discusses various models that have emerged to encourage and assist patients shopping for lower-cost health care. The models vary with respect to the level of voluntary versus potentially coercive impact on patients. With this report, the Council emphasizes the protection of patients and the patient/physician relationship; and recommends a series of principles to address the potential of FIPs to further fragment patient care.

POTENTIAL BENEFITS AND RISKS OF FIPs

Potential Benefits

FIPs could benefit patients, payers, and the health care system in several ways. Both underinsurance and cost-related non-adherence pose significant challenges to patients and providers. Even when a service is covered by a health plan, patients may incur significant costs in

the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo necessary care. 6 Similarly, cost-related non-adherence refers to a state in which patients are unable to pursue recommended medical care due to financial barriers. For example, greater out-of-pocket costs for medication to treat certain chronic conditions have been found to reduce initiation and adherence, lower the likelihood of achieving desired health outcomes, and sometimes, increase utilization of acute care services.⁸ In contrast, studies have demonstrated that reducing or eliminating cost-sharing leads to improvements in medication adherence⁹ and reductions in socioeconomic and racial disparities.¹⁰ Accordingly, FIPs could potentially increase patients' access to medical care that may have been financially out-of-reach for them. Additionally, when patients make cost-effective treatment choices, those savings can benefit payers and the health care system. Moreover, even if patients do not alter their treatment plans, having information about the cost of planned medical care provides much needed transparency. Finally, if the care being incentivized by FIPs is, in fact, high-quality care, these programs could be consistent with longstanding American Medical Association (AMA) policy supporting value-based insurance design, as an opportunity to align clinical and financial incentives for patients to pursue high-value care.

FIPs could also be significantly enhanced by including referring/prescribing physicians in the "shopping" experience at the point of care. Treating physicians' referral recommendations play a critical role in patients' choices regarding follow-up care. FIPs that embrace the importance of physician referrals could benefit patients, physicians and other elements of the health care system. If patients' FIP benefits could be made available to treating physicians in real time during patient consultations, patients and their trusted physicians could work together to choose the best referral and/or prescription option, considering both quality and cost of care. Such fully informed referrals could enhance efficiency, quality, and cost of care.

Potential Risks

FIPs raise many questions that must be answered to determine whether they are truly in patients' best interests. As an initial matter, FIPs raise several administrative questions. Health care is uniquely complex and cannot simply be shopped like retail goods. Key limits on shopping for

health care include:

Patient Limits: Even if a service is shoppable for some patients, for other patients, shopping for that service may not be convenient, practical or advisable. Similarly, prescription drugs can be shoppable in some cases, but not in others. Some patients find less expensive drugs just as efficacious as more expensive alternatives, but specific formulations are required by others. While some patients may find that a lower-priced prescription drug could be appropriate, it might require additional burden for the patient (such as more frequent dosing) and/or the provider (such as required monitoring and/or testing). In such cases, patients must fully understand and be willing to accept the additional burden.

<u>Care Coordination and Quality of Care</u>: If shopping for lower-cost care leads patients to obtain care from a variety of physicians and facilities, absent an integrated records system, there is a potential for fragmentation of care, which creates additional challenges for patients and physicians in receiving and providing quality care.

<u>Administrative Burden</u>: If, after receiving a referral or prescription from their physicians, patients shop for and choose to pursue lower-cost care, both the patients and their physicians may face time-consuming administrative burdens. Patients may need to reach out to their referring

physicians for new prescriptions and/or new referrals, and they may have to seek copies of their medical records to facilitate care coordination.

FIPs also raise concerns about quality of care and unintended consequences, and these become especially fraught when working with already vulnerable patient populations, such as those with low incomes and/or costly chronic conditions, who may be unduly persuaded by enticing financial incentives. Here the question of whether patients are truly presented with meaningful choices versus the extent to which they are somewhat coerced into accepting a non-preferred care option becomes more complicated. Key considerations include continuity of care and the tradeoff between quality and cost.

Continuity of Care: It is unclear whether FIPs will interfere in patient-physician relationships and/or attempt to substitute for medical advice. Patients should be empowered to reach out to whomever they would like in researching their care options. However, if patients have received referrals or prescriptions from their physicians and have not made efforts to shop for alternative options, programs that proactively reach out to such patients to suggest alternative courses of treatment risk harming the trust built between patients and their physicians and risk substituting their judgement for medical advice. Additionally, it is not clear how the "health professionals" providing patient assistance through some FIPs are trained, but even if providing referrals is within their scope of practice, these "health professionals" could disrupt existing patient-physician relationships.

Quality/Cost Tradeoffs: Any program that encourages physicians or patients to make quality tradeoffs to reduce cost raises significant questions about unintended consequences. While some care, even if that care is of less than ideal quality, could be better than cost-related non-adherence, the obvious preference is to direct patients to appropriate care while minimizing financial burden. For patients experiencing significant financial burden, either due to expensive medical conditions or due to other social determinants of health, it is especially important to acknowledge and safeguard against crossing the fine line between an optional financial incentive and implicit coercion to accept the least expensive care.

While the FIPs described in this report claim to base their decisions on care quality, it is not clear what metrics or data are used to evaluate quality, nor is it clear if their metrics align with well-established, evidence-based quality criteria developed by national medical specialty societies. Accordingly, it is possible that these programs could steer patients to care that is of lesser quality than the original physician referral. Transparency regarding FIPs quality data and analyses is essential.

INTRODUCTION TO CURRENT FIPS

Generally, shopping programs are available through preferred provider organization (PPO)-style plans that offer patients broader choices of providers from whom they can receive care. Patients enrolled in Health Maintenance Organizations (HMOs) and/or narrow-network plans are restricted to a smaller set of medical providers and may be unable to access higher quality and lower cost health care. ¹² Additionally, patient cost-sharing varies significantly based on insurance benefit design, and some design features will provide greater or lesser incentives for patients to shop for lower-cost care. ¹³

The decision to implement an FIP can come from the private and/or public sector. In the private sector, employers can choose to implement FIPs as part of their employees' benefits packages, or health insurance companies can implement FIPs for their enrollees. In the public sector, some

states have chosen to implement FIPs as part of state employees' benefits packages (eg, New Hampshire) or via legislation that requires some private insurers to offer pay-to-shop incentives (eg, Maine). ¹⁴ Multiple tools have emerged to encourage and assist patients shopping for a broad spectrum of care.

Sapphire Digital: More than 350 health plans and employers, representing over 95 million members, use the Sapphire Digital platform to incentivize patients to shop for care. Sapphire Digital's SmartShopper program works by integrating directly with an employer's benefit program. SmartShopper reaches patients through several channels: call centers, web chat assistants, direct mail campaigns, and an online platform where patients can compare prices. SmartShopper is aimed at patients, but it requires partnerships with local providers, employers, and payers. The FIP provides cash incentives to encourage patients to shop for what the company describes as "routine care" including, imaging services, labs, specialty drugs, preventive exams and outpatient surgeries. The extent to which these services are truly routine, however, is subjective. Approximately 200 procedures can be shopped through the SmartShopper program, with about 50 services being responsible for the bulk of the savings. After comparing prices, if patients choose to receive care from one of the identified lower-cost providers, they will be mailed a check, with incentives on average ranging from \$25 to \$500 per individual service. In 2018, the most shopped medical procedures were lab/blood work, mammogram, magnetic resonance imaging (MRI), colonoscopy, and computerized tomography (CT) scan.

Critically, it is unclear what quality metrics Sapphire Digital uses to determine whether the lower-cost services it incentivizes are in fact "better value" and "high-quality." Sapphire Digital provides shoppers with quality data from Quantros which has been described as, "a patent pending proprietary composite scoring system which integrates outcome quality measures, such as readmission, complication and mortality rates, into a single, multidimensional composite quality score. The data are risk-adjusted and rendered as an easy-to-understand rating for individual physicians, hospitals and health systems." Previously, Sapphire Digital had described its quality data as incorporating "structure" and "patient experience" measures.

Sapphire Digital recently took health care shopping a step further when it launched its Medical Expertise Guide (MEG) in late 2018.²³ MEG builds upon the SmartShopper tool in two critical ways: first, it focuses specifically on influencing patients' choices for surgical procedures; and second, rather than relying on patients to engage with the tool because they are interested in shopping for care, MEG enables Sapphire Digital to predict which patients might need care and proactively reaches out to those patients. The program's engagement strategy is based on predictive analytics and modeling, used to identify patients on a clinical path that could lead to expensive surgery. In describing their methods for identifying high-quality care, Sapphire Digital explains that MEG applies quality measures such as infection and complication rates, patient reviews, predictive analytics, and "proprietary confidence measures." MEG also provides assistance from "highly-trained health care professionals." This novel technology has the potential for both significant benefits and risks.

<u>UnitedHealthcare (UHC)</u>: In addition to incentivizing patients to shop for lower-cost health care services, FIPs can incentivize patients to choose lower-cost prescription drugs. UHC recently launched its My ScriptRewards program that allows patients to earn up to \$500 in prepaid debit cards that can be used to pay medical expenses when they choose "doctor-approved, guideline-recommended and cost-effective medications" to treat HIV.²⁵ UHC explains that the Department of Health and Human Services (HHS) has recommended several HIV treatment regimens, and the cost among these regimens can vary significantly. UHC has selected two regimens (Cimduo® + Tivicay® (two-pill regimen) and Cimduo + Isentress®/Isentress HD® (three-pill regimen)) and

incentivizes patients to choose one of these lower-cost regimens by offering these regimens with no patient cost-sharing, plus the prepaid debit card rewards.

With the lower cost of UHC's preferred regimens, however, come some key distinctions between UHC's preferred HIV treatments and other options. Critically, HHS guidelines issued in late 2018 selected Biktarvy, a treatment that is not eligible for the UHC incentive, as a preferred regimen, whereas UHC's preferred regimens do not appear on the list of HHS recommended initial treatments. However, UHC's preferred regimens require patients to take two or three pills a day, whereas Biktarvy is a once-a-day pill regimen. UHC does not explicitly force patients to accept one of the lower-cost prescription options and stresses the importance of patients working with their physicians to determine whether one of the lower-cost treatment regimens is right for them. However, if the lower-cost regimens are not appropriate, the only recourse is to reach out to UHC to determine which alternative regimens are covered under patients' pharmacy benefits, and patients or providers may be forced to explicitly opt out of the My ScriptRewards program in order to fill a non-preferred antiretroviral prescription. Hull UHC plans to expand its My ScriptRewards program to additional high-cost specialty drug categories in the future.

<u>Walmart</u>: In contrast to FIPs focused on identifying lower-cost care, some payers are creating financial incentives that preference demonstrated quality over cost. Concerned that employees were being misdiagnosed, leading to unnecessary surgery and spending, Walmart Inc., the nation's largest private employer, created a program to encourage patients to go to specific imaging centers based on diagnostic accuracy, not price. Walmart employees do not have to choose a preferred imaging center, but if they do not, they pay additional cost-sharing. Walmart's imaging program is aligned with its efforts over the past decade to create financial incentives for patients to obtain care at designated hospitals where it believes patients will achieve better results. As part of its Centers of Excellence program, Walmart has selected hospitals across the country that it believes have the expertise and resources to provide its members with the highest-quality care for several medical conditions, including various surgeries and cancer diagnoses. For many of these treatments, patients travel to one of the designated Centers of Excellence, where their care is covered 100 percent and travel and lodging costs are covered for the patient and a companion caregiver.

Anthem/UHC: A similar but clearly distinguishable insurance benefit design feature imposes prior authorization requirements and/or denies coverage when patients choose a higher-priced site of service. Such benefit design features jeopardize physician and patient choice. Anthem and UHC provide examples of this type of program. In addition to Anthem's preapproval process to review the medical necessity of a non-emergency outpatient MRI or CT scan, an Anthem subsidiary also evaluates where the scan should be performed, and provides the requesting physician with a list of eligible imaging centers. Citing the "huge cost disparities for imaging services, depending on where members receive their diagnostic tests," Anthem's program ultimately prevents many patients from receiving MRIs and CT scans at hospital-owned, outpatient facilities, instead requiring them to use independent imaging centers. Similarly, starting in 2019, UHC began conducting site of care reviews, in addition to their prior authorization reviews, when specific advanced diagnostic imaging procedures are requested at an outpatient hospital setting (no additional review is required if the test is to be performed at a freestanding diagnostic radiology center or office setting).

IMPACT OF HEALTH CARE SHOPPING PROGRAMS

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Objective Data

Despite the increasing popularity of FIPs, there is little objective evidence of their impact.³⁵ A working paper from the National Bureau of Economic Research highlights the crucial role of the referring physician. The study suggests that rather than focusing on patient cost-sharing, payers could more effectively help patients pursue lower-cost health care services by providing price information to physicians and incentivizing them to make cost-efficient referrals.³⁶ The study found that patients did not "shop" for care, even when the care at issue was a non-invasive MRI scan, when they were exposed to significant out-of-pocket costs, when they were provided ready access to a price transparency tool, and when they had the opportunity to reduce the price they would pay without traveling a long distance.³⁷ Instead, the study found that referring physicians influence where patients will receive further care far more than patient exposure to out-of-pocket costs, with referring physician influence accounting for 51 percent of variance, and out-of-pocket cost exposure accounting for 2.4 percent of the variance.³⁸ The data studied were comprised of insurance claims data provided by a large national insurer that covers tens of millions of lives annually and is active in all 50 states. However, the main analysis uses data from 2013. The study authors infer that given the weight patients ascribe to the advice of their referring physicians versus the influence of out-of-pocket cost in the context of a lower-limb MRI scan, patients are even less likely to actively price shop for more complex services. Supporting these conclusions, a 2016 analysis by the Health Care Cost Institute, which is funded in part by Aetna, Humana, Kaiser Permanente, and UHC, found only "modest" potential gains from the consumer price shopping aspect of price transparency efforts.³⁹

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In another recent study, the Health Care Service Corporation (the fourth-largest health plan in the United States) collaborated with academic researchers to analyze the impact of the SmartShopper program. 40 Critically, this study did not examine any impacts on quality of care; rather, it was focused on financial impacts and changes in utilization. While the study identified some cost savings for employers and patients, the financial impact was limited. 41 The study estimated a 5.2 percent reduction in annual spending on reward-eligible services, a savings of \$2.3 million per year, or approximately \$8 per patient per year. The study authors noted that, to receive a reward, patients may not be able to receive care from the provider their physician initially recommended. and patients may feel more comfortable seeking a second referral for imaging services, rather than invasive procedures. Moreover, switching providers is particularly complex for surgical procedures, and patients may be more concerned about quality of surgical services. Additionally, the study noted that the availability of lower priced providers may play a role in the results observed. The study authors suggested that the small reduction in utilization among patients in receipt of any reward eligible services could be due to patients using the price comparison tool, becoming aware of the still high out-of-pocket cost of reward eligible services, and choosing not to pursue care. The study concludes that while rewards programs are appealing to employers, they may not be the most effective way to reduce spending.

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50 51 Another recent study specifically focused on quality of care variations that exist among sites of care providing MRIs. ⁴² A first of its kind study analyzed MRI reports following complete lumbar MRI examinations of the same patient, performed at 10 different regional imaging centers, over a period of three weeks. All of the study centers had valid accreditation from the American College of Radiology. The study found "marked variability" in the reported interpretive findings and "an alarmingly high number" of interpretive errors in the MRI reports. ⁴³ Specifically, no interpretive findings were reported in all 10 MRI reports, and only 1 finding (out of 49 total findings) was reported in 9 out of 10 reports. Moreover, the high average miss rate across the examinations

means that important pathologies are routinely under detected, and the high false positive rates for specific pathologies indicate that some diagnostic findings may be routinely over detected. These findings have clear and critical implications for appropriate diagnosis and treatment. Moreover, since payers heavily rely on MRI reports during utilization and authorization review processes, an inaccurate diagnosis on MRI can lead to significant delays in appropriate care. ⁴⁴ In the context of incentive programs, knowing that such significant variation exists among equally accredited providers of a non-invasive imaging examination raises serious questions about the quality of care evaluations FIPs perform before making referral recommendations that may differ from the patient's treating clinician.

Data from Sapphire Digital

In contrast to the objective research studies that question the impact of patients shopping for lower-cost health care, Sapphire Digital claims its tools have achieved more significant cost savings across the continuum of care. As of 2018, Sapphire Digital claims that, over the course of four years, its program saved employers over \$56 million, and employers paid \$6.7 million in cash incentives to their employees. Sapphire Digital stated that, on average, patients save \$606 per procedure shopped on SmartShopper. In 2016, Sapphire Digital published an analysis that extrapolated potential health care system wide savings of \$17.6 billion on colonoscopies alone. Data provided by plans that have implemented SmartShopper can support Sapphire Digital's claims. For example, HealthTrust, a non-profit organization that provides insurance benefits to public employees and began using SmartShopper in 2014, saved \$1.5 million by the end of 2015, \$2.8 million by the end of 2016, and \$2.75 million in the first 10 months of 2017. However, despite increases in engagement, as of 2018, only 10 percent of HealthTrust members regularly used SmartShopper.

AMA POLICY

FIPs relate to a wide variety of AMA policy. Policy H-450.941 expresses the AMA's uncompromising commitment to primacy of the patient-physician relationship free from intrusion from third parties. The policy specifically supports initiatives that protect patient access and that do not contain requirements that permit third party interference in the patient-physician relationship, and it strongly opposes attempts to steer patients towards certain physicians primarily based on cost of care factors. Policy H-450.947 sets forth extensive pay-for-performance principles and guidelines. Especially relevant elements of Policy H-450.947 include a focus on patient-centered, evidence-based care; allowances for variations in individual patient care based on a physician's clinical judgement; providing proactive explanations of programs to the patients impacted; and programs that do not create conditions that limit access to improved care or directly or indirectly disadvantage patients and their physicians based on geographic, ethnic, cultural, or socioeconomic groups, their medical conditions, or the setting where care is delivered.

AMA policy regarding drug pricing also informs discussion of FIPs. Policy H-110.997 supports programs that contain the rising costs of prescription drugs, with caveats to ensure that physicians have input into such programs, that all patients have access to all prescription drugs necessary to treat their illnesses, and that physicians have the freedom to prescribe the most appropriate drug(s) and method(s) of delivery for individual patients. Policy H-125.991 guides drug formularies and therapeutic interchange, discouraging switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen, while encouraging mechanisms such as incentive-based formularies.

AMA policies on the patient-centered medical home underscore the patient/physician relationship as essential for maintaining continuity of care (Policies H-160.919 and H-160.918). In addition, the Council notes the relevance of AMA Policy H-450.937 regarding medical tourism, which advocates that employers, insurance companies, and other entities that facilitate or incentivize medical care outside the US adhere to several principles, including that such incentives must be voluntary and ensure continuity of care and necessary follow-up care.

AMA policy strongly supports value-based care. Policy H-110.986 provides principles to guide value-based pricing programs for pharmaceuticals, including: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable data; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; and (d) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion. Policy H-155.960 supports value-based decision-making and recognizes the role of physician leadership and importance of collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives. Policy D-185.979 supports value-based insurance design plans and encourages national medical specialty societies to collaborate with payers to promote alignment of patient financial incentives with utilization of high-value services. Policy H-185.935 guides use of reference pricing and supports consideration of reference pricing strategies for elective services for which there is evidence of a significant variation in cost that does not correspond to a variation in quality of care.

DISCUSSION

Patients, physicians, and health care payers alike benefit when it is possible to identify high-quality health care that minimizes patient financial burden and ensures continuity of care. With payers increasingly looking to FIPs as an avenue for reducing patient costs, it is essential that health care quality not be sacrificed in the process, and that fragmentation of care is minimized. To protect these and other critical elements of high-quality care, the Council recommends a set of guiding principles for use in the development and implementation of FIPs.

Physicians are committed to providing and helping their patients obtain evidence-based, high-quality, cost-effective care. Accordingly, patients will benefit if physicians are involved in the development and implementation of patient incentives. Physicians should also be consulted by FIPs to identify high-value referral options. FIP benefit information should be integrated into health care information technology with real-time access to empower patients and physicians to make optimal referral and prescription choices efficiently, reduce subsequent administrative burden, and promote improved quality and cost of care.

FIPs must avoid adding to the fragmentation of patient care by informing referring and/or primary care physicians when their patients have selected an FIP service and by providing a full record of the service encounter. In addition, it is critical that patient care plans are first developed and discussed between patients and their physicians. FIPs should make it clear that only the treating physician can determine whether a lower-cost option is appropriate. Patients should be encouraged to consult with their physicians prior to deviating from established patient care plans.

It is also essential that FIPs remind patients that they can choose their physician or facility, consistent with their health plan benefits. FIPs should provide transparency regarding the quality data they use in making referral recommendations so that patients and physicians can be confident that lower-cost care meets their quality expectations. Similarly, FIPs should provide transparency

of their quality ratings of participating physicians and facilities and provide physicians with directions for appealing exclusion from lists of preferred lower-cost physicians. The Council also recommends that patients and physicians should have access to a process for publicly reporting unsatisfactory care with FIP options.

FIPs should provide meaningful transparency of both prices and vendors. Patients should fully understand any cost-sharing, other burdens or trade-offs, and incentives associated with receiving care from FIP-preferred physicians and facilities.

To further promote the ideals articulated in the principles, the Council recommends that health insurers that contract with FIPs should indemnify patients for any additional medical expenses that result as follow-up in cases where the FIP service is inadequate, such as a scan that is not useful to the referring physician. The insurer should cover the follow-up scan with no patient cost-sharing. The Council also recommends that state and medical associations and national medical specialty societies apply these principles and seek opportunities to collaborate in the design and implementation of FIPs to empower physicians and patients to make high-value referral choices and recommends objective studies of the impact of FIPs. With FIPs at the intersections of local health care and nation-wide large employer benefit plans, as well primary care referrals to specialists, the AMA and the Federation of Medicine have complementary roles to play in promoting optimal patient care.

Finally, given the lack of data on the impact of current FIPs, the Council recommends objective studies on various aspects of FIPs.

RECOMMENDATIONS

patient incentives.

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the following continuity of care principles for any financial incentive program (FIP):

a) Collaborate with the physician community in the development and implementation of

b) Collaborate with the physician community to identify high-value referral options based on both quality and cost of care.

c) Provide treating physicians with access to patients' FIP benefits information in real-time during patient consultations, allowing patients and physicians to work together to select appropriate referral options.

d) Inform referring and/or primary care physicians when their patients have selected an FIP service prior to the provision of that service.

e) Provide referring and/or primary care physicians with the full record of the service

f) Never interfere with a patient-physician relationship (eg, by proactively suggesting health care items or services that may or may not become part of a future care plan).

g) Inform patients that only treating physicians can determine whether a lower-cost care option is medically appropriate in their case and encourage patients to consult with their physicians prior to making changes to established care plans. (New HOD Policy)

1 2. That our AMA support the following quality and cost principles for any FIP:

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- a) Remind patients that they can receive care from the physician or facility of their choice consistent with their health plan benefits.
 - b) Provide publicly available information regarding the metrics used to identify, and quality scores associated with, lower and higher-cost health care items, services, physicians and facilities.
 - c) Provide patients and physicians with the quality scores associated with both lower and higher-cost physicians and facilities, as well as information regarding the methods used to determine quality scores.
 - d) Respond within a reasonable timeframe to inquiries of whether the physician is among the preferred lower-cost physicians; the physician's quality scores and those of lower-cost physicians; and directions for how to appeal exclusion from lists of preferred lower-cost physicians.
 - e) Provide a process through which patients and physicians can publicly report unsatisfactory care experiences with referred lower-cost physicians or facilities.
 - f) Provide meaningful transparency of prices and vendors.
 - g) Inform patients of the health plan cost-sharing and any financial incentives associated with receiving care from FIP-preferred, other in-network, and out-of-network physicians and facilities.
 - h) Inform patients that pursuing lower-cost and/or incentivized care, including FIP incentives, may require them to undertake some burden, such as traveling to a lower-cost site of service or complying with a more complex dosing regimen for lower-cost prescription drugs. (New HOD Policy)
- 3. That our AMA support requiring health insurers to indemnify patients for any additional medical expenses resulting from needed services following inadequate FIP-recommended services. (New HOD Policy)
- 4. That our AMA oppose FIPs that effectively limit patient choice by making alternatives other than the FIP-preferred choice so expensive, onerous and inconvenient that patients effectively must choose the FIP choice. (New HOD Policy)
- 5. That our AMA encourage state medical associations and national medical specialty societies to apply these principles in seeking opportunities to collaborate in the design and implementation of FIPs, with the goal of empowering physicians and patients to make high-value referral choices. (New HOD Policy)
- 38 6. That our AMA encourage objective studies of the impact of FIPs that include data collection on dimensions such as:
 - a) Patient outcomes/the quality of care provided with shopped services;
 - b) Patient utilization of shopped services;
 - c) Patient satisfaction with care for shopped services;
- d) Patient choice of health care provider;
- e) Impact on physician administrative burden; and
- 45 f) Overall/systemic impact on health care costs and care fragmentation. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-19

Subject: Improving Risk Adjustment in Alternative Payment Models

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

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Medicare and other payers are shifting away from the fee-for-service (FFS) model toward alternative payment models (APMs). A goal of APMs is to better deliver high quality care in a cost-efficient manner to improve outcomes. APMs can eliminate barriers to care coordination that are often present in traditional payment systems. For example, FFS generally does not support the resources that would be required to take after-hours calls from patients to help them avoid emergency visits; provide self-management education to help patients manage their conditions at home; or conduct proactive outreach to ensure patients get needed preventive services.

Often, the complex FFS patient will have additional insurance claims filed for their additional needed services. APMs that pay for services in a more aggregated way, such as a bundled payment for an episode of care or a monthly payment for each patient, need to have a means of adjusting payments to account for patients that need more services. Risk adjustment can serve as a tool to make APM payments better reflect differences in patient characteristics and need for services.

It is important to note that risk adjustment is distinct from both the assumption of financial risk and risk associated with professional liability. In an APM with downside financial risk, APM providers may be accountable for providing care within a capped payment amount and need to either absorb or repay spending in excess of that amount. Risk adjustment, the focus of this report, is a mechanism for adjusting payment rates, budgets, or both, based on the health status and expected spending on a patient population. Improved risk adjustment models will have positive spillover effects in other areas of payment policy, importantly in the Merit-based Incentive Payment System (MIPS), which adjusts FFS payments up or down according to performance in four categories. Similar to APMs, MIPS scores should be risk adjusted to account for variations in patient complexity, sociodemographic factors, and costs outside of the physician's control. As many small and specialty practices will stay in MIPS, better risk adjustment is needed to avoid unfairly penalizing those who care for the sickest and most vulnerable.

This report, initiated by the Council, provides background on risk adjustment; outlines refinement strategies; summarizes relevant policy; details American Medical Association (AMA) work on adjustment improvements; and presents policy recommendations to improve risk adjustment.

BACKGROUND

Risk is the process of modifying payments and benchmarks and allowing payers to estimate future spending. Risk adjustment systems assign patients a risk score based on demographic factors and health status. Demographic factors may include age, gender, dual eligibility for Medicare and Medicaid (a proxy for socioeconomic status or disability), and whether the patient resides in the community or in a health care facility. Patient health status is usually based on the diagnosis codes

submitted on claims in a calendar year. The importance of accurate risk adjustment is increasing as organizations such as Accountable Care Organizations (ACOs) and other APMs bear financial risk for managing a patient population as well as understanding the needs of individual patients and tailoring care delivery to each patient.

Despite the rising importance of risk adjustment, there are fundamental problems with current risk adjustment methodologies. Most risk adjustment systems only predict about 20-30 percent of the variation in services and spending across patients and are designed to predict spending on a large insured patient population, not adjust for differences in patient needs. For example, risk adjustment that significantly weighs factors such as age and gender communicates a limited picture of the patient. Such simplistic design can reinforce inappropriate spending, penalize efforts to reduce overuse, and cause providers to focus spending reduction efforts on the wrong patients. Additionally, the current risk adjustment methodologies do not adequately address treatment and outcome differences related to patient characteristics. They do not consider the complexity of a patient's disease nor social risk factors that are outside of the physician's control, such as lack of transportation or food insecurity. Basing risk scores solely on diagnosis, age and gender, for example, can lead to the same scores being assigned to patients who have drastically different needs. Poorly designed risk adjustment likely distorts comparisons of physician spending.

Moreover, most risk adjustment systems use historical information on patient characteristics and not the most current information. Many systems rely on ICD codes via retrospective review of claims data. Basing risk adjustment on prior claims data means that it accounts for the health conditions patients experienced in previous years but not for significant changes in the patient's health status or permanent conditions. Some risk adjustment methods do not account for a patient's disease stage, such as cancer or a patient's functional status, and they often do not account for factors that influence whether a patient is an appropriate candidate for a procedure or treatment. For instance, risk adjustment systems do not distinguish between patients with different cancer stage diagnoses nor do they account for how the patient's disease affects activities of daily living or whether they have a caregiver at home.

Importantly, most risk adjustment systems do not account for social determinants of health (SDOH). The link between non-medical factors and poor health outcomes is well documented; however, non-medical factors largely are absent from risk adjustment methods. To enhance fairness in performance assessment, some hospitals have implemented peer group methodology aimed at creating groups of similar hospitals for comparison purposes to account for hospitals that treat a significant number of patients with SDOH challenges. However, peer group comparisons do not take place at a more micro level, and risk adjustment methods are not sophisticated enough to reliably differentiate between poor quality of care and high medical and social risk. These methodological flaws have the unfortunate effect of inappropriately penalizing physicians who care for patients with SDOH challenges. Ultimately, not accounting for SDOH can make it harder for physicians caring for vulnerable patients to maintain a sustainable practice and therefore can reduce access to care for these populations exacerbating the challenge of getting vulnerable populations the care they need.

VARIOUS RISK ADJUSTMENT STRATEGIES

Risk Stratification

Risk stratification is the process of segmenting patients into groups of similar complexity and care needs.⁵ The first step in risk stratification is to identify high-risk patients. After stratifying patients into groups, practices can more easily make targeted care management decisions and identify those

patients that may have particular care needs. Consequently, the usefulness of stratification models relies on data availability, which should encompass the patient's own assessment of his or her health including SDOH. To date, most risk stratification models use a diagnosis-based formula and do not include many SDOH that materially affect patient's health and ability to follow a particular treatment plan.

One popular method of risk stratification is Medicare Advantage's (MA) Hierarchical Condition Categories (HCC). Both MA plans and Medicare Shared Savings Program (MSSP) ACOs use the HCC methodology, which relies on ICD-10 coding to assign risk scores derived from retrospective claims data review. The algorithm takes into account demographic factors like age and gender, and insurance companies use HCC coding to assign patients a risk adjustment factor (RAF). In turn, insurers then use the RAF score to help portray patients' conditions and predict future costs.

Outlier Payments or Individual Stop Loss Insurance

Outlier payments are additional payments paid for by insurers to physicians or organizations to account for encounters and patients that are exceptionally costly. Outlier payments function as a form of stop-loss insurance. Stop-loss insurance protects the provider against significantly higher than intended patient costs. This strategy is particularly useful when available for providers who care for vulnerable populations. Because many SDOH are not yet included in risk stratification systems and overall risk adjustment systems, the ability to access outlier payments after caring for individuals with known high costs is critical for practice financial viability. The strategy also ensures access to care and appropriate treatment for high-risk populations.

Risk Corridors or Aggregate Stop Loss Insurance

Risk corridors are another mechanism that can protect against adverse selection and insufficient physician payments. Risk corridors function by limiting losses and gains beyond an allowable range. Risk corridors set a target spending amount, and insurers pay into the program to compensate those physicians with patient costs exceeding the target. Risk corridors mirror aggregate stop loss insurance in that physicians are protected against higher than expected total spending.

Payment Adjustment for External Price Changes

Adjustment for external price changes is an important protection for physicians operating in a value-based payment delivery system. Under this mechanism, the physician payment is adjusted for changes in the prices of drugs or services from other providers that are beyond the control of the provider accepting the APM payment. Physicians must only be responsible for the services that they deliver and cannot be held financially or otherwise accountable for spending outside of their control. Payment adjustments protect physicians from spending costs outside of their control.

AMA POLICY

AMA policy promotes physician-led payment reform programs that serve as models for others working to improve patient care and lower costs (Policy D-385.963). Policy H-390.844 emphasizes the importance of physician leadership and accountability to deliver high quality and value to patients. The AMA advocates for providing opportunities for physicians to determine payment models that work best for their patients, their practices, and their regions (Policy H-390.844).

- Policy D-390.953 directs the AMA to advocate with the Centers for Medicare & Medicaid Services (CMS) and Congress for APMs developed with specialty and state medical societies.
- With respect to risk adjustment, Policy H-165.842 states that health insurance coverage of high-risk
 - individuals should be subsidized through mechanisms such as risk adjustment. Policy H-395.908
- 5 states that the AMA will work with CMS and interested organizations to design systems that
- 6 identify new data sources to enable adequate analyses of clinical and non-clinical factors that
- 7 contribute to a patient's health and success of treatment, such as disease stage and SDOH factors. It
- 8 also calls to account for differences in patient needs, such as functional limitations, changes in
- 9 medical conditions compared to historical data, and ability to access health care services. Policy
- 10 H-395.908 further calls for the AMA to explore an approach in which physicians managing patient
- 11 care can contribute additional information, such as disease severity, that may not be available in
- existing risk adjustment methods to more accurately determine the appropriate risk stratification.
- Policy H-390.849 calls for adequate risk adjustment methodologies and encourages attribution
- processes that emphasize voluntary agreements between patients and physicians. The policy also
- states that reformed payment rates must be sufficient to maintain a sustainable medical practice and
- that payment reform implementation should be undertaken within a reasonable timeframe and with
- 17 adequate assistance.

AMA ACTIVITY

Risk adjustment and risk stratification for APMs have been important components of AMA advocacy on ACOs and other APMs. The AMA has long called for Medicare to allow ACO patients' risk scores to increase over time if their health care needs warrant, and the 2018 Pathways to Success ACO regulation finally permits such an increase for the first time since the program's inception. The AMA also has discussed new approaches to risk stratification and risk adjustment in physician-focused APMs at its APM workshops. AMA comments to the Physician-focused Payment Model Technical Advisory Committee and the Center for Medicare and Medicaid Innovation on proposed APMs have repeatedly urged improved approaches to risk adjustment and urged Medicare to provide organizations developing APM proposals with claims and other data analyses that they can use to improve their risk adjustment methods.

The AMA also is advocating for improvements to the risk adjustment methodologies in MIPS. For instance, the AMA supports and is engaged in developing episode-based cost measures which account for Medicare Parts A and B spending around a clinically cohesive set of medical services rendered to treat a given medical condition. With AMA input, CMS has developed risk adjustment methods for the episodes that account for patient characteristics that can influence spending outside of the control of the clinician. These measures were first introduced in 2019, and more evidence and testing are needed to determine the accuracy and validity of these measures and their methodologies. In addition, the AMA has advocated for the elimination of the flawed total cost of care measure, which holds physicians accountable for costs outside of their control.

The AMA continues to support the complex patient bonus in MIPS, which applies at the final score to adjust for patient complexity. The complex patient bonus is based on the physician's attributed beneficiaries' average HCC risk score and the proportion of dually eligible patients. This serves as a proxy to capture the clinical complexity of the patient panels for a physician or practice. However, this approach does not sufficiently identify patients with social risk factors that can affect a patient's access to medications, treatments, and other services. While adjustment based on the clinical complexity of the patients served through the complex patient bonus is a step toward addressing disparities, CMS must continue to explore and incorporate additional risk factors and strategies.

Additionally, the AMA's Integrated Health Model Initiative (IHMI) has developed a data model related to the common data elements and terminologies for communicating SDOH. The AMA is collaborating with the largest SDOH standards project in the health information technology community, known as the Gravity Project hosted by the Social Interventions Research and Evaluation Network at the University of California – San Francisco (SIREN). 10 IHMI and UnitedHealth Group (UHG) plan to jointly develop a set of use cases that leverage this common data set and publish this use case via the Gravity project. Once the data are standardized and there are sufficient data in the form of patient outcomes related to the standardized SDOH, data driven predictive risk analyses can be formulated. At this point, SDOH risk calculation can be achieved and is based on published research and limited and non-standardized data sets. The goal is to ensure the industry-backed and accepted SDOH data set is complete and suitable for clinician decision making to improve patient outcomes. Moreover, IHMI is working on the creation of 23 new ICD-10 codes related to SDOH such as access to nutritious food and the financial ability to pay for medications.

DISCUSSION

Adverse selection of high-risk patients is an impediment to equitable patient care and successful payment reform. Evidence confirms that factors such as functional impairment and socioeconomic status are strongly associated with increased costs and hospital readmissions, and the exclusion of such factors from risk adjustment systems negatively affects the financial viability of physicians and organizations serving high-risk individuals. Thus, poorly designed risk adjustment systems are a harm to vulnerable populations who may experience decreased access to care. ¹¹ The Council reiterates that this report is about risk adjustment, not the assumption of risk. However, it recognizes that the two concepts are linked in that physicians must have better risk adjustment methods available if they are to be expected to access risk arrangements. ¹² The Council believes that proper risk adjustment is essential if providers are to be held accountable for outcomes.

Throughout the transition to value-based care, the AMA has been vocal that physician accountability must be limited to aspects of spending and quality that they can reasonably influence. Accordingly, the Council recommends supporting payment adjustment for external price changes that are beyond the physician's control and supporting accountability measures that exclude services that the physician does not deliver, or order, or otherwise have the ability to influence. The AMA also continues to advocate for reduced administrative burden, particularly that related to electronic health records, and the Council reaffirms this commitment.

Additionally, a payment formula that relies solely on medical problems but ignores social risk and functional status can have the effect of underpaying those who care for vulnerable populations and exacerbate health disparities. ¹³ Clinical coding must be coupled with risk adjustment systems, and the two concepts must work in concert to find ways to distinguish between disease states and functional status. Meaningful risk adjustment must allow for variance within existing general diagnoses to capture characteristics specific to individual patients. To that end, the Council recommends supporting risk stratification that varies payment rates based on patient characteristics, including SDOH. Further, the Council recommends supporting outlier payments that increase payment if spending on an individual exceeds a pre-defined threshold or supporting individual stop-loss insurance paid by insurers. Similarly, the Council recommends supporting risk corridors that increase payment if spending on all patients exceeds a pre-defined percentage above the payments or supporting aggregate stop loss insurance. If physicians received extra payments for caring for high-risk and vulnerable populations, these payments could help not only sustain physician practices but also fund services that improve health equity.

 1 Improving risk adjustment and its functions will become increasingly relevant to the viability of 2 practices and the overall health care system. Thorough and accurate risk adjustment not only helps 3 physicians garner the appropriate payment to support practice sustainability, but also helps 4 physicians become more successful in managing their patients. The Council believes that the goal 5 of proper risk adjustment and delivery system reform is tailored interventions and better patient 6 outcomes, and it believes that its recommendations are a step in the right direction. The Council 7 will continue to monitor the rapidly evolving area of risk adjustment methodologies.

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RECOMMENDATIONS

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The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

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21 22 1. That our American Medical Association (AMA) reaffirm Policy H-385.908 stating that the AMA will work with the Centers for Medicare & Medicaid Services and interested organizations to design systems that identify data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as disease stage and socio-demographic factors; account for differences in patient needs, such as functional limitations, changes in medical conditions, and ability to access health care services; and explore an approach in which the physician managing a patient's care can contribute additional information, such as disease severity, that may not be available in existing risk adjustment methods to more accurately determine the appropriate risk stratification. (Reaffirm HOD Policy)

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2. That our AMA reaffirm Policy D-478.995 advocating for appropriate, effective, and less burdensome documentation requirements in the use of electronic health records so that capturing patient characteristics and risk adjustment measures do not add to physician and practice administrative burden. (Reaffirm HOD Policy)

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3. That our AMA support risk stratification systems that use fair and accurate payments based on patient characteristics, including socioeconomic factors, and the treatment that would be expected to result in the need for more services or increase the risk of complications. (New HOD Policy)

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That our AMA support risk adjustment systems that use fair and accurate outlier payments if spending on an individual patient exceeds a pre-defined threshold or individual stop loss insurance at the insurer's cost. (New HOD Policy)

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5. That our AMA support risk adjustment systems that use risk corridors that use fair and accurate payment if spending on all patients exceeds a pre-defined percentage above the payments or support aggregate stop loss insurance at the insurer's cost. (New HOD Policy)

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43 6. That our AMA support risk adjustment systems that use fair and accurate payments for external 44 price changes beyond the physician's control. (New HOD Policy)

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47 48 7. That our AMA support accountability measures that exclude from risk adjustment methodologies any services that the physician does not deliver, order, or otherwise have the ability to influence. (New HOD Policy)

Fiscal Note: Less than \$500

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REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-19) Mechanisms to Address High and Escalating Pharmaceutical Prices (Reference Committee J)

EXECUTIVE SUMMARY

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and concluded that additional policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for pharmaceuticals.

The Council has long prioritized the importance of competition and transparency in the pharmaceutical marketplace, but recognizes that there are multiple situations in which payers have weakened bargaining power, due to lack of competition for some drugs. In addition, there is often limited recourse following an unjustifiable price hike of a prescription medication, leaving patients questioning whether they will be able to continue to afford their medication. As such, the Council recommends policies to promote reasonable pricing behavior in the pharmaceutical marketplace, as an alternative to price controls.

First, the Council recommends principles to guide the use of arbitration in determining the price of prescription drugs, which build upon existing policy in favor of drug price negotiation, and opposed to price controls. Arbitration should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases. Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability. Importantly, arbitration provides an incentive for drug manufacturers and payers to arrive at a negotiated price.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that upholds market-based principles and preserves patient access to necessary medications.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-19

Subject: Mechanisms to Address High and Escalating Pharmaceutical Prices

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, determining whether additional policy was needed to guide future AMA advocacy efforts. In its review, the Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for

 pharmaceuticals.

This report provides background on the impacts of high and escalating prescription drug prices and costs; outlines emerging approaches to address pharmaceutical pricing; and presents policy recommendations.

THE IMPACTS OF HIGH AND ESCALATING PRESCRIPTION DRUG PRICES AND COSTS

Retail prescription drugs account for 10 percent of total health spending,¹ with estimates suggesting that spending on prescription drugs is closer to 15 percent of total health spending when other factors, including the non-retail drug markets and gross profits of other stakeholders involved in drug distribution, payment, and reimbursement are included.² Of significance, spending on specialty drugs is approaching one-half of drug spending.³ The most recent National Health Expenditure projections showed that retail prescription drug spending was estimated to have increased by 3.3 percent to \$344.5 billion in 2018, with a 4.6 percent increase in spending expected in 2019. Drivers behind the rate of growth in prescription drug spending include a higher number of new drug introductions, increased utilization of prescription drugs, and an increase in drug price growth. The projected annual growth in prescription drug spending is expected to average 6.1 percent from 2020 through 2027. Contributions to future growth in spending in the prescription drug sector include increased prescription drug utilization resulting from employer and insurer efforts to remove barriers associated with medications for chronic conditions; expected market release of more expensive drugs for conditions including cancer, diabetes, and Alzheimer's disease; the aging of the population; and modifications to pharmacotherapy guidelines.⁴

Approximately 5.8 billion prescriptions were dispensed in the US in 2018, 90 percent of which were dispensed as generics. The retail price differentials between specialty, brand-name and generic drugs are noteworthy. Examining the retail prices of drugs widely used by older Americans, in 2017 the average annual retail price of therapy for specialty drugs was \$78,781, dropping to \$6,798 for brand-name drugs, and \$365 for generics.⁵ Overall, the list price of the

average brand drug was \$657.08 for a 30-day prescription in 2018, a noteworthy increase from \$364.92 in 2014. The average prices of brand-name drugs at pharmacies before coupons and discounts are applied were \$229 lower than list prices in 2018 for a 30-day prescription.⁶ Average generic pharmacy prices for a 30-day prescription were relatively stable from 2014 to 2018, increasing to \$19.10 from \$18.50.⁷

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Health plans, payers, employers, physicians and patients are facing the increasing financial burden posed by prescription drugs, both brand and generic. In the Medicare program, between 2007 and 2017, Part D program spending has seen an annual growth rate of 5.6 percent, and amounted to \$79.9 billion in 2017. Premiums paid by Part D enrollees for basic benefits (not including low-income subsidy enrollees) amounted to \$14 billion in 2017, which has increased by 13 percent on average annually since 2007. High-cost enrollees are a primary contributor to Part D spending growth, with the associated spending growth for high-cost enrollees resulting from higher drug prices. Under Medicare Part B, drug spending has increased on average by 9.6 percent annually between 2009 and 2017, with the largest driver of this growth in spending being price growth – a combination of increasing prices for existing drugs as well as the introduction of new high-cost drugs in the market. In 2017, \$18 billion of total Part B spending was for drugs administered in physician offices, approximately \$12.3 billion was for drugs administered in hospital outpatient departments, and \$1.8 billion was for drugs provided by suppliers. Page 100.

Rising and high prescription drug prices are impacting Medicaid budgets and state budgets overall. Under the Medicaid drug benefit, drug manufacturers pay rebates to states in return for Medicaid reimbursement for their prescription drugs. Drug manufacturers are required to pay an additional rebate amount if the average manufacturer price (AMP) for a drug rises faster than inflation. From 2014 to 2017, Medicaid outpatient prescription drug spending before rebates increased from \$45.9 billion to \$63.6 billion. The \$34.9 billion collected in rebates brought net Medicaid spending on prescription drugs down significantly in fiscal year (FY) 2017. The proportion of spending geared to brand-name versus generic drugs in Medicaid increased – from 76.6 percent in FY 2014 to 80.5 percent in FY 2017. This growth resulted from an increase in average spending per claim for brand drugs – from \$294 per claim in FY 2014 to \$411 per claim in FY 2017. Of note, the share of spending on specialty drugs has significantly increased in Medicaid – accounting for approximately 44 percent of spending in FY 2017.

Employer-sponsored health plans as well as health plans sold in the individual market have also had to absorb the higher costs of prescription drugs, which often translate to higher premiums, higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the higher costs of specialty and certain generic drugs. In 2018, 88 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs. ¹² This year, almost all standalone Medicare Part D plans have a benefit design with five tiers for generic and brand-name drugs and cost-sharing that deviates from the standard 25 percent coinsurance for all covered drugs between the deductible and the initial coverage limit. ¹³

 The higher costs of prescription drugs are in part passed down to health plan enrollees, and impact physician practices. Ultimately, prescription drug costs can impact the ability of physicians to place their patients on the best treatment regimen, due to the regimen being unaffordable for the patient, or being subject to coverage limitations and restrictions, as well as utilization management requirements, by the patient's health plan. In the worst-case scenario, patients entirely forgo necessary treatments involving drugs and biologics due to their high cost.

In 2018, overall out-of-pocket costs for prescription drugs reached \$61 billion, an increase from \$56 billion in 2014. Across Medicare, Medicaid and commercial health plans, 8.8 percent of

patients pay more than \$500 per year out-of-pocket for prescriptions. Medicare beneficiaries have a notably higher incidence rate of high out-of-pocket expenses for prescription drugs, with almost 20 percent paying more than \$500 out-of-pocket. Nonpreferred generic tiers in many cases have higher copayments than patients have become accustomed to for generic medications. In addition, plans with specialty drug cost-sharing tiers often require coinsurance amounts of 25 to 50 percent, versus requiring a fixed copayment. Considering the costs of many specialty medications, patients could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of specialty drugs in Medicare could cause the number of Part D enrollees who reach the catastrophic coverage threshold to grow substantially, resulting in increases in Medicare spending to plans for reinsurance.

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Increasing patient cost-sharing is associated with declines in medication adherence, which in turn can lead to poorer health outcomes. Among those currently taking prescription drugs, approximately a quarter of adults and seniors have reported difficulties in affording their prescription drugs. Approximately 30 percent of all adults have reported not taking their medications as prescribed at some point in the past year due to cost. Drilling down further, 19 percent of adults have not filled a prescription in the past year due to cost, 18 percent chose to take an over-the-counter medication instead, and 12 percent cut pills in half or skipped doses. Of significance, almost 10 percent of all adults reported that their condition worsened from not taking their medication as prescribed.¹⁵

Notably, out-of-pocket costs for prescription drugs are linked to the rate at which patients newly prescribed a drug either do not pick up their prescription or switch to another product. The rate at which such patients, enrolled in either Medicare or a commercial health plan, abandon their prescription increases significantly once out-of-pocket costs reach \$50. At this point, 31.2 percent of commercially insured patients and 27.6 percent of Medicare patients abandon their prescriptions. ¹⁶

High prescription drug costs, and any declines in medication adherence that may result, can also impact physicians participating in alternative payment models (APMs). For example, Part B drug costs are included in calculations of APM financial risk, even though physicians cannot influence or control drug prices. In addition, physicians in APMs can be affected if poor medication adherence leads to complications or exacerbations that in turn lead to emergency department visits and/or hospital admissions.

EMERGING APPROACHES TO ADDRESS HIGH AND ESCALATING DRUG PRICES

 Escalating and increasingly unaffordable drug prices have caused the Administration, members of Congress and policy experts to put forward innovative proposals to put downward pressure on prices, or more closely tie a drug's price to its value. Whereas proposals that would allow for binding arbitration and contingent exclusivity periods could build upon existing market-based approaches to address pharmaceutical prices and costs, caution would have to be exercised in implementing proposals that leverage international price indices, so as to not merely import international price controls into the US.

Utilizing Binding Arbitration

An emerging policy option that has been put forward to address high and escalating drug prices is using binding arbitration in the event of failed drug price negotiations in order to settle on the final price of the drug. Supporters argue that binding arbitration has the potential to build upon the negotiations that currently take place along the pharmaceutical supply chain that determine

coverage of and payment for prescription drugs. In the US, binding arbitration is currently used in public-sector labor-management negotiations, and Major League Baseball uses the approach in the event of failed negotiations for baseball players' salaries. While negotiated prices between the pharmaceutical company and the payer/government entity in question would remain the preferred solution, arbitration has the potential to help equalize the bargaining power of both parties of the negotiation, while incentivizing negotiating parties to negotiate in good faith. If negotiations fail to conclude with a price agreeable to both parties, they could submit to final offer arbitration or conventional arbitration.

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In final offer arbitration, the arbitrator would be given final bids by the drug manufacturer and the payer/government entity in question. Such bids would be accompanied by data justifying the price put forward by each party, and there would be potential for an independent third party to offer a third price, which can be informed by value-based price benchmarks, comparative effectiveness research, and cost-effectiveness analysis. The arbitrator under final offer arbitration would be required to choose one of three prices: 1) the bid of the drug manufacturer; 2) the bid of the payer/government entity; or 3) the price submitted by the independent third party, if applicable. Alternatively, under conventional arbitration, the arbitrator would not be tied to any of the bids or options put forward; they could select any price they believe is fair. ¹⁷

Case Study: Germany

Germany uses arbitration as one potential pathway to determine the price of a drug in the German market. After a drug is approved by the European Medicines Agency, allowing for the drug to be sold in Germany, a drug manufacturer unilaterally sets the drug's price, applicable for 12 months. At the same time, the manufacturer also is required to submit a report outlining the benefits of the drug to the Federal Joint Committee, comprised of physicians, dentists, hospitals, and health insurers (sickness funds). The Federal Joint Committee forwards the report to the nongovernmental Institute for Quality and Efficiency in Health Care (IQWiG), which conducts an assessment of the clinical effectiveness and benefits of the new drug compared with one or more comparator therapies. After the IQWiG submits its finding, the Federal Joint Committee issues a final decision regarding the level of benefit of the new drug relative to existing therapies that treat the condition in question. Such benefits can include prolonged life expectancy, reduction in side effects, health status improvement, shortening of disease duration and quality of life improvement. A drug is then assigned one of six benefit ratings:

- 1. Major added benefit
- 2. Considerable added benefit
- 3. Minor added benefit
- 4. Nonquantifiable added benefit
- 5. No evidence of added benefit
- 6. Lower benefit than comparator(s)

Depending on a drug's benefit rating, and whether there is a reference group to guide a reference price of a drug, a drug manufacturer can either enter into negotiations with Germany's sickness funds (health insurers), or be assigned to a therapeutic class subject to reference pricing – pricing based on other drugs in the same therapeutic class, including generics. Drugs that enter into negotiations have six months from the Federal Joint Committee decision to agree to a price. If they cannot agree on a price, an arbitration panel is required to set a price within three months, which is binding for the following year. Either party can challenge the decision, which would then trigger IQWiG conducting a cost-benefit analysis. In addition, new findings can serve as cause for the parties to revisit an agreement or arbitration decision after one year. ^{18,19,20}

Relevant AMA Policy

Policy D-330.954 supports federal legislation which gives the Secretary of Health and Human Services (HHS) the authority to negotiate contracts with manufacturers of covered Part D drugs; and states that the AMA will work toward eliminating Medicare prohibition on drug price negotiation and prioritize its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS. Policy H-155.962 states that our AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.

Policy H-110.986 supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion. Policy H-110.986 also supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. Policy H-460.909 outlines principles for creating a centralized comparative effectiveness research entity.

Leveraging an International Pricing Index

Recent proposals put forward by the Administration and members of Congress attempt to lower US drug costs by tying them to international prices, and/or would use an average of international prices, or an international reference price, to help define whether a price of a drug is excessive. In October of 2018, the Administration released an Advance Notice of Proposed Rulemaking (ANPRM) for a proposal entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but outlined the Administration's current thinking and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. At the time that this report was written, a proposed rule on the international pricing index model was expected to be released, which has the potential to differ markedly from what was outlined in the ANPRM.

The ANPRM outlined a new payment model for physician-administered drugs paid under Medicare Part B that will transition Medicare payment rates for certain Part B drugs to lower rates that are tied to international reference prices – referred to as the "international pricing index" – except where the average sales price (ASP) is lower. The international reference price would partly be based on an average of prices paid by other countries. To accomplish this, the proposal would create a mandatory demonstration through the Centers for Medicare & Medicaid Innovation (CMMI), which would apply to certain randomly selected geographic areas, representing approximately 50 percent of Medicare Part B drug spending. Initially, the program would apply only to sole-source drug products and some biologics for which there is robust international pricing data available.

In geographic areas included in the demonstration, CMS would contract with private-sector vendors that will negotiate for, purchase, and supply providers with drug products that are included in the demonstration. CMS would directly reimburse the vendor for the included drugs, starting with an amount that is more heavily weighted toward the ASP instead of the international pricing index, and transitioning toward a target price that is heavily based on the international pricing index. Providers would select vendors from which to receive included drugs, but would not be responsible for buying from and billing Medicare for the drug product.

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An alternative international drug price index has been put forward, which differs from that introduced in the ANPRM: the Market-Based International Index (MBII). Unlike the international price index included in the ANPRM, the MBII excludes developed countries with single-payer health systems that use price controls. Therefore, unlike the index provided for the ANPRM, the MBII does not include Canada, Finland, Greece, Italy, Spain, Sweden and the United Kingdom. The MBII benchmark has two tiers. The first tier represents 60 percent of the benchmark, and includes the Netherlands, Singapore and Switzerland – countries with truly market-based health systems – as well as Denmark, which does not regulate drug prices. The second tier, which constitutes 40 percent of the benchmark, includes Austria, Belgium, the Czech Republic, France, Germany, Ireland, Japan, Portugal, and Slovakia – countries that have a mix of private and public health insurance.²¹

Legislation has also been introduced in Congress that would use international drug prices to determine whether a drug's price is excessive, trigger additional interventions, and serve as an upper limit in drug price negotiations. Senator Bernie Sanders (I-VT) and Representative Ro Khanna (D-CA) have introduced S 102/HR 465, the Prescription Drug Price Relief Act of 2019. Notably, under the bill, the price of a prescription drug would be considered "excessive" if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan. Even if a drug's price does not meet this criterion, or if pricing information is unavailable in at least three of the five countries, a drug's price could still be considered excessive if it is higher than reasonable in light of factors outlined in the legislation, including cost, revenue, and the size of the affected patient population. If brand-name drugs are found to be excessively priced, the drug would be included on a public excessive price database. Open, nonexclusive licenses would be issued for the drug; and review of corresponding applications for generic drugs and biosimilar biological products would be expedited to facilitate competition as well as the entry of lower-cost options into the marketplace. 22,23

In addition, Congressman Frank Pallone (D-NJ) has introduced HR 3, the Lower Drug Costs Now Act of 2019. The legislation would incorporate an international price average as part of authorizing the Secretary of HHS to negotiate drug prices, limited to drugs that lack competition and have the greatest financial impact to the Medicare program and the US health system as a whole, as well as insulin. The Secretary of HHS would directly negotiate with drug manufacturers to establish a maximum fair price for drugs selected for negotiation, which would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. In addition, the drug manufacturer would be required to offer the negotiated price to private group and individual health insurance plans. An "average international market price" would be established to serve as an upper limit for the price reached in any negotiation, if practicable for the drug at hand, defined as no more than 120 percent of the drug's volume-weighted net average price in six countries – Australia, Canada, France, Germany, Japan and the United Kingdom. There would be a financial penalty if a pharmaceutical manufacturer does not participate in or comply with the negotiations.

Relevant AMA Policy and Advocacy

Pursuant to AMA Policy, the AMA submitted comments in response to the "International Pricing Index Model for Part B Drugs" in December 2018. Policy H-155.962 opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. Policy H-110.983 advocates that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- it must be genuinely voluntary and not penalize practices that choose not to participate;
- it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
- it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate health care inflation rate:
- it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of (CAP)-acquired drugs at multiple office locations:
- it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Tying Pharmaceutical Pricing to Market Exclusivity

Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the US, or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for Food & Drug Administration (FDA) review and meet the statutory requirements. Biologic manufacturers have 12 years of exclusivity for innovator (brand-name) products. Innovator biologics also have additional patent protection that generally exceeds exclusivity period by a few years.²⁴

Exclusivity periods for pharmaceuticals are not tied to the list price at which they enter the market, nor to the rate at which they increase in price from year to year. The Council notes that two potential options have been proposed to more closely tie drug market exclusivity to pricing behavior. First, a policy strategy has been put forward to implement contingent exclusivity periods for new brand drugs. Under this policy option, drug manufacturers with a newly approved drug would be able to set their list price at whatever they wish, but the length of the exclusivity period would depend on whether their list price is reasonable, ie, if it aligns with the drug's value. Multiple options could be utilized to assess a drug's value, including cost per quality-adjusted life

year (QALY), or a value-based price benchmark. Contingent exclusivity periods, therefore, could potentially lengthen the exclusivity period for drugs with lower cost per QALY, and reduce the exclusivity period for drugs priced too highly to align with their value. For example, in the case of an innovator biologic, a biologic with a low cost per QALY could see its exclusivity period extended to 15 years from 12 years, whereas a biologic priced too high relative to its value could have its exclusivity period set to 7 years.²⁵

Second, Senator Richard Durbin (D-IL) and Representative Jared Golden (D-ME) introduced S 366/HR 1188, the Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act, which would shorten (but not automatically void) the Food, Drug, and Cosmetic Act market exclusivity period for prescription drugs that experience sudden increases in price. Under the FLAT Prices Act, an increase of the wholesale acquisition cost of a prescription drug of more than 10 percent over a one-year period, more than 18 percent over a 2-year period, or more than 25 percent over a three-year period would result in a reduction of market exclusivity of 180 days. For every five percent increase over these thresholds, the market exclusivity would be reduced an additional 30 days. Manufacturers would be required to report such price increase within 30 days of meeting the criteria for a price increase. Failure to report within the allotted time would result in 30 days of reduced exclusivity daily until the report is submitted. The Secretary of HHS would have discretion to grant a waiver to a manufacturer if the Secretary determines that the price increase is justified and does not unduly restrict patient access to the drug or impact public health. 26,27

Relevant AMA Policy

Policy H-110.987 supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations. The policy also supports drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase; legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment. In addition, it advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase. Finally, it states that our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.

Policy H-110.986 supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help

assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

Policy H-110.986 also supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. Finally, it supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including Hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

DISCUSSION

 Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on patients, on physician practices, and the broader health care system. Patients delay, forgo, or ration their medication when treatments are cost-prohibitive, putting their health at risk. At a time of significantly increasing drug prices, and the launch of products with high list prices, the Council believes that more needs to be done to improve access to and lower the costs of prescription drugs, without stifling innovation.

The Council has long prioritized the importance of competition and transparency in the pharmaceutical marketplace, and believes that negotiation of drug prices between drug manufacturers and payers should continue to be the preferred mechanism to determine how drugs are covered and paid for. That being said, the Council recognizes that there are multiple situations in which payers have weakened bargaining power, due to a drug's lack of competition in the marketplace. In addition, there is often limited recourse following an unjustifiable price hike of a prescription medication, leaving patients questioning whether they will be able continue to afford their medication. As such, the Council recommends policies to promote reasonable pricing behavior in the pharmaceutical marketplace, as an alternative to price controls.

First, the Council recommends principles to guide the use of arbitration in determining the price of prescription drugs, which build upon existing policy in favor of drug price negotiation, and opposed to price controls. Of note, arbitration can serve a role in many circumstances, from negotiating drug prices in Medicare Part D, to any negotiations that take place following a drug product's market entry, as executed in Germany. The Council believes that arbitration should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases. Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability. Importantly, arbitration provides an incentive for drug manufacturers and payers/government entities to arrive at a negotiated price.

To ensure that there is a pathway to use arbitration in Medicare Part D, the Council recommends the reaffirmation of Policy D-330.954, which supports removing the current prohibition that restricts the Secretary of HHS from being able to negotiate drug prices in Part D. In whatever setting arbitration for drug prices is used, the Council underscores that the process should be overseen by objective, independent entities, which would have the authority to select neutral arbitrators or an arbitration panel, with strong conflict-of-interest protections built in.

The Council believes that as part of the arbitration process, and to guide the results, the use of comparative effectiveness research and cost-effectiveness analysis will be critical. Related, the arbitration process should include the submission of a value-based price benchmark for the drug in question to inform the arbitrator's decision, pursuant to Policy H-110.986.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug product to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that uphold market-based principles and preserve patient access to necessary medications. In addition, the Council recommends reaffirmation of Policy H-110.983 outlining standards for any revised Medicare Part B Competitive Acquisition Program, which is relevant considering recent proposals to incorporate an international pricing index in Medicare Part B.

The Council believes that the recommendations of this report add to the already large body of AMA policies that address the high cost of prescription medications, which guide AMA advocacy efforts to improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. Pursuant to these policies, the AMA supports: (1) requiring manufacturer and pharmaceutical supply chain transparency; (2) increasing competition and curtailing anti-competitive practices; (3) ensuring prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow including in the electronic health record; and (4) streamlining and modernizing the utilization control methods used by health insurers in response to higher prescription drug costs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:

a. The arbitration process should be overseen by objective, independent entities;

 b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;

 All conflicts of interest of arbitrators must be disclosed and safeguards developed to
minimize actual and potential conflicts of interest to ensure that they do not undermine the
integrity and legitimacy of the arbitration process;

d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question;

e. The arbitration process should include the submission of a value-based price benchmark for the drug in question to inform the arbitrator's decision;

f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer/government entity;

 g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases; and

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h. The arbitration process should include a mechanism for either party to appeal the

2 arbitrator's decision. (New HOD Policy) 3 4 That our AMA advocate that any use of international price indices and averages in determining 5 the price of and payment for drugs should abide by the following principles: 6 7 a. Any international drug price index or average should exclude countries that have single-8 payer health systems and use price controls; 9 b. Any international drug price index or average should not be used to determine or set a 10 drug's price, or determine whether a drug's price is excessive, in isolation; 11 c. The use of any international drug price index or average should preserve patient access to 12 necessary medications; and 13 d. The use of any international drug price index or average should limit burdens on physician 14 practices. (New HOD Policy) 15 16 3. That our AMA support the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its 17 18 list price at the time of market introduction. (New HOD Policy) 19 20 That our AMA reaffirm Policy H-110.983, which advocates that any revised Medicare Part B 21 Competitive Acquisition Program meet certain outlined standards to improve the value of the 22 program by lowering the cost of drugs without undermining quality of care. (Reaffirm HOD 23 Policy) 24 25 5. That our AMA reaffirm Policy H-110.986, which outlines principles for value-based pricing 26 programs, initiatives and mechanisms for pharmaceuticals, and supports the inclusion of the 27 cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. 28 (Reaffirm HOD Policy) 29 30 That our AMA reaffirm Policy H-460.909, which outlines principles for creating a centralized 31 comparative effectiveness research entity. (Reaffirm HOD Policy) 32

That our AMA reaffirm Policy D-330.954, which states that our AMA will work toward

eliminating Medicare prohibition on drug price negotiation. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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Resolution: 801

(I-19)

Introduced by: Medical Student Section

Subject: Reimbursement for Post-Exposure Protocol for Needlestick Injuries

Referred to: Reference Committee J

Whereas, Needlestick injuries (NSI) occur in a clinical setting and introduce the risk of transmitting bloodborne pathogens such as Hepatitis B, Hepatitis C, and HIV¹; and

Whereas, The Centers for Disease Control and Prevention (CDC) estimates that about 385,000 sharps-related injuries occur annually among health care workers with medical students also at risk of sustaining NSIs^{2,3}; and

Whereas, Due to the risk of contracting aforementioned bloodborne pathogens, the protocol for NSIs is to receive the appropriate post-exposure prophylaxis (PEP) as a means of disease prevention with appropriate diagnostic follow up^{2,3}; and

Whereas, According to recommendations from the International Antiviral Society, the protocol for PEP of HIV specifically for health care workers includes at least 4 weeks of three antiretroviral drug regimen with appropriate laboratory and clinical follow up³; and

Whereas, A systematic review that analyzed the costs associated with NSIs among healthcare workers found these costs to range from \$650 to \$750, while also noting extraneous factors, such as time lost at work, that led to variations in costs⁴; and

Whereas, The review also noted that frequent changes in the indicated antiretroviral therapy further leads to a greater variation and increase in costs, with an approximated median cost of \$1,187⁴; and

Whereas, A cost analysis published by the Kaiser Family Foundation indicated that since 2014, the prices of branded common and specialty drugs have risen by 60% and 57%, respectively⁵; and

Whereas, In addition to presenting a significant financial implication, aforementioned processes related to PEP potentially create a severe emotional burden on those who sustain such an injury^{1,2,4}; and

Whereas, Many NSIs often go unreported, with studies citing the fear of punishment, the financial costs, and the "time consuming process" as a major factor for not immediately reporting an injury^{2,6-8}; and

Whereas, Health care workers that sustain NSI are required to undergo appropriate protocol for exposure, of which all related costs are financially covered under their employer's workers' compensation program⁹; and

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Whereas, While these programs vary by state, medical students are often exempt from the mandatory coverage of workers' compensation that their institution offer to health care workers since they are not considered employees¹⁰; and

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Whereas, As an exception to this, the state of Utah amended policy 53B-14-401 to include medical students within its definition of "interns" stating that interns can become recipients of medical benefits from workers' compensation in the event of occupational injuries and diseases¹¹; and

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Whereas, Although a majority of medical schools require medical students to have a form of health insurance prior to matriculation, the comprehensive costs associated with NSIs are not explicitly stated, and insurance providers inconsistently provide complete coverage of these costs⁴; and

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Whereas, Existing AMA policy addresses the costs and debts associated with undergraduate medical education (H-305.925); therefore be it

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RESOLVED, That our American Medical Association encourage medical schools to ensure medical students can be reimbursed for the costs associated with post-exposure protocol for blood or body substance exposure sustained during clinical rotations either by their insurance provider or the state's workers' compensation fund, where applicable (Directive to Take Action); and be it further

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RESOLVED, That our AMA encourage state societies to work with their respective workers' compensation fund to include medical students as recipients of medical benefits in the event of blood or body substance exposure during clinical rotations. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 08/28/19

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RELEVANT AMA POLICY

Insurance Coverage for Medical Students and Resident Physicians H-295.942

1. Our AMA urges all medical schools to pay for or offer affordable policy options and, assuming the rates are appropriate, require enrollment in disability insurance plans by all medical students;

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- 2. Our AMA urges all residency programs to pay for or offer affordable policy options for disability insurance, and strongly encourage the enrollment of all residents in such plans;
- 3. Our AMA urges medical schools and residency training programs to pay for or offer comprehensive and affordable health insurance coverage, including but not limited to medical, dental, and vision care, to medical students and residents which provides no less than the minimum benefits currently recommended by the AMA for employer-provided health insurance and to require enrollment in such insurance.
- 4. Our AMA urge carriers offering disability insurance to: (a) offer a range of disability policies for medical students and residents that provide sufficient monthly disability benefits to defray any educational loan repayments, other living expenses, and an amount sufficient to continue payment for health insurance providing the minimum benefits recommended by the AMA for employer-provided health insurance; and (b) include in all such policies a rollover provision allowing continuation of student disability coverage into the residency period without medical underwriting.
- 5. Our AMA: (a) actively encourages medical schools, residency programs, and fellowship programs to provide access to portable group health and disability insurance, including human immunodeficiency virus positive indemnity insurance, for all medical students and resident and fellow physicians; (b) will work with the ACGME and the LCME, and other interested state medical societies or specialty organizations, to develop strategies and policies to ensure access to the provision of portable health and disability insurance coverage, including human immunodeficiency virus positive indemnity insurance, for all medical students, resident and fellow physicians; and (c) will prepare informational material designed to inform medical students and residents concerning the need for both disability and health insurance and describing the available coverage and characteristics of such insurance.

Citation: (BOT Rep. W, I-91; Reaffirmed: BOT Rep. 14, I-93; Appended: Res. 311, I-98; Modified: Res. 306, A-04; Modified: CME Rep. 2, A-14)

HIV Postexposure Prophylaxis for Medical Students During Electives Abroad D-295.970

- 1. Our AMA recommends that US medical schools ensure that medical students who engage in clinical rotations abroad have immediate access to HIV prophylaxis.
- 2. Our AMA encourages medical schools to provide information to medical students regarding the potential health risks of completing a medical rotation abroad, and on the appropriate precautions to take to minimize such risks.

Citation: (Res. 303, A-02; Reaffirmed: CCB/CLRPD Rep. 4, A-12)

Pre-Exposure Prophylaxis (PrEP) for HIV H-20.895

- 1. Our AMA will educate physicians and the public about the effective use of pre-exposure prophylaxis for HIV and the US PrEP Clinical Practice Guidelines.
- 2. Our AMA supports the coverage of PrEP in all clinically appropriate circumstances.
- 3. Our AMA supports the removal of insurance barriers for PrEP such as prior authorization, mandatory consultation with an infectious disease specialist and other barriers that are not clinically relevant.
- 4. Our AMA advocates that individuals not be denied any insurance on the basis of PrEP use. Citation: Res. 106, A-16; Modified: Res. 916, I-16; Appended: Res. 101, A-17

Prophylaxis for Medical Students Exposed to Bloodborne Pathogens D-365.999

- 1. Our AMA will work with the Department of Health and Human Services to seek that references to "staff" in the proposed conditions of participation for hospitals expressly include "students and/or trainees" before they are finalized.
- 2. Our AMA is unsuccessful in achieving the desired outcome in Recommendation 1, our AMA will work with OSHA to obtain a clarifying interpretation of the current OSHA requirements that would have the effect of broadening the application of their bloodborne pathogen standards to include medical students and trainees.
- 3. Our AMA is unsuccessful in fulfilling Recommendation 2, our AMA will develop model legislation to establish new standards to ensure appropriate prophylaxis and counseling are made available to medical students and trainees exposed to bloodborne pathogens.
- 4. Our AMA will make a concerted effort to encourage medical schools to require, as part of their affiliation agreements with medical centers, that CDC and other applicable guidelines and standards be applied also to medical students and trainees. Additionally, Our AMA draft and disseminate model contract language for medical schools to use when contracting with hospitals. And further, Our AMA incorporate an effective enforcement mechanism into the model contract language.

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Health and Disability Coverage for Health Care Workers at Risk for HIV and Other Serious Infectious Diseases H-20.906

1. Health Insurance

A currently held health insurance policy of a healthcare worker should not be terminated, coverage reduced or restricted, or premiums increased solely because of HIV infection.

- 2. Disability Coverage
- a) Each health care worker should consider the risks of exposure to infectious agents posed by his/her type of practice and the likely consequences of infection in terms of changes needed in that practice mode and select disability insurance coverage accordingly. The policy selected should contain a reasonable definition of "sickness" or "disability," an own-occupation clause, and guaranteed renewability, future insurability, and partial disability provisions;
- b) In making determinations of disability, carriers should take into consideration the recommendations of the professional and institutional staff with whom an infected health care worker is associated, including the worker's own personal physician;
- c) Since there are a variety of disability insurance coverages available and a diversity of practice modes, each health care professional should individually assess his/her risk of infection and that of his/her employees and select disability coverage accordingly.

Citation: (BOT Rep. 21, I-00; Reaffirmed: CSAPH Rep. 1, A-10)

Principles of and Actions to Address Medical Education Costs and Student Debt H-305.925

The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue, our American Medical Association (AMA) will:

- 1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.
- 2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs--such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector--to promote practice in underserved areas, the military, and academic medicine or clinical research.
- 3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.
- 4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.
- 5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
- 6. Work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of trainees with educational debt.
- 7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.
- 8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.
- 9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).
- 10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.
- 11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.

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- 12. Encourage medical schools to (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education; (b) Engage in fundraising activities to increase the availability of scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, low-interest loan programs; (c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students; (d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students; (e) Counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation; (f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen; (g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees; (h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; (i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.
- 13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.
- 14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals: (a) Eliminating the single holder rule; (b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training; (c) Retaining the option of loan forbearance for residents ineligible for loan deferment; (d) Including, explicitly, dependent care expenses in the definition of the "cost of attendance": (e) Including room and board expenses in the definition of tax-exempt scholarship income; (f) Continuing the federal Direct Loan Consolidation program, including the ability to "lock in" a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs; (g) Adding the ability to refinance Federal Consolidation Loans; (h) Eliminating the cap on the student loan interest deduction; (i) Increasing the income limits for taking the interest deduction; (j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001; (k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating; (I) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.
- 15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.
- 16. Continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.
- 17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.
- 18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.
- 19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.
- 20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will: (a) Advocate that all resident/fellow physicians have access to PSLF during their training years; (b) Advocate against a monetary cap on

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PSLF and other federal loan forgiveness programs; (c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed; (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note; (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer; (f) Advocate that the profit status of a physicians training institution not be a factor for PSLF eligibility; (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed; (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas; (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.

- 21. Advocate for continued funding of programs including Income-Driven Repayment plans for the benefit of reducing medical student load burden.
- 22. Formulate a task force to look at undergraduate medical education training as it relates to career choice, and develop new polices and novel approaches to prevent debt from influencing specialty and subspecialty choice.

Citation: CME Report 05, I-18; Appended: Res. 953, I-18; Reaffirmation: A-19; Appended: Res. 316, A-19;

Resolution: 802

(I-19)

Introduced by: Medical Student Section

Subject: Ensuring Fair Pricing of Drugs Developed with the United States Government

Referred to: Reference Committee J

Whereas, The United States spends almost twice as much on healthcare as other comparable high income countries despite similar utilization rates, driven in part by higher spending on prescription drugs than other comparable nations^{1,2,3,4,5,6,7}; and

Whereas, The United States spends between 30% and 190% more on pharmaceutical drugs per capita as compared to other comparable high income countries despite similar utilization rates^{3,4,5,6}; and

Whereas, Many drugs cost significantly more in the United States than in other comparable industrialized countries, imposing an undue financial burden on American consumers of pharmaceutical compounds, particularly the uninsured, Medicare beneficiaries, and those whose insurance plans do not cover medicines they need^{3,4,5,6,7,8}; and

Whereas, The United States government is the world's largest funder of the basic science research that supports the development of new pharmaceutical compounds^{9,10,11}; and

Whereas, The United States government licenses drugs discovered in its laboratories to forprofit entities in order to facilitate commercialization^{12,13,14}; and

Whereas, Numerous examples exist of drugs funded in whole or in part by the US government being sold in the United States for higher prices than in other comparable industrialized countries^{3,15,16,17,18,19,20,21,22,23}; and

Whereas, Pharmaceutical companies and industry advocacy groups excuse high prices by explaining they are necessary for research and development of new drugs^{25,26,27}; and

Whereas, A report by the US Government Accountability Office found that pharmaceutical sales increased by 45% globally over the period from 2006 to 2015 and two thirds of pharmaceutical companies saw their profit margins increase over that time period, while annual research and development investment in the United States increased by only 8% over the period from 2008 to 2014²⁸; and

Whereas, Pharmaceutical companies have a higher average profit margin than all comparable industries, including software development which is often cited as a similar industry with high upfront R&D costs and low relative distribution costs^{28,29}; and

Whereas, The United States pays an estimated 70% of all pharmaceutical profits obtained from OECD nations despite only accounting for 34% of the OECD's GDP³⁰; and

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Whereas, While the 1980 Bayh-Dole Act grants US government agencies the authority to unilaterally revoke licenses to companies or order that additional licenses be granted in order to ensure access (so-called "march in rights"), this extraordinary power has never been used to ensure fair pricing^{31,32,33}; and

Whereas, The NIH has repeatedly decided that it does not have the statutory authority to use its march-in rights to force licensees to set fair prices for American consumers as this is under the purview of Congress^{34,35,36}; and

Whereas, 29 European countries currently use a model called international reference pricing (IRP) to set drug prices whereby insurers and/or socialized healthcare programs agree to pay a maximum price for drugs set to an index of prices paid by comparable nations or use such an index as a benchmark for negotiations to set prices^{37,38}; and

Whereas, Studies of the effectiveness of IRP have found that it lowers prices, increases utilization of drug classes to which the model is applied, and reduces expenditures with no negative effects on health outcomes^{39,40,41,42,43}; and

Whereas, One of the most common concerns regarding IRP is that it may incentivize pharmaceutical companies to delay or eliminate product launches in countries with a lower willingness to pay^{44,45,46,47}; and

Whereas, Analyses of IRP's effects on pharmaceutical product launch delay have found the effect is weak and is limited to countries with a lower willingness to pay^{48,49,50}; and

Whereas, The United States is one of the nations with the highest willingness to pay in aggregate, implying IRP's tendency to delay pharmaceutical product launch in lower-income countries would likely not apply to the United States^{8,9,47,48}; and

Whereas, The Institute for Medicare and Medicaid Innovation in the Department of Health and Human Services (HHS) has proposed a new model for Medicare Part B reimbursement for single-source pharmaceuticals and biologics to be phased into 50% of Medicare Part B plans between 2020 to 2025 that shifts the reimbursement structure to an IRP model, using 126% of the average price paid for a drug in 16 comparable OECD countries for which drug pricing information is widely and publicly available as a benchmark^{2,49,50,51}; and

Whereas, Over the five years of its implementation, the proposed model is expected to save \$17.2 billion overall including \$3.4 billion in direct out-of-pocket savings without changing Medicare Part B's benefit structure^{50,51}; and

Whereas, The AMA has expressed concern that the involuntary nature of the trial program may pose risks to patient access to necessary medications should third party vendors be unable to negotiate prices for drugs that fall at or under Medicare's target price for reimbursement⁵²; and

Whereas, Existing AMA Policy (H-110.997, H-110.988, H-110.987, D-110.993, H-110.991, D-110.988, H-110.998, D-330.954) highlights the AMA's continuing commitment to lowering prescription drug costs, so long as physician freedom of choice is preserved and appropriate incentives for pharmaceutical research and development are maintained; therefore be it

Resolution: 802 (I-19) Page 3 of 7

1 RESOLVED, That our American Medical Association amend Policy H-110.987 by addition to read as follows:

Pharmaceutical Costs, H-110.987

- 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
- 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
- 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
- 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
- 7. Our AMA supports legislation to shorten the exclusivity period for biologics.
- 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
- 10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
- 11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
- 12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
- 13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
 - 14. Our AMA will support trial programs using international reference pricing for pharmaceuticals as an alternative drug reimbursement model for Medicare, Medicaid, and/or any other federally-funded health insurance programs, either as in individual solution or in conjunction with other approaches. (Modify Current HOD Policy)

Solution of the Conference with Carter approaches.

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Cost of Prescription Drugs H-110.997

Our AMA:(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs; (2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in

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making these choices; (3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products; (4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies; (5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies; (6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and (7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.

Citation: BOT Rep. O, A-90 Sub. Res. 126 and Sub. Res. 503, A-95 Reaffirmed: Res. 502, A-98 Reaffirmed: Res. 520, A-99 Reaffirmed: CMS Rep. 9, I-99 Reaffirmed: CMS Rep.3, I-00 Reaffirmed: Res. 707, I-02 Reaffirmation A-04 Reaffirmed: CMS Rep. 3, I-04 Reaffirmation A-06 Reaffirmed in lieu of Res. 814, I-09 Reaffirmed in lieu of Res. 201, I-11 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988

- 1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
- 2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.
- 3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.
- 4. Our AMA supports measures that increase price transparency for generic prescription drugs. Citation: Sub. Res. 106, A-15 Reaffirmed: CMS 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

Pharmaceutical Costs H-110.987

- 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
- 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
- 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
- 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
- 7. Our AMA supports legislation to shorten the exclusivity period for biologics.
- 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
- 10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

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11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

- 12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
- 13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.

Citation: CMS Rep. 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Appended: Res. 201, A-17 Reaffirmed in lieu of: Res. 207, A-17 Modified: Speakers Rep. 01, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Appended: BOT Rep. 14, A-19 Reaffirmed: Res. 105, A-19

Reducing Prescription Drug Prices D-110.993

Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.

Citation: CMS Rep. 3, I-04 Modified: CMS Rep. 1, A-14 Reaffirmation A-14 Reaffirmed in lieu of Res. 229, I-14

Price of Medicine H-110.991

Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.

Citation: CMS Rep. 6, A-03 Appended: Res. 107, A-07 Reaffirmed in lieu of: Res. 207, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Reaffirmation: A-19 Appended: Res. 126, A-19

Prescription Drug Price and Cost Transparency D-110.988

1. Our AMA will continue implementation of its TruthinRx grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmacy benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.

2. Our AMA will report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign.

Citation: Alt. Res. 806, I-17

Cost of New Prescription Drugs H-110.998

Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Citation: Res. 112, I-89 Reaffirmed: Res. 520, A-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of Res. 229, I-14

Prescription Drug Prices and Medicare D-330.954

- 1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
- 2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
- 3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Citation: Res. 211, A-04 Reaffirmation I-04 Reaffirmed in lieu of Res. 201, I-11 Appended: Res. 206, I-14 Reaffirmed: CMS Rep. 2, I-15 Appended: Res. 203, A-17

Resolution: 803

(I-19)

Introduced by: Medical Student Section

Subject: Encourage Federal Efforts to Expand Access to Scheduled Dialysis for

Undocumented People

Referred to: Reference Committee J

Whereas, There are 6,480 undocumented immigrants with end-stage renal disease (ESRD) living in the United States¹; and

Whereas, Scheduled hemodialysis is the standard of care in patients with ESRD and is an effective treatment for prolonging survival and improving quality of life^{2,3}; and

Whereas, Undocumented immigrants with ESRD are more likely to be employed than US citizens with ESRD,^{4,5} and they contribute more to the Medicare Trust Fund than they withdraw⁶; and

Whereas, Despite this substantial financial contribution to the US economy, undocumented immigrants are unable to obtain health benefits through Medicaid and Medicare, which cover dialysis for beneficiaries with ESRD¹; and

Whereas, In most states, there is no public funding for undocumented immigrants to receive scheduled dialysis so they must resort to emergency-only dialysis, meaning they must wait until they develop critical illness before presenting to the emergency department, where they undergo dialysis and are often admitted to a medical ward^{1,7,8}; and

Whereas, While emergency departments are mandated to provide emergent dialysis through the 1986 Emergency Medical Treatment and Active Labor Act (EMTALA),^{9,10} they can provide only 1-2 sessions per week (rather than the recommended 3 sessions per week) and even then, high demand compromises the availability of dialysis chairs⁸; and

Whereas, Without consistent access to dialysis, many patients have experienced multiple cardiac arrests and severe psychosocial distress leading to debilitating, long-term health consequences that add further cost and burden to the healthcare system⁸; and

Whereas, Emergency-only hemodialysis patients experienced a 5-year mortality rate >14-fold higher than patients undergoing scheduled maintenance dialysis, more ICU admissions, and an almost 10-fold greater use of acute-care days^{11,12}; and

Whereas, Compared with emergency-only dialysis, scheduled dialysis involves cost savings of \$72,000 per person per year; extending dialysis coverage to 6,480 undocumented immigrants nationwide could lead to cost savings of more than \$400 million over 1 year¹³; and

Whereas, 11 states and the District of Columbia offer scheduled hemodialysis to undocumented immigrants through state emergency Medicaid programs⁸; and

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Whereas, H.R. 2644 Chronic Kidney Disease Improvement in Research and Treatment Act of 2017 was proposed "to understand the progression of kidney disease and the treatment of kidney failure in minority populations and improve access to kidney disease treatment for those in underserved rural and urban areas^{14,15}; and

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Whereas, The Renal Physicians Association's position on dialysis of undocumented individuals states that "the federal government has a responsibility to provide care for all patients within the borders of the United States, and the financial burden of care provided to citizens and noncitizens is both a federal and state responsibility... difficult access to or denial of dialysis services will invariably hasten the patient's demise and ultimate death" therefore be it

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RESOLVED, That our American Medical Association support expanded access to scheduled dialysis for undocumented persons with end-stage renal disease. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Health Care Payment for Undocumented Persons D-440.985

Our AMA shall assist states on the issue of the lack of reimbursement for care given to undocumented immigrants in an attempt to solve this problem on a national level.

Citation: Res. 148, A-02; Reaffirmation A-07; Reaffirmed: CMS Rep. 01, A-17; Reaffirmation: A-19

Federal Funding for Safety Net Care for Undocumented Aliens H-160.956

Our AMA will lobby Congress to adequately appropriate and dispense funds for the current programs that provide reimbursement for the health care of undocumented aliens.

Citation: Sub. Res. 207, A-93; Reaffirmed BOT Rep. 17 - I-94; Reaffirmed by Ref. Cmt. B, A-96; Reaffirmation A-02; Reaffirmation A-07; Reaffirmed: BOT Rep. 22, A-17; Reaffirmation: A-19

Resolution: 804

(I-19)

Introduced by: Indiana

Subject: Protecting Seniors from Medicare Advantage Plans

Referred to: Reference Committee J

Whereas, Medicare Advantage plans are heavily marketed to seniors by insurance companies, with less than ideal transparency in advertising; and

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Whereas, These plans produce higher insurance company profits at cost to CMS because Advantage plans are paid at a higher rate than traditional Medicare; and

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Whereas, There also is the potential for higher annual and lifetime costs for the patient under an Advantage Plan; and

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Whereas, Presentations by insurance company officials to seniors can overemphasize the value of different options and can create confusion; therefore be it

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- 13 RESOLVED, That our American Medical Association encourage AARP, insurance companies
- 14 and other vested parties to develop simplified tools and guidelines for comparing and
- 15 contrasting Medicare Advantage plans. (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/27/19

RELEVANT AMA POLICY

https://policvsearch.ama-

<u>assn.org/policyfinder/detail/comparing%20Medicare%20Advantage%20Plans?uri=%2FAMADoc</u>%2FHOD.xml-H-285.902.xml

Resolution: 805

(I-19)

Introduced by: International Medical Graduates Section

Subject: Fair Medication Pricing for Patients in United States: Advocating for a Global

Pricing Standard

Referred to: Reference Committee J

Whereas, Patients in the United States spend more on prescription medications than any other industrialized country according to the National Healthcare Expenditure, 333 billion dollars in 2017, up from 236 billion dollars in 2007; and

Whereas, Increases in prescription drug prices have resulted in many patients foregoing medication and putting lives at risk; while other countries such as Britain, the world's 20 top selling medications are three times cheaper than in the United States; and

Whereas, Data from a study of generic and brand name drug costs published in Health Affairs in January 2019 shows that generic drugs and brand name drugs increased in price from 9 to 21 percent per annum from 2005 through 2016; and

Whereas, Up to 85% of the raw ingredients used in the medications sold in the United States are produced outside of the country while our prices for pharmaceuticals per capita are the highest in the world; and

Whereas, Recent efforts to create an International Pricing Index to allow the Centers for Medicaid and Medicare to negotiate prices for medications in Part B, which leaves the majority of medications prescribed that are in Medicare Part D and from other sources unaffected; and

Whereas, New legislation efforts are focusing on the creation of an International Pricing Index that would identify only the 250 most costly medications each year and negotiate prices for only 25 of these medications per annum, would continue to leave the majority of medications unaffected; and

Whereas, The current legislative proposal would cap the price of medications at 120% of an International Pricing Index for only 25 medications each year, which may potentially still result in consumers experiencing an unfair burden of medication prices for the majority of medications; and

Whereas, The AMA is dedicated to promoting patient-centered quality healthcare that is accessible and affordable; it would be in the best interest for patient care and to minimize cost to better control medication prices; therefore be it

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1 RESOLVED, That our American Medical Association advocate for legislation to create an

2 International Pricing Index that would track global medication prices for all prescription

medications and keep U.S. medication costs aligned with prices paid in other countries to help

4 control costs and reduce unreasonable patient financial barriers to treatment (Directive to Take

Action); and be it

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RESOLVED, That our AMA advocate for legislation that would ensure that patients are charged fairly for prescription medications based on the International Pricing Index and that additional costs will not be arbitrarily assigned or passed onto patients. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/01/19

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- 4) "International Pricing Index: Outsourcing Negotiations Will Continue the US Drug Cost Crisis", Health Affairs Magazine: https://www.healthaffairs.org/do/10.1377/hblog20190307.887201/full/
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- 6) "Why are Prescription Drug Prices Rising?" U.S. News & World Report, https://health.usnews.com/health-care/for-better/articles/2019-02-06/why-are-prescription-drug-prices-rising
- 7) "How the U.S. Pays 3 Times More for Drugs", Scientific American: https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/

RELEVANT AMA POLICY

Price of Medicine H-110.991

Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.

Citation: CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19

Cost of Prescription Drugs H-110.997

Our AMA:

- (1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;
- (2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
- (3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;

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- (4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
- (5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
- (6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
- (7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients. Citation: BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Cost Sharing Arrangements for Prescription Drugs H-110.990 Our AMA:

- 1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
- 2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and
- 3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.

Citation: CMS Rep. 1, I-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 1, I-12; Reaffirmed in lieu of Res. 105, A-13; Reaffirmed in lieu of: Res. 205, A-17; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS Rep. 07, A-18

Drug Issues in Health System Reform H-100.964

The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.

- (2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
- (3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
- (4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.
- (5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
- (6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
- (7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
- (7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
- (8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.
- (9) reaffirms AMA Policies H-115.995 and H-115.997, opposing FDA-mandated patient package inserts for all marketed prescription drugs.
- (10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.
- (11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
- (12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public

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disclosure of patient and reporter identities.

- (13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.
- (14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.
- (15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.
- (16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.
- (17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.

Citation: (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97; Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11)

Controlling Cost of Medical Care H-155.966

The AMA urges the American Hospital Association and all hospitals to encourage the administrators and medical directors to provide to the members of the medical staffs, housestaff and medical students the charges for tests, procedures, medications and durable medical equipment in such a fashion as to emphasize cost and quality consciousness and to maximize the education of those who order these items as to their costs to the patient, to the hospital and to society in general.

Citation: (Sub. Res. 75, I-81; Reaffirmed: CLRPD Rep. F, I-91; Res. 801, A-93; CMS Rep. 12, A-95; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmation A-08; Reaffirmed in lieu of Res. 5, A-12)

Patient and Public Education about Cost of Care H-155.980

The AMA, as a part of its program to strengthen the US health care system, supports intensifying its efforts to better understand patient concerns regarding fees and other costs of health care in all settings, including the cost of medication, and supports attempts to relieve these concerns.

Citation: (Res. 153, I-89; Sub. Res. 42, I-89; Reaffirmed in lieu of Res. 811, I-93; CMS Rep. 12, A-95; Reaffirmed: CMS Rep. 7, A-05; Modified: CMS Rep. 1, A-15)

Medicare Part B Competitive Acquisition Program (CAP) H-110.983

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- (1) it must be genuinely voluntary and not penalize practices that choose not to participate;
- (2) it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
- (3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;
- (4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;
- (5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- (6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- (7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- (8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Citation: Res. 216, I-18

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988

- 1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
- 2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.

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3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.

4. Our AMA supports measures that increase price transparency for generic prescription drugs. Citation: Sub. Res. 106, A-15; Reaffirmed: CMS 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Pharmaceutical Costs H-110.987

- 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
- 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
- 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
- 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
- 7. Our AMA supports legislation to shorten the exclusivity period for biologics.
- 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
- 10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
- 11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
- 12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
- 13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.

Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19

Maximum Allowable Cost of Prescription Medications H-155.962

Our AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. Citation: CMS Rep. 2, A-07; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed: CMS Res. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmation: A-17

Managed Care Cost Containment Involving Prescription Drugs H-285.965

- (1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.
- (2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-

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containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

- (3) Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a change to discuss the change with the patient.
- (4) Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.
- (5) Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.
- (6) Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.
- (7) Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.
- (8) When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.
- (9) Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.
- (10) Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting.
- (11) In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed.
- (12) For physicians who do not have electronic access, hard copies must be available.

Citation: CÉJA Rep. 2, A-95; Res. 734, A-97; Appended by Res. 524 and Sub. Res.714, A-98; Reaffirmed: Res. 511, A-99; Modified: Res. 501, Reaffirmed: Res. 123 and 524, A-00; Modified: Res. 509, I-00; Reaffirmed: CMS Rep. 6, A-03; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmation A-08; Reaffirmation A-10; Reaffirmed in lieu of Res. 822, I-11; Reaffirmation A-14; Reaffirmed: CMS Rep. 05, A-19

Low Cost Drugs to Poor Countries During Times of Pandemic Health Crises H-250.988

Our AMA: (1) encourages pharmaceutical companies to provide low cost medications to countries during times of pandemic health crises; and (2) shall work with the World Health Organization (WHO), UNAID, and similar organizations that provide comprehensive assistance, including health care, to poor countries in an effort to improve public health and national stability.

Citation: (Res. 402, A-02; Reaffirmed: CSAPH Rep. 1, A-12)

1.2.13 Medical Tourism

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequate screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.

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Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patients decision to seek health care abroad. (IV, V, VI) Physicians need to be aware of the implications of medical tourism for individual patients and the community. Collectively, through their specialty societies and other professional organizations, physicians should:

- (a) Support collection of and access to outcomes data from medical tourists to enhance informed decision making.
- (b) Advocate for education for health care professionals about medical tourism.
- (c) Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.
- (d) Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.

Individually, physicians should:

- (e) Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individuals concerns and wishes about care.
- (f) Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.
- (g) Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.
- (h) Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.
- (i) Offer their best professional guidance about a patients decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patients best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.
- (j) Physicians should respond compassionately when a patient who has undergone treatment abroad without the physicians prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider:
- (i) the nature and duration of the patient-physician relationship;
- (ii) the likely impact on the individual patients well-being;
- (iii) the burden declining to provide follow-up care may impose on fellow professionals;
- (iv) the likely impact on the health and resources of the community.

Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.

AMA Principles of Medical Ethics: IV, V, VI

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2018

Resolution: 806

(I-19)

Introduced by: Medical Student Section

Subject: Support for Housing Modification Policies

Referred to: Reference Committee J

Whereas, Falls amongst the elderly population cost approximately 30,000 lives and nearly \$32 billion every year¹; and

Whereas, For US adults ages 65 and older in 2012, there were 24,190 deaths and 3.2 million non-fatal, fall-related injuries²; and

Whereas, US citizens with low socioeconomic status or greater neighborhood disadvantage had higher rates of falls⁷; and

Whereas, Minorities, those with lower levels of education, and those with less social support were less likely to have home modifications⁸; and

Whereas, Blacks were 30-40% less likely than whites to have fall-related injuries when controlling for these differences⁹; and

Whereas, Home modifications led by an occupational therapist had the greatest potential to affect the most elderly when compared to six other fall prevention strategies, including Tai Chi, Otago, medication management, Vitamin D supplements, expedited first eye cataract surgery, and single-vision distance lenses for outdoor activities¹⁰; and

Whereas, Homes are the most likely setting of falls in the elderly with high morbidity and mortality and prevention in the single most effective intervention^{5,18,19}; and

Whereas, Home hazards to the elderly include physical limitations, loose rugs, unstable furniture, obstructed walkways, and poor lighting give way to falls within the home²⁰; and

Whereas, Simple modifications aimed at increasing lighting and tacking down loose rugs or carpets have shown to statistically reduce the risk of falling in the home ¹⁶; and

Whereas, Other interventions include grab bars and grips in the bathroom, hand-rails on both sides of the steps, and lever-style handles on doors and faucets, wheelchair ramps, stair lifts, first-floor bathroom or kitchen renovations, and other more extensive renovations²¹; and

Whereas, There are currently three insurance-based funding schemes for housing modifications, including Medicare Advantage, Medicaid's Money Follows the Person Initiative, and the Veteran's Health Administration Home Improvements and Structural Alterations (HISA) benefits; and

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Whereas, Housing modifications are comparatively clinically effective, cost effective, and actionable in preventing fall related injuries among the elderly: therefore be it

3

RESOLVED, That our American Medical Association support legislation for health insurance

- 5 coverage of housing modification benefits for: (a) the elderly; (b) other populations that require
- 6 these modifications in order to mitigate preventable health conditions, including but not limited to
- 7 the disabled or soon to be disabled; and (c) other persons with physical and/or mental
- 8 disabilities. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Date Received: 10/01/19

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RELEVANT AMA POLICY

Community-Based Falls Prevention Programs H-25.988

Our American Medical Association will work with relevant organizations to support community-based falls prevention programs.

Citation: (Res. 408, A-15)

Exercise Programs for the Elderly H-25.995

The AMA recommends that physicians: (1) stress the importance of exercise for older patients and explain its physiological and psychological benefits; (2) obtain a complete medical history and perform a physical examination that includes exercise testing for quantification of cardiovascular and physical fitness as appropriate, prior to the specific exercise prescription; (3) provide appropriate follow-up of patients' exercise programs; and (4) encourage all patients to establish a lifetime commitment to an exercise program.

Citation: (CSA Rep. C, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Health Care for Older Patients H-25.999

The AMA: (1) endorses and encourages further experimentation and application of home-centered programs of care for older patients and recommends further application of other new experiments in providing better health care, such as rehabilitation education services in nursing homes, chronic illness referral centers, and progressive patient care in hospitals; (2) recommends that there be increased emphasis at all levels of medical education on the new challenges being presented to physicians in health care of the older person, on the growing opportunities for effective use of health maintenance programs and restorative services with this age group, and on the importance of a total view of health, embracing social, psychological, economic, and vocational aspects; (3) encourages continued leadership and participation by the medical profession in community programs for seniors; and (4) will explore and advocate for policies that best improve access to, and the availability of, high quality geriatric care for older adults in the post-acute and long term care continuum..

Citation: (Committee on Aging Report, I-60; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmation A-11; Appended: Res. 709, A-13)

Policy Recommendations in the Field of Aging H-25.998

It is the policy of the AMA that: (1) Older individuals should not be isolated;

- (2) a health maintenance program is necessary for every individual;
- (3) more persons interested in working with the older people in medical and other professional fields are needed:
- (4) more adequate nursing home facilities are an urgent health need for some older people in many communities;
- (5) further development of service and facilities is required;
- (6) extension of research on both medical and socioeconomic aspects of aging is vital;
- (7) local programs for older persons, especially those which emphasize the importance of self-help and independence by the senior citizen, should be a major concern of medicine, both collectively and individually; and
- (8) local medical society committees along with other leaders in community service, should be equipped to appraise the advantage or disadvantage of proposed housing for older people.

Citation: CMS Rep. A, I-60; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: CMS Rep. 01, A-18;

5.1 Advance Care Planning

The process of advance care planning is widely recognized as a way to support patient self-determination, facilitate decision making, and promote better care at the end of life. Although often

Page 4 of 4

thought of primarily for terminally ill patients or those with chronic medical conditions, advance care planning is valuable for everyone, regardless of age or current health status. Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions. Importantly, these discussions also give individuals the opportunity to identify who they would want to make decisions for them should they not have decision-making capacity.

Proactively discussing with patients what they would or would not want if recovery from illness or injury is improbable also gives physicians opportunity to address patientsconcerns and expectations and clarify misunderstandings individuals may have about specific medical conditions or interventions. Encouraging patients to share their views with their families or other intimates and record them in advance directives, and to name a surrogate decision maker, helps to ensure that patientsown values, goals, and preferences will inform care decisions even when they cannot speak for themselves.

Physicians must recognize, however that patients and families approach decision making in many different ways, informed by culture, faith traditions, and life experience, and should be sensitive to each patients individual situations and preferences when broaching discussion of planning for care at the end of life.

Physicians should routinely engage their patients in advance care planning in keeping with the following guidelines:

- (a) Regularly encourage all patients, regardless of age or health status, to:
- (i) think about their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness or injury, including any preferences they may have about specific medical interventions (such as pain management, medically administered nutrition and hydration, mechanical ventilation, use of antibiotics, dialysis, or cardiopulmonary resuscitation);
- (ii) identify someone they would want to have make decisions on their behalf if they did not have decision-making capacity;
- (iii) make their views known to their designated surrogate and to (other) family members or intimates.
- (b) Be prepared to answer questions about advance care planning, to help patients formulate their views, and to help them articulate their preferences for care (including their wishes regarding time-limited trials of interventions and surrogate decision maker). Physicians should also be prepared to refer patients to additional resources for further information and guidance if appropriate.
- (c) Explain how advance directives, as written articulations of patientspreferences, are used as tools to help guide treatment decisions in collaboration with patients themselves when they have decision-making capacity, or with surrogates when they do not, and explain the surrogates responsibilities in decision making. Involve the patients surrogate in this conversation whenever possible.
- (d) Incorporate notes from the advance care planning discussion into the medical record. Patient values, preferences for treatment, and designation of surrogate decision maker should be included in the notes to be used as guidance when the patient is unable to express his or her own decisions. If the patient has an advance directive document or written designation of proxy, include a copy (or note the existence of the directive) in the medical record and encourage the patient to give a copy to his or her surrogate and others to help ensure it will be available when needed.
- (e) Periodically review with the patient his or her goals, preferences, and chosen decision maker, which often change over time or with changes in health status. Update the patients medical records accordingly when preferences have changed to ensure that these continue to reflect the individuals current wishes. If applicable, assist the patient with updating his or her advance directive or designation of proxy forms. Involve the patients surrogate in these reviews whenever possible.

AMA Principles of Medical Ethics: I,IV

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

Resolution: 807

(I-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Addressing the Need for Low Vision Aid Devices

Referred to: Reference Committee J

Whereas, An estimated 1,082,790 patients in the United States live with a vision of 20/200 or worse, constituting severe visual disability, and the incidence of low vision and blindness is expected to more than double in the next 30 years;¹ and

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Whereas, Visual disability and blindness negatively impact patients' educational opportunities, income, and economic prospects;² and

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Whereas, Visual disability is determined by low vision specialists (optometrist, ophthalmologist, or occupational therapist) based on decreased (relative to age-norms) measures of visual ability, including best corrected visual acuity, contrast sensitivity, and/or visual fields combined with a validated visual functioning questionnaire score (e.g., National Eye Institute Visual Functioning questionnaire or Impact of Visual Impairment Scale); and

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Whereas, Vision rehabilitation services provide critical guidance, education, and devices to patients with visual impairment, including low vision aids (LVA) (magnifying lenses, electronic magnifiers, smartphone applications for text reading) that help individuals improve or maximize their remaining vision;² and

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Whereas, Vision rehabilitation with LVAs has been shown to have a positive impact on visual functioning in up to 45 to 50 percent of patients with low vision;³ and

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Whereas, LVAs offered to veterans through the Veterans Affairs hospital system showed significant improvement in all levels of visual function, including reading, mobility, and visual motor skills;⁴ and

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Whereas, Vision rehabilitation service consultation by trained clinicians are currently covered by Medicare;⁵ and

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Whereas, Historically, Medicare by statute does not cover LVAs, as the US Center for Medicare and Medicaid Services has interpreted a statute stating that Medicare will not cover eye glasses

¹ Chan T, Friedman DS, Bradley C, Massof R. Estimates of Incidence and Prevalence of Visual Impairment, Low Vision, and Blindness in the United States. *JAMA Ophthalmol.* 2018;136(1):12–19.

² Huber J, Jutai J, Strong G, Plotkin A. The Psychosocial Impact of Closed-Circuit Televisions on Persons with Age-Related Macular Degeneration. *J Vis Impair Blind* 2008;102:690-701.

³ Judith E. Goldstein, OD; Mary Lou Jackson, MD; Sandra M. Fox, OD; James T. Deremeik, CLVT; Robert W. Massof, PhD; for the Low Vision Research Network Study Group. Clinically Meaningful Rehabilitation Outcomes of Low Vision Patients Served by Outpatient Clinical Centers. *JAMA Ophthalmol.* 2015;133(7):762-769.

⁴ Joan A. Stelmack, OD, MPH; X. Charlene Tang, MD, PhD; Domenic J. Reda, PhD; Stephen Rinne, MA; Rickilyn M. Mancil, MA; Robert W. Massof, PhD; for the LOVIT Study Group. Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT). *Arch Ophthalmol.* 2008;126(5):608-617.

⁵ The Blind Guide. Medicare for People with Low Vision. Accessed March 13, 2019. Available at: https://www.theblindguide.com/medicare-low-vision.

Resolution: 807 (I-19) Page 2 of 2

for beneficiaries, except in the setting of vision correction after cataract surgery, to include LVAs;^{6,7} and

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Whereas, LVAs have been shown to be more impactful on low vision patients' visual functioning than either power wheelchairs or support canes, which are currently paid for by Medicare under the durable medical equipment benefit;⁸ and

Whereas, Visual impairment is more likely to be present in older patients, patients in poverty, and in patients with risk factors such as diabetes, indicating that a large number of patients with visual impairment rely on Medicare and/or Medicaid for health care services coverage; and

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Whereas, LVAs can cost hundreds to thousands of dollars if purchased out-of-pocket; 10 and

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Whereas, A greater need for services for patients with low vision is expected to rise, necessitating strategic allocation of resources and policy planning;¹¹ therefore be it

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RESOLVED, That our American Medical Association support legislative and regulatory actions promoting insurance coverage and adequate funding for low vision aids for patients with visual disabilities. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/02/19

⁶ 42 U.S.C. § 1395y(a)(7), SSA § 1862(a)(7).

⁷ 42 U.S.C. § 1395x(s)(3), SSA § 1861(s)(8).

⁸ Houston, K. Massachusetts Eye and Ear Outcomes Book: Vision Rehabilitation Service, Psychosocial Impact of Assistive Devices Scale (PIADS), Final Analysis. 2019.

⁹ Ko F, Vitale S, Chou CF, Cotch MF, Saaddine J, Friedman DS. Prevalence of nonrefractive visual impairment in US adults and associated risk factors, 1999-2002 and 2005-2008. *JAMA*. 2012;308(22):2361-2368.

¹⁰ Enhanced Vision. DaVinci Pro HD/OCR - Full Page Text-to-Speech. Accessed March 13, 2019. Available at: https://www.enhancedvision.com/shop/davinci-pro-electronic-desktop-magnifier.

¹¹ Chan T, Friedman DS, Bradley C, Massof R. Estimates of Incidence and Prevalence of Visual Impairment, Low Vision, and Blindness in the United States. *JAMA Ophthalmol.* 2018;136(1):12–19.

Resolution: 808

(I-19)

Introduced by: American Academy of Physical Medicine & Rehabilitation

Subject: Protecting Patient Access to Seat Elevation and Standing Features in Power

Wheelchairs

Referred to: Reference Committee J

Whereas, Seat elevation is an accessory to power wheelchairs that assists an individual with mobility impairment to raise and lower themselves in the seated position through the use of an electromechanical lift system, and standing feature is an accessory that allows an individual to transition from a seated position to a standing position without the need to transfer out of the wheelchair; and

Whereas, These features provide individuals with significantly improved abilities to perform mobility-related activities of daily living (MRADLs) and to function independently within the home; and

Whereas, Seat elevation is especially important for assisting individuals with transfers to/from a wheelchair to/from a commode, bed, or other surface with less risk of falls and shoulder and other injuries secondary to long-term wheelchair use; and

Whereas, Standing feature has been demonstrated to both assist with MRADLs and provide numerous medical benefits, including improved circulation, promotion of bone density, improved GI tract function, improved mobility and lower limb function, reduced risk of contractures, and reduced occurrence of pressure ulcers and skeletal deformities; and

Whereas, The Centers for Medicare and Medicaid Services' (CMS) National Coverage Determination (NCD) for mobility assistance equipment (MAE) grants coverage for power wheelchairs and other mobility devices when they are determined to be reasonable and necessary for beneficiaries with personal mobility deficits to assist in the performance of MRADLs; and

Whereas, HCFA Ruling 96-1 clearly states that accessories that are integral to wheelchairs are considered DME and are part of the DME benefit; and

Whereas, The four DME Medicare Administrative Contractors (MACs) have taken the position that both seat elevation and standing feature are non-covered benefits for Medicare beneficiaries because they are not primarily medical in nature and, therefore, do not meet the definition of DME; and

Whereas, CMS's position on seat elevation and standing feature stands in stark contrast to its position that the tilt and recline feature in power wheelchairs is, in fact, considered primarily medical in nature and has been since 2006; and

Page 2 of 2

Whereas, The DME MACs' position on coverage of standing feature and seat elevation is contrary to the NCD for MAE, ignores CMS national policy, and results in categorical denials regardless of individual need; and

Whereas, Patients who are not eligible for Medicare, such as patients on Medicaid and patients who receive health care benefits through commercial insurance, experience similar access and coverage barriers, therefore be it

RESOLVED, That our American Medical Association request that the Centers for Medicare and Medicaid Services (CMS) render a benefit category determination (BCD) that establishes that the seat elevation and standing features of power wheelchairs are primarily medical in nature and qualify under the definition of durable medical equipment (DME) when used in a power wheelchair (Directive to Take Action); and be it further

RESOLVED, That our AMA urge CMS to require the DME Medicare Administrative Contractors (MACs) to determine an appropriate coverage policy for Medicare beneficiaries in need of the seat elevation and standing features in their power wheelchairs on an individual basis according to the National Coverage Determination (NCD) for mobility assistance equipment (MAE), activate the existing Healthcare Common Procedure Coding System (HCPCS) codes for seat elevation and standing feature in power wheelchairs, and determine appropriate reimbursement levels for these codes in order to facilitate access to these important benefits for Medicare beneficiaries with mobility impairments (Directive to Take Action); and be it further

 RESOLVED, That if CMS is not able or willing to provide access to seat elevation and standing feature through its administrative authority, our AMA advocate before Congress to support legislation that will clarify the DME benefit to include coverage, coding and reasonable reimbursement of standing feature and seat elevation in power wheelchairs for appropriate Medicare beneficiaries with mobility impairments (Directive to Take Action); and be it further

- RESOLVED, That our AMA encourage all health insurance carriers to cover standing feature and seat elevation in power wheelchairs for appropriate beneficiaries with mobility impairments.
- 32 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/03/19

Resolution: 809

(I-19)

Introduced by: Utah

Subject: AMA Principles of Medicaid Reform

Referred to: Reference Committee J

Whereas, Medicaid is a state/federal program that pays for healthcare services for low-income pregnant women and adults with and without children, children, individuals who are elderly or have a disability, parents and women with breast or cervical cancer, and

Whereas, Some low-income individuals eligible for Medicaid may qualify for private health insurance funded by Medicaid; and

Whereas, Spending on Medicaid is about one-tenth of the federal budget, \$630 million in 2018; and

Whereas, The average annual growth in Medicaid spending is 5.5 percent, exceeding that of private health insurance; and

Whereas, Medicaid member obligations do not always encourage use of the most appropriate care and avenues of care; and

Whereas, Medicaid reimbursement does not always support the most effective and efficient interaction between clinicians and patients; and

Whereas, Some Medicaid policies regarding enrollment qualification and leaving the program encourage patients to behave in ways that are not in the patients' best interest (e.g., Medicaid spend-down); and

Whereas, Physician-directed oversight of access, quality, and cost can greatly improve Medicaid; and

Whereas, Unnecessary and burdensome administrative requirements on clinicians could be evaluated and reduced; therefore be it

Resolution: 809 (I-19) Page 2 of 2

1 RESOLVED, That our American Medical Association support the following principles of 2 Medicaid reform:

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- Provide appropriate access to care that is the most cost effective and efficient to our citizens.
- Encourage individuals to be enrolled in private insurance supported by Medicaid funding, ifpossible.
 - 3. Create the best coverage at the lowest possible cost.
 - 4. Incentivize Medicaid patient behavior to improve lifestyle, health, and compliance with appropriate avenues of care and utilization of services.
- 5. Establish a set of specialty specific high-quality metrics with appropriate remuneration and
 incentives for clinicians to provide high quality care.
- 13 6. Seek to establish improved access for Medicaid patients to primary care providers and referrals to specialists for appropriate care.
 - Assure appropriate payment and positive incentives to encourage but not require clinician participation in Medicaid for both face-to-face and non-face-to-face encounters, under appropriate establishment of clinician-patient relationship.
- 18 8. Include payment incentives to clinicians for after-hours primary care to assist patients with
 19 an inability to access care during normal business hours.
 - 9. Avoid tactics and processes that inhibit access to care, delay interventions and prevent ongoing maintenance of health.
 - 10. Eliminate current disincentives (e.g., Medicaid spend-down in order to qualify) to patients improving their lives while on Medicaid, to increase successful transition into the private insurance market.
 - 11. Cease any tax, or attempt to tax, any health care profession for the purpose of supporting the cost of Medicaid.
 - 12. Develop a physician directed clinician oversight board at the state level to insure the proper access, quality and cost of care under the Medicaid program throughout all geographically diverse areas of the states.
 - 13. Allow clinicians to see patients for more than one procedure in a visit so that patients do not have to return for another service at an extra cost to the Medicaid program and extra time and effort to the Medicaid patient (e.g., if patient comes because they are sick, allow them to have a diabetes check-up at the same time).
 - 14. Strategically plan to reduce administrative costs and burdens to clinicians, and of the Medicaid program itself, by reducing at least, but not limited to, burdensome documentation requirements, administrative obstacles, and regulatory impediments. (New HOD Policy) and be it further

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RESOLVED, That our AMA pursue action to improve the federal requirements for Medicaid programs based on the AMA's principles of Medicaid reform (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/03/19

Resolution: 810

(I-19)

Introduced by: Utah

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Subject: Hospital Medical Staff Policy

Referred to: Reference Committee J

Whereas, Hospital medical staff play a critical role in the function and operations of hospitals and in the relationship that physicians have with hospitals; and

Whereas, The core responsibilities of the organized medical staff are the promotion of patient safety and quality of care; and

Whereas, Members of the organized medical staff may choose to act as a group for the purpose of communicating and dealing with the governing board and others with respect to matters that concern the interest of the organized medical staff and its members; and

Whereas, Individual physician involvement in the political process is important to the good of the nation and for wise decision-making regarding healthcare matters; and

Whereas, Hospital medical staff in a nonprofit setting could endanger the nonprofit status through political actions; and

Whereas, The hospital medical staff leadership should be focused on high quality medical care delivery and not be politicized; therefore be it

RESOLVED, That our American Medical Association support and advocate that hospital medical staff leadership should be fully licensed physicians and that if others are included, they should be non-voting or advisory to the hospital medical staff members (Directive to Take Action); and be it further

RESOLVED, That our AMA support and advocate that the decisions made by hospital medical staffs focus on quality patient care, medical staff standards and the operation of the hospital, and that those decisions not engage the medical staff in external political matters (e.g., advanced practice clinician scope of practice expansion, etc.) (Directive to Take Action); and be it further

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 31 RESOLVED, That AMA Policy H-225.993, "Medical Staff Policy Determination," be rescinded.
 32 (Rescind HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Resolution: 810 (I-19)

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RELEVANT AMA POLICY

Medical Staff Policy Determination H-225.993

The AMA believes that only fully licensed physicians on the medical staff should establish overall medical staff standards and policy for quality medical care, where consistent with local, state and federal laws.

Citation: (Res. 115, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CMS Rep. 7, A-05;

Reaffirmed: CMS Rep. 1, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811

(I-19)

Introduced by: Michigan

Subject: Require Payers to Share Prior Authorization Cost Burden

Referred to: Reference Committee J

1 Whereas, "Pre-authorization" takes up a significant portion of time; and

Whereas, Prior authorization remains a primarily manual, time-consuming process that often delays patient access to indicated therapy or even alters the course of therapy and places excessive burden on providers, including nurses and pharmacists, health care practices, and hospitals; and

Whereas, Prior authorization disrupts workflow and diverts valuable resources away from direct patient care; and

 Whereas, Despite estimates varying by type and size of health care practice, one survey found that, on average, in United States medical practices, physicians spent three hours per week interacting with payers, nurses spent 19.1 hours, clerical staff spent 35.9 hours, and lawyers/accountants spent 7.2 hours; and

Whereas, This translates into substantial increase in uncompensated overhead health care costs; and

Whereas, A critical consequence is nonpayment if prior authorization is not obtained in advance of providing the therapy or service; and

Whereas, There are substantial costs with processing prior authorizations for nonformulary drugs on the physician office side of managed care as well as on the insurance side of the process; and

Whereas, There is some evidence that prior authorization requirements reduce non drug-related costs but little evidence that they have a positive impact on clinical or humanistic outcomes; and

Whereas, It has been found that preauthorization is a measurable burden on physician and staff time with the mean annual projected cost per full-time equivalent physician for prior authorization activities ranged from \$2,161 in one study to \$3,430 in another; therefore be it

RESOLVED, That our American Medical Association reaffirm policies H-320.939, "Prior Authorization and Utilization Management Reform," and H-385.951, "Remuneration for Physician Services." (Reaffirm HOD Policy)

35 Physician Services." (Reaffirm HOD PolicyFiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Resolution: 811 (I-19)

Page 2 of 2

- 1. The Journal of Cardiovascular Nursing: May/June 2017 Volume 32 Issue 3 p 209-211
- Allergy & Asthma Proceedings . Mar/Apr2006, Vol. 27 Issue 2, p119-122
 J Manag Care Spec Pharm, 2001 Jul;7(4):297-303 4. 4. J Am Board Fam Med January 2013, 26 (1) 93-95
- 4. J Am Board Fam Med January 2013, 26 (1) 93-95

RELEVANT AMA POLICY

Prior Authorization and Utilization Management Reform H-320.939

- 1. Our AMA will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
- 2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
- 3. Our AMA supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. Citation: CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19;

Remuneration for Physician Services H-385.951

- 1. Our AMA actively supports payment to physicians by contractors and third party payers for physician time and efforts in providing case management and supervisory services, including but not limited to coordination of care and office staff time spent to comply with third party payer protocols.
- 2. It is AMA policy that insurers pay physicians fair compensation for work associated with prior authorizations, including pre-certifications and prior notifications, that reflects the actual time expended by physicians to comply with insurer requirements and that compensates physicians fully for the legal risks inherent in such work.
- 3. Our AMA urges insurers to adhere to the AMA's Health Insurer Code of Conduct Principles including specifically that requirements imposed on physicians to obtain prior authorizations, including pre-certifications and prior notifications, must be minimized and streamlined and health insurers must maintain sufficient staff to respond promptly.

Citation: (Sub. Res. 814, A-96; Reaffirmation A-02; Reaffirmation I-08; Reaffirmation I-09; Appended: Sub. Res. 126, A-10; Reaffirmed in lieu of Res. 719, A-11; Reaffirmed in lieu of Res. 721, A-11; Reaffirmation A-11; Reaffirmed in lieu of Res. 822, I-11; Reaffirmed in lieu of Res. 711, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812

(I-19)

Introduced by: College of American Pathologists, National Association of Medical

Examiners, United States and Canadian Academy of Pathology, American

Society for Clinical Pathology, American Society of Cytopathology

Subject: Autopsy Standards as Condition of Participation

Referred to: Reference Committee J

Whereas, The Centers for Medicare & Medicaid Services (CMS) decision to remove the autopsy standards §482.22 (d) for hospitals was released in the Omnibus Burden Reduction (Conditions of Participation (COP)) Final Rule on September 26, 2019; and

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Whereas, As a condition for Medicare reimbursement, hospitals have been previously required to provide autopsies as part of COP; and

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Whereas, The removal of this standard will contribute to the further decline in the national autopsy rate, limiting the contributions to medical education and research that have the potential to affect the quality of patient care; and

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Whereas, The autopsy plays a unique and indispensable role in supporting the ability of health care professionals to provide and improve high quality patient care; and

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Whereas, Failure to provide autopsies in appropriate circumstances will have an adverse effect on quality assurance and education; and

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Whereas, Removal of this requirement, despite other mechanisms for encouraging hospitals to retain their programs, will further erode the national clinical autopsy rates; therefore be it

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RESOLVED, That our American Medical Association call upon the Centers for Medicare and Medicaid Services to reinstate the Autopsy Standard as a Medicare Condition of Participation.

23 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

Resolution: 812 (I-19)

Page 2 of 2

RELEVANT AMA POLICY

Importance of Autopsies H-85.954

- 1. Our AMA supports seeking the cooperation of the National Advisory Council on Aging of the National Institutes of Health in recommending to physicians, hospitals, institutes of scientific learning, universities, and most importantly the American people the necessity of autopsy for pathological correlation of the results of the immeasurable scientific advancements which have occurred in recent years. Our AMA believes that the information garnered from such stringent scientific advancements and correlation, as well as coalitions, should be used in the most advantageous fashion; and that the conclusions obtained from such investigations should be widely shared with the medical and research community and should be interpreted by these groups with the utmost scrutiny and objectivity.
- 2. Our AMA: (a) supports the efforts of the Institute of Medicine and other national organizations in formulating national policies to modernize and promote the use of autopsy to meet present and future needs of society; (b) promotes the use of updated autopsy protocols for medical research, particularly in the areas of cancer, cardiovascular, occupational, and infectious diseases; (c) promotes the revision of standards of accreditation for medical undergraduate and graduate education programs to more fully integrate autopsy into the curriculum and require postmortems as part of medical educational programs; (d) encourages the use of a national computerized autopsy data bank to validate technological methods of diagnosis for medical research and to validate death certificates for public health and the benefit of the nation; (e) requests The Joint Commission to consider amending the Accreditation Manual for Hospitals to require that the complete autopsy report be made part of the medical record within 30 days after the postmortem; (f) supports the formalization of methods of reimbursement for autopsy in order to identify postmortem examinations as medical prerogatives and necessary medical procedures; (g) promotes programs of education for physicians to inform them of the value of autopsy for medical legal purposes and claims processing, to learn the likelihood of effects of disease on other family members, to establish the cause of death when death is unexplained or poorly understood, to establish the protective action of necropsy in litigation, and to inform the bereaved families of the benefits of autopsy; and (h) promotes the incorporation of updated postmortem examinations into risk management and quality assurance programs in hospitals.
- 3. Our AMA reaffirms the fundamental importance of the autopsy in any effective hospital quality assurance program, and urges physicians and hospitals to increase the utilization of the autopsy so as to further advance the cause of medical education, research and quality assurance.
- 4. Our AMA representatives to the Liaison Committee on Medical Education ask that autopsy rates and student participation in autopsies continue to be monitored periodically and that the reasons that schools do or do not require attendance be collected. Our AMA will continue to work with other interested groups to increase the rate of autopsy attendance.
- 5. Our AMA requests that the National Committee on Quality Assurance (NCQA) and other accrediting bodies encourage the performance of autopsies to yield benchmark information for all managed care entities seeking accreditation.
- 6. Our AMA calls upon all third party payers, including CMS, to provide adequate payment directly for autopsies, and encourages adequate reimbursement by all third party payers for autopsies.
- 7. It is the policy of our AMA: (a) that the performance of autopsies constitutes the practice of medicine; and (b) in conjunction with the pathology associations represented in the AMA House, to continue to implement all the recommendations regarding the effects of decreased utilization of autopsy on medical education and research, quality assurance programs, insurance claims processing, and cost containment.
- 8. Our AMA affirms the importance of autopsies and opposes the use of any financial incentives for physicians who acquire autopsy clearance.

Citation: (CCB/CLRPD Rep. 3, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813

(I-19)

Introduced by: American College of Rheumatology

American Society of Clinical Oncology

Subject: Public Reporting of PBM Rebates

Referred to: Reference Committee J

Whereas, Pharmacy Benefit Managers (PBMs) are third-parties that create drug formularies for insurers; and

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Whereas, PBMs negotiate rebates and discounts with pharmaceutical manufacturers under the pretense of lowering drug costs and insurance costs for consumers and insurers; and

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Whereas, The amount of rebates and discounts made available to PBMs can create a perverse incentive to raise prices for preferred formulary placement or otherwise serve as a mechanism to influence a drug's placement on a formulary; and

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Whereas, There is no legal requirement that PBMs pass these savings back to plans or consumers; and

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Whereas, Under the prevailing regulatory regimes PBMs may reclassify rebates and discounts to retain the benefit of the bargain for themselves; and

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Whereas, The details of these rebates and discounts are not currently made available to the public; and

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Whereas, In states where the details of the rebates and discounts are disclosed to state regulatory bodies, as required in Arkansas, Minnesota, and Utah, they should be made available to the public; therefore be it

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RESOLVED, That our American Medical Association advocate for Pharmacy Benefit Managers (PBMs) and state regulatory bodies to make rebate and discount reports and disclosures available to the public (Directive to Take Action); and be it further

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RESOLVED, That our AMA advocate for the inclusion of required public reporting of rebates and discounts by PBMs in federal and state PBM legislation. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

Resolution: 813 (I-19)

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RELEVANT AMA POLICY

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987

- 1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
- 2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
- 3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
- 4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
- 5. Our AMA supports improved transparency of PBM operations, including disclosing:
- Utilization information;
- Rebate and discount information:
- Financial incentive information:
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
- Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
- Percentage of sole source contracts awarded annually.
- 6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.

Citation: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814

(I-19)

Introduced by: American Society of Clinical Oncology

Subject: PBM Value-Based Framework for Formulary Design

Referred to: Reference Committee J

Whereas, The Centers for Medicare and Medicaid Services recently updated the Minimum 2 Specialty Tier Eligibility criteria for drugs covered by in-network specialty pharmacies through 3 Medicare Part D to be drugs that cost more than \$670 a month¹: and

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Whereas, In a typical Medicare Part D plan, medications classified as "specialty drugs" are set at the highest specialty benefit tier which is subject to the highest cost-sharing²; and

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Whereas, According to the 2018 Express Scripts Drug Trend Report, specialty medications now account for 44.7 percent of total drug spending in the United States³; and

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Whereas, In 2017 the median monthly out of pocket drug expenditure for insured cancer patients was roughly \$703--equating to roughly 11% of household income for the average cancer patient4; and

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Whereas, Many employers and other plan sponsors use pharmacy benefit managers (PBMs) to outsource the complicated work of designing and maintaining formularies in order to generate potential cost savings for payers and plan sponsors--however it is not clear those savings necessarily accrue to patients⁵; and

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Whereas, Most PBM companies follow a definition similar to the Magellan Rx definition of "specialty drugs" -- drugs that are high cost (for Magellan Rx this means \$1000+ per 30-day supply), high complexity, and/or high touch oral or injectable medications used to treat complex or chronic conditions⁶; and

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Whereas, PBMs obtain revenue from pharmaceutical manufacturers in the form of rebate payments for "preferred" formulary status, which results in increased market-share by encouraging utilization of the drugs chosen⁷; and

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Whereas, Despite PBMs negotiating lower drug prices through rebates, this lower price may not translate to patient savings if the price reduction is not enough to trigger the plan to place the drug on a lower cost-sharing tier; and

¹ Centers for Medicare and Medicaid Services. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2, 2018. (Accessed: September 26, 2019). URL: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

Paris/webica/eAdvigSpeckaleStals/Downloads/Arinouncementa/19.pdf 2 Silverscript, Medicare RX. Medicare Part D Formulary Tiers. October 10, 2018. (Accessed: September 30, 2019). URL: https://www.silverscript.com/learn/formulary-tiers

3 Express Scripts. 2018 Express Scripts Drug Trend Report. 2019. (Accessed September 30, 2019). URL: https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf

4 Forbes. Even Insured Patients are Overwhelmed by the Cost of Cancer Care. August 10, 2017. (Accessed: September 26, 2019). URL:

https://www.forbes.com/sites/arleneweintraub/2017/08/10/even-insured-patients-are-overwhelmed-by-the-cost-of-cancer-care/#6b80188b51c4

⁵ American Society of Clinical Oncology. ASCO Policy Statement on Pharmacy Benefit Managers and Their Impact on Cancer Care. August 2018. (Accessed: October 3, 2019). URL: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2018%20ASCO%20PBM%20Statement.pdf

⁶ Magellan Rx Management. Specialty Pharmacy Drug List (Accessed: September 24, 2019). URL: https://magellanrx.com/member/external/commercial/common/doc/enus/MRx Formulary Specialty.pdf

⁷ American Society of Clinical Oncology. ASCO Policy Statement on Pharmacy Benefit Managers and Their Impact on Cancer Care.

Resolution: 814 (I-19) Page 2 of 3

Whereas, The relatively lower price of a drug compared to other treatments does not necessarily equate to value--value ultimately comes down to the relationship between price and meaningful improvements in health outcomes at the level of individual patients; and

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Whereas, The trend toward tiered formularies burdens vulnerable patients with high levels of coinsurance, does not guarantee that they are receiving the most effective possible treatment, and places them in the cross hairs of a drug pricing problem that they did not create⁸; therefore be it

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RESOLVED, That our American Medical Association emphasize the importance of physicians' choice of the most appropriate pharmaceutical treatment for their patients in its advocacy; (Directive to Take Action) and be it further

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RESOLVED, That our AMA advocate for pharmacy benefit managers (PBMs) and health plans to use a value-based decision-making framework that is transparent and includes applicable specialty clinical oversight when determining which specialty drugs to give preference on their formularies. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

RELEVANT AMA POLICY

Incorporating Value into Pharmaceutical Pricing H-110.986

- 1. Our AMA supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.
- 2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
- 3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

Citation: CMS Rep. 05, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS-CSAPH Rep. 01, A-17; Reaffirmed: CMS Rep. 07, A-18

Value-Based Insurance Design H-185.939

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

- a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
- b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.

⁸ American Society of Clinical Oncology. ASCO Position Statement on the Affordability of Cancer Drugs.

Resolution: 814 (I-19)

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- c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
- d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
- e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
- f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
- g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
- h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
- i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).

Citation: CMS Rep. 2, A-13; Reaffirmed in lieu of Res. 122, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed: CMS Rep. 05, I-16; Reaffirmation I-16; Reaffirmed: Joint CMS/CSAPH Rep. 01, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: Joint CMS CSAPH Rep. 01, I-18; Reaffirmed: CMS Rep. 06, A-19

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987

- 1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
- 2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
- 3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
- 4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
- 5. Our AMA supports improved transparency of PBM operations, including disclosing:
- Utilization information;
- Rebate and discount information;
- Financial incentive information:
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
- Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
- Percentage of sole source contracts awarded annually.
- 6. Our AMA encourages increased transparency in how DIR fees are determined and calculated. Citation: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815

(I-19)

Introduced by: American Society of Clinical Oncology, American College of Rheumatology,

American College of Gastroenterology, American Association of Clinical Endocrinologists, American Gastroenterological Association, American

Academy of Ophthalmology

Subject: Step Therapy

Referred to: Reference Committee J

Whereas, In 2017 our AMA along with 17 other medical specialty and healthcare organizations established the Prior Authorization and Utilization Management Reform Principles urging health plans, pharmacy benefit managers and third-party administrators to reform utilization management protocols including step therapy;¹ and

Whereas, Our AMA, at its June 2019 House of Delegates Annual Meeting, resolved to continue to advocate against the use of step therapy protocols in Medicare Advantage plans with the additional patient protections laid out in Policy D-320.981, "Medicare Advantage Step Therapy"; and

Whereas, On April 16, 2019 Representative Raul Ruiz (D-CA) and Representative Brad Wenstrup (R-OH) filed H.R. 2279 "The Safe Step Act", bipartisan legislation that mirrors patient protections against step therapy protocols that have been enacted legislatively in more than 20 states across the country²; and on September 25, 2019 Senator Lisa Murkowski (R-AK), Senator Doug Jones (D-AL), and Senator Bill Cassidy (R-LA) introduced S. 2546, the Senate version of this legislation; and

Whereas, Legislators in Colorado (2018 HB 1148), Connecticut (2017 HB 7023), Georgia (2016 HB 975), and Maryland (2017 HB74/SB919) have all gone above and beyond the general protections against step therapy protocols by enacting "Jimmy Carter" legislation- allowing more cancer patients to receive the same lifesaving treatment that the former president received by preventing health plans from limiting coverage of drugs for stage IV cancer patients; and

Whereas, Health plans' use of step therapy frequently reduces access to innovative and complex drugs including biologics and chemotherapy, which have been a lifeline for patients with chronic and life-threating conditions including but not limited to cancer, rheumatoid arthritis, Crohn's disease, ulcerative colitis, macular degeneration, multiple sclerosis, osteoporosis, primary immunodeficiency diseases, and others; and

Whereas, Health plans also apply often step therapy to antiemetics in cancer care, negatively impacting patient quality of life, adherence to treatments, and in some cases leading to increased emergency room visits or hospitalizations; therefore be it

¹American Medical Association. Prior Authorization Reform Principles. 2017. Date Accessed: September 26, 2019. URL: https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf

National Psoriasis Foundation. Press Release: Patient Advocates Applaud Filing of the Safe Step Act' in the US House of Representatives. April 16, 2019. Date Accessed: September 30, 2019. URL: https://www.prnewswire.com/news-releases/patient-advocates-applaud-filing-of-the-safe-step-act-in-us-house-of-representatives-300832818.html

Resolution: 815 (I-19)

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- 1 RESOLVED, That our American Medical Association extend its advocacy for the patient
- 2 protections against step therapy protocols outlined in D-320.981, "Medicare Advantage Step
 - Therapy," to all health plans (Directive to Take Action); and be it further

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- 5 RESOLVED, That our AMA actively support state and federal legislation that would allow timely
- 6 clinician-initiated exceptions to, and place reasonable limits on, step therapy protocols imposed
- 7 by health care plans. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

RELEVANT AMA POLICY

Medicare Advantage Step Therapy D-320.981

- 1. Our AMA believes that step therapy programs create barriers to patient care and encourage health plans to instead focus utilization management protocol on review of statistical outliers.
- 2. Our AMA will advocate that the Medicare Advantage step therapy protocol, if not repealed, should feature the following patient protections:
- a. Enable the treating physician, rather than another entity such as the insurance company, to determine if a patient "fails" a treatment;
- b. Exempt patients from the step therapy protocol when the physician believes the required step therapy treatments would be ineffective, harmful, or otherwise against the patients' best interests:
- c. Permit a physician to override the step therapy process when patients are stable on a prescribed medication;
- d. Permit a physician to override the step therapy if the physician expects the treatment to be ineffective based on the known relevant medical characteristics of the patient and the known characteristics of the drug regimen; if patient comorbidities will cause, or will likely cause, an adverse reaction or physical harm to the patient; or is not in the best interest of the patient, based on medical necessity;
- e. Include an exemption from step therapy for emergency care;
- f. Require health insurance plans to process step therapy approval and override request processes electronically;
- g. Not require a person changing health insurance plans to repeat step therapy that was completed under a prior plan; and
- h. Consider a patient with recurrence of the same systematic disease or condition to be considered an established patient and therefore not subject to duplicative step therapy policies for that disease or condition.

Citation: Res. 714, A-19

Medicare Advantage Step Therapy D-320.984

Our AMA will continue strong advocacy for the rejection of step therapy in Medicare Advantage plans and impede the implementation of the practice before it takes effect on January 1, 2019. Citation: Res. 810, I-18

Medicare Part B Competitive Acquisition Program (CAP) H-110.983

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- (1) it must be genuinely voluntary and not penalize practices that choose not to participate;
- (2) it should provide supplemental payments to reimburse for costs associated with special

Resolution: 815 (I-19)

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handling and storage for Part B drugs;

- (3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;
- (4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;
- (5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- (6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- (7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- (8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Citation: Res. 216, I-18

Eliminate Fail First Policy in Addiction Treatment H-320.941

Our AMA will advocate for the elimination of the "fail first" policy implemented at times by some insurance companies and managed care organizations for addiction treatment.

Citation: Res. 802, I-16

Reference Committee K

CSAPH Report(s)

- 01 Mandatory Reporting of Diseases and Conditions
- 02 Real-World Data and Real-World Evidence in Medical Product Decision Making
- 03 Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals

Resolution(s)

- 901 Health Impact of Per- and Polyfluoroalkyl Substances (PFAS) Contamination in Drinking Water
- 902 Amending H-490.913, Smoke-Free Environments and Workplaces, and H-409.907, Tobacco Smoke Exposure of Children in Multi-Unit Housing, to Include E-Cigarettes
- 903 Encouraging the Development of Multi-Language, Culturally Informed Mobile Health Applications
- 904 Amendment to AMA Policy H-150.949, "Healthy Food Options in Hospitals"
- 905 Sunscreen Dispensers in Public Spaces as a Public Health Measure
- 906 Ensuring the Best In-School Care for Children with Sickle Cell Disease
- 907 Increasing Access to Gang-Related Laser Tattoo Removal in Prison and Community Settings
- 908 Request for Benzodiazepine-Specific Prescribing Guidelines for Physicians
- 909 Decreasing the Use of Oximetry Monitors for the Prevention of Sudden Infant Death Syndrome
- 910 Ban on Electronic Nicotine Delivery System (ENDS) Products
- 911 Basic Courses in Nutrition
- 912 Improving Emergency Response Planning for Infectious Disease Outbreaks
- 913 Public Health Impacts and Unintended Consequences of Legalization and Decriminalization of Cannabis for Medicinal and Recreational Use
- 914 Nicotine Replacement Therapy for Minors
- 915 Preventing Death and Disability Due to Particulate Matter Produced by Automobiles
- 916 Sale of Tobacco in Retail Pharmacies
- 917 Supporting Research into the Therapeutic Potential of Psychedelics
- 918 Banning Flavors, Including Menthol and Mint, in Combustible and Electronic Cigarettes and Other Nicotine Products
- 919 Raising Awareness of the Health Impact of Cannabis
- 920 Maintaining Public Focus on Leading Causes of Nicotine-Related Death
- 921 Vaping in New York State and Nationally
- 922 Understanding the Effects of PFAS on Human Health
- 923 Support Availability of Public Transit System
- 924 Update Scheduled Medication Classification
- 925* Suspending Sales of Vaping Products/Electronic Cigarettes Until FDA Review
- 927* Climate Change
- 928* CBD Oil and Supplement Use in Treatment
- 929* Regulating Marketing and Distribution of Tobacco Products and Vaping-Related Products

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-19

Subject: Mandatory Reporting of Diseases and Conditions (Resolution 915-I-18)

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

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Resolution 915-I-18, introduced by the American College of Emergency Physicians and referred by the House of Delegates asks:

That our American Medical Association oppose mandated reporting of entire classes of patients and specific diagnoses unless compelling evidence exists to demonstrate that a serious public health and/or safety risk will be mitigated as a result of such reporting.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and
Cochrane Library databases from January 2009 to August 2019 using the search terms: "mandatory reporting," "nationally notifiable condition," "electronic case reporting," "public health surveillance," "chronic disease registry," "mandatory reporting" and "noncommunicable disease."
Additional articles were identified by manual review of the reference lists of pertinent publications.
Web sites managed by federal agencies, applicable professional organizations, and foundations were also reviewed for relevant information.

CURRENT AMA POLICY

The AMA has numerous policies calling for improved public health surveillance (e.g., antibiotic use and resistance, cannabis, Creutzfeldt-Jakob disease, firearm-related injuries and deaths, human immunodeficiency virus, infant mortality, lead poisoning, maternal mortality, new psychoactive substances, radon exposure, tobacco consumption, tuberculosis, vector-borne diseases, zoonotic diseases, etc). These policies do not address mandatory reporting or the burden of reporting on physicians. AMA policy also does not address the work underway to modernize public health surveillance and implement electronic case reporting (eCR) thereby removing the burden on physicians, labs, hospitals, and others required to report for the purposes of public health surveillance.

This report will define public health surveillance, explain the difference between mandatory reporting and nationally notifiable conditions, discuss the history of public health surveillance and its expansion beyond infectious diseases, and explain work underway to implement electronic case reporting (eCR) to both improve surveillance and alleviate the burden of reporting on those required to report. The Council on Science and Public Health recognizes public health surveillance is not without risks for individual participants and can pose ethical dilemmas. However, when conducted ethically, public health surveillance is justified for the common good to promote population health and reduce inequalities. The ethical framework for conducting public health surveillance is outside the scope of this report.

BACKGROUND

Public health surveillance is the ongoing systematic collection, analysis, interpretation and dissemination of health data for the planning, implementation and evaluation of public health action." Public health surveillance is an essential public health function. Surveillance data can be used to estimate the magnitude of health problems, determine the distribution of illness in a population, depict the natural history of a disease, generate hypotheses, stimulate research, evaluate control measures, monitor changes, and facilitate planning.⁴

 Disease surveillance usually begins in the health care setting as public health agencies collect disease information from health care providers, facilities, and clinical laboratories required to report diseases and conditions to public health agencies.⁵ In the United States, the authority to require notification of cases of diseases resides with the jurisdiction's state legislature.⁶ As a result, the list of diseases and conditions that are reported varies by state.⁶ In addition, the time frames for reporting, agencies receiving reports, persons required to report, and conditions under which reports are required also differ.⁶ Traditionally, disease reports were made manually or by telephone, mail, or fax.⁵ Reporters have indicated that manual submission of disease reports is time-consuming and disruptive to workflow.⁵

The Nationally Notifiable Disease List differs from mandatory reporting in that notifiable diseases are reported to the Centers for Disease Control and Prevention (CDC) on a voluntary basis by each jurisdiction. The Council of State and Territorial Epidemiologists works with the CDC to determine which conditions reported to local, state, and territorial public health departments are nationally notifiable.⁸

 This Council on Science and Public Health report stems from the enactment of legislation in California in 2017 that requires the State Department of Public Health to collect data on the incidence of Parkinson's disease in California. The legislation also requires a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment to Parkinson's disease patients to report each case of Parkinson's disease to the department, beginning July 1, 2018.

DISCUSSION

Historically, surveillance focused on infectious diseases, it then broadened to other topics, including chronic diseases (e.g., cancer and diabetes), occupational health, environmental health, hazard surveillance (toxic chemicals and physical and biological agents), and injury control (e.g., firearm-related injury). It is expected that additional diseases and conditions will be explored in the future. As state legislatures consider adding to their jurisdiction's list of diseases and conditions that are required to be reported to public health agencies, they should consult with state and national medical societies and public health agencies to ensure the requirements are based on scientific evidence and will meet the needs of population health.

Chronic Disease Surveillance

Chronic diseases are conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both. Chronic diseases such as heart disease, cancer, and diabetes are the leading causes of death and disability in the United States and the leading drivers of health care costs. ¹⁰ The rise in chronic disease burden led to the development of chronic disease surveillance systems. In the 1970s, morbidity from select chronic diseases came under surveillance through disease registries. ¹¹ In the 1980s and 1990s, CDC and state health agencies

collaboratively developed additional surveillance systems to monitor behavioral risk factors for chronic disease. ¹¹ This led to the use of the Behavioral Risk Factor Surveillance System and the Youth Risk Behavioral Surveillance System to monitor health risk behaviors. ¹¹ In 1992, Congress authorized the National Program of Cancer Registries at CDC to monitor local trends in cancer incidence and mortality with statewide, population-based cancer registries. ¹¹ The benefits of public health surveillance on these conditions include determining incidence and survival rates, evaluating treatment efficacy, targeting educational and screening programs, and conducting research on etiology, diagnosis and treatment.

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Neurological Conditions Surveillance

In 2016, as part of the 21st Century Cures Act, Congress authorized CDC to initiate development of a National Neurological Conditions Surveillance System to begin collecting and analyzing data on neurological disorders. The CDC will begin by exploring and synthesizing data from existing sources to gain an increased understanding of multiple sclerosis and Parkinson's disease. Once model approaches for surveillance are identified, the NCSS will be extended to other neurological conditions as resources allow.

On the state level, Nebraska was the first jurisdiction to implement a Parkinson's disease registry. The law requires that physicians and pharmacists report individuals diagnosed with Parkinson's and patients taking anti-Parkinson's medications to the Nebraska Department of Health and Human Services Regulation and Licensure. In 2015, Utah launched its Parkinson's Disease Registry to understand the apparent rise in the disease in the state and uncover causes of the disease. Effective March 12, 2015, the Utah State Board of Health began requiring health care providers to report cases of Parkinson's Disease and related movement disorders. California was the third state to require reporting of Parkinson's Disease. Since July of 2018, 122,727 records have been submitted to the California Parkinson's Disease Registry. These data will be used to: (1) determine the incidence and prevalence of Parkinson's disease in California; (2) examine disparities in Parkinson's disease risk; and (3) conduct demographic and epidemiological research and other studies of Parkinson's disease. These provisions under the California law are set to expire in 2020, but legislation is currently being considered to extend the registry and reporting requirements beyond 2020.

DIGITAL BRIDGE

 The Digital Bridge, funded by the Robert Wood Johnson Foundation and the de Beaumont Foundation, provides a forum for key decision-makers in health care, public health and health information technology (IT) committed to promoting bidirectional, or two-way, information exchange between the health care and public health sectors. The Digital Bridge promotes the use of national health IT infrastructure to alleviate the administrative burden and costs of outdated, siloed data exchange practices. Goals for the Digital Bridge include: (1) easing the burden and costs for all stakeholder groups through a unified approach to information exchange; (2) advancing greater standards-based information exchange across public health and health care; and (3) laying the foundation for greater bidirectional exchange of data so that clinicians can be more informed about population health, environmental risks and outbreaks. The AMA is currently a member of the Governance Body for the Digital Bridge. Electronic case reporting (eCR) was the first use case for the Digital Bridge.

Electronic Case Reporting (eCR)

With more than 80 percent of office-based physicians having adopted electronic health record (EHR) systems, it is not surprising the future of public health surveillance is eCR, a process by which reportable conditions are automatically generated from EHR systems to public health agencies for review and action, in accordance with applicable health care privacy and public health reporting laws¹⁷ (see Figure). The advancement of eCR could lead to more accurate and timely case data for public health action resulting in improved detection of outbreaks, earlier identification of disease risk factors, and a decreased burden on mandatory reporters, including physicians.¹⁷

The electronic initial case report (eICR) would be identified in the EHR through a standard set of trigger codes that flag when a provider diagnoses a reportable condition based on International Classification of Diseases, Tenth Revision codes for diagnoses, LOINC (Logical Observation Identifiers Names and Codes) for laboratory testing orders, or SNOMED CT (Systematized Nomenclature of Medicine–Clinical Terms) for clinical information and laboratory results. ¹⁶ The Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, and CDC have already vetted the reportable trigger codes for 5 conditions (e.g., gonorrhea, chlamydia, salmonella, pertussis, and Zika virus infections) and are in the process of identifying codes for all reportable conditions. ¹⁷

After potential cases are identified through trigger codes, the eICR will automatically be generated with case information. The eICR will contain a minimum set of data elements that have been established to be used for all conditions in all jurisdictions. The eICR will be transmitted from the EHR to an intermediary platform via secure, broadly used data transport mechanisms. On these platforms, a software application will assess the reportability of the disease or condition via a logic model based on the jurisdiction's mandated reporting requirements and then will route adjudicated cases to the appropriate agencies.

The Reportable Conditions Knowledge Management System (RCKMS) is a software application that will unpack, transform, and adjudicate the eICR automatically in a secure environment to determine whether the potential case meets minimal criteria consistent with mandated reporting based on a standard logic specific to jurisdictional requirements. RCKMS will transmit reportable cases to jurisdictions for final classification and action. Health care providers will be informed when cases have been reported. CDC has supported the Health Level 7 Consolidated Clinical Document Architecture as the initial structure for transmitting the eICR, based on standards that are already in use.

Houston was the first pilot site under the Digital Bridge initiative to successfully launch eCR. Partners involved in the Houston demonstration include Houston Health Department, Houston Methodist, and Epic Systems. ¹⁸ California, Kansas, Massachusetts, Michigan, New York, and Utah have also been selected as pilot sites. ¹⁹ The CDC recently identified Parkinson's disease for inclusion as a test case for the Digital Bridge. The Digital Bridge and CDC have committed to working with the California Department of Public Health to implement eCR across California health systems to collect data on Parkinson's disease cases seen by health care providers in a burden-free manner.

CONCLUSION

Public health surveillance is an essential public health function and coordination between health care and public health agencies is essential for the monitoring, control, and prevention of disease. The AMA has numerous policies calling for improved public health surveillance on a wide range

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of topics. A policy opposing mandatory reporting for specific conditions due the burden it places on physicians could jeopardize our understanding of disease occurrence and severity (e.g., cancer), as well as new causes, risk factors, and early identification of disease clusters. In addition to increases in disease incidence, reporting can also demonstrate the decline in disease among the population and help with the evaluation of prevention programs (e.g., vaccines).

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To ensure that new diseases reporting requirements are based on the scientific evidence and will meet the needs of population health, the AMA encourages state legislatures to engage state and national medical specialty societies and public health agencies when proposing mandatory disease reporting requirements. The AMA should also support the modernization of public health surveillance systems and recognize the benefits of eCR in both improving public health surveillance through more accurate and timely data and alleviating the reporting burden on physicians.

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RECOMMENDATIONS

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The Council recommends that the following recommendation for new policy be adopted in lieu of Resolution 915-I-18, and the remainder of the report be filed.

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Public Health Surveillance

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35 36 That our AMA: (1) recognizes public health surveillance as a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats; (2) recognizes the important role that physicians play in public health surveillance through reporting diseases and conditions to public health authorities; (3) encourages state legislatures to engage relevant state and national medical specialty societies as well as public health agencies when proposing mandatory reporting requirements to ensure they are based on scientific evidence and meet the needs of population health; (4) recognizes the need for increased federal funding to modernize our nation's public health data systems to improve the quality and timeliness of data; (5) supports electronic case reporting, which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from electronic health records to public health agencies for review and action in accordance with applicable health care privacy and public health reporting laws; (6) will share updates with physicians and medical societies on public health surveillance and the progress made toward implementing electronic case reporting. (New HOD Policy)

Fiscal Note: less than \$1,000.

Figure



Source: The Digital Bridge

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REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-19) Real-World Data and Real-World Evidence in Medical Product Decision Making (Reference Committee K)

EXECUTIVE SUMMARY

Objective. The Council on Science and Public Health initiated this report to inform physicians of the evolving use of real-world data (RWD) and real-world evidence (RWE) in medical product decision making, specifically how the U.S. Food and Drug Administration (FDA) is using RWD and RWE for the approval of new products, new indications for products, or new labeling on products that are used in patient care. This report will define and clarify the current working definition and types/sources of RWD and RWE, evaluate challenges and benefits in using RWD, provide examples of RWD platforms and use of RWE, and explore considerations for generating RWE that is fit for regulatory purposes.

Methods. English-language articles were selected from a search of the PubMed database through August 2018 using the search terms "real-world data" and "real-world evidence." Due to the volume of results, the date range was limited to 2017 to present. Additional articles were identified from a review of the references cited in relevant, retrieved publications. Searches of websites of international and national government agencies and outcomes research organizations and associations were conducted to identify guidelines, position statements, and reports.

Results. Data is more widely collected, available, and accessible than in the past. Evidence and opportunities are mounting on ways to leverage new data sources such as RWD and RWE to support regulatory efforts and value-based payment arrangements for medical products, yet accessibility and privacy concerns remain. The FDA is actively engaged in understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations and pursing its integration into drug development and regulatory review, the support of new indications for an approved drug, and its ability to satisfy post-approval study requirements. Advocates note that the use of RWD and RWE is crucial for incorporating patient experiences, currently often a gap in knowledge, into decision-making by drug companies, insurers, providers, and regulators. If RWD and RWE are to be effectively leveraged for public health purposes, then shared learning and collaboration across clinicians, patients, health care systems, pharmaceutical companies, and regulators are necessary. An understanding of the limitations and barriers associated with the use of RWD must also be acknowledged and addressed.

Conclusion. With its increasing availability and recognized worth, RWE has the potential to support, improve, and potentially accelerate the delivery of safe and cost-effective medical products. A component of the AMA's strategic work starting in 2018 and beyond is to provide the physician perspective across health care technology sectors by promoting improved usability of and ready access to data for use in medical decision making and respect for the patient-physician relationship. Although extensive existing policies support the ideas and aims of RWD collection and the development of RWE, no policies specifically address the practice. This report sets the stage for additional information to come on the topic of RWD and RWE and provides foundational policy related to RWD and RWE to build on for other applications.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-19

Subject: Real-World Data and Real-World Evidence in Medical Product Decision Making

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

INTRODUCTION

Physicians are trained to implement the 5 steps of evidence-based practice (EBP) and rely on appropriate evidence to guide the clinical care they provide to their patients. The evidence relied upon in EBP has typically been generated from traditional randomized controlled trials (RCTs). Today, real-world data (RWD) and real-world evidence (RWE) are increasingly being used in health care decision making to augment evidence from RCTs.

The Council on Science and Pubic Health offers this overview of RWD and RWE to practicing physicians because it is important for all physicians to understand the genesis of data and derivation of evidence from sources other than traditional RCTs that is increasingly being used by the FDA in its approval of new products, new indications for products, or new labeling on products that are used in patient care. Although RWD and RWE have many applications in health care, this report remains narrow in scope and will focus only on the use of RWD and RWE that is fit for purpose to be used in medical product (that is, drug, biologic, and device) decision-making (Figure 1), such as the FDA's consideration of a new drug indication, labeling revision, or safety revision. The use of RWD and RWE as it applies to other topics, including augmented intelligence (AI), will be addressed at a later time.

RWD are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWE is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.¹⁻³ RWD and RWE are playing an increasing role in health care decisions. Additionally, the use of RWD and RWE to answer scientific questions and guide more effective and cost-efficient medical product decision making is an active area of engagement for regulatory agencies. Stakeholder groups are actively working on ways to improve the development and use of RWD and RWE across a range of clinical and regulatory activities.

The 21st Century Cures Act (Cures Act), signed into law in December 2016, is designed to accelerate medical product development and bring new innovations and advances faster and more efficiently to patients.⁴ Among the provisions in the Cures Act is an added section to the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to RWE which requires that the U.S. Food and Drug Administration (FDA) increase its use of evidence from clinical practice settings. Pursuant to this provision and the sixth Prescription Drug User Fee Act (PDUFA VI),⁵ FDA created a framework for evaluating the potential use of RWE to support the approval of a new indication for a drug or biological product already approved or to support or satisfy drug post-approval study requirements.¹ The FDA under the fourth Medical Device User Fee Act (MDUFA IV)⁶ is required

to, among other things, evaluate the published guidance in 2017, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.*⁷

In addition to the FDA's activities related to RWD, the National Institutes of Health (NIH) has developed its first Strategic Plan for Data Science providing a roadmap for modernizing the NIH-funded biomedical data science ecosystem;⁸ The National Academies of Sciences, Engineering, and Medicine (NASEM) remain engaged in RWD conversations with diverse stakeholders;⁹⁻¹² part of the Patient Centered Outcomes Research institute (PCORI) mandate is to improve the quality and relevance of evidence to advance health care;¹³ and several thought leaders, including former FDA Commissioners, are commenting on the use of RWD for the advancement of heath care.¹⁴⁻¹⁷

Many different types and sources of RWD exist, there is increasing availability of RWD, and new potential data sources are emerging. Both challenges and benefits to the use of these data exist. The Council on Science and Public Health initiated this report to inform physicians of the evolving use of RWD and RWE in medical product decision making. This report will define and clarify the current working definition and types/sources of RWD and RWE, evaluate challenges and benefits in using RWD, provide examples of RWD platforms and use of RWE, and explore considerations for generating RWE that is fit for regulatory purposes.

METHODS

 English-language articles were selected from a search of the PubMed database through August 2018 using the search terms "real-world data" and "real-world evidence." Due to the volume of results, the date range was limited to 2017 to present. Additional articles were identified from a review of the references cited in relevant, retrieved publications. Searches of websites of international and national government agencies and outcomes research organizations and associations were conducted to identify guidelines, position statements, and reports.

OVERVIEW OF RWD AND RWE

RWD are collected from a variety of sources with varied quality, reliability, and applicability including electronic health records (EHRs) from hospitals, physician offices, and clinics (diagnoses and medical history); medical and billing claims; product and disease registries; administrative data; pharmacies (including dose, dose regimen, and route of administration of medications); laboratory, radiology, and diagnostic test results; cost studies; prospective observational data; vital records databases; primary and secondary care data; and patient-generated data, including from inhome-use settings, wearables, biosensors, remote monitoring devices, mobile devices and applications, consumer surveys, and social media (Figure 2).^{1,9,17} Post-marketing data is the type of RWD currently used most often. RWD are typically more proximate to the patient and the patient experience; thus, they include primary source data, but they have a high potential for unstructured/inconsistent data collection and for missing data elements as compared to data collected for research or during clinical trials.¹⁸

The FDA is advancing a total product life cycle (TPLC) approach, a holistic approach that takes into account all of the steps and processes in the evolution of a medical product from conception to obsolescence, integrating information and knowledge across pre-market and post-market activities, to increase information-sharing and enhance decision-making. RWD and RWE are not a replacement for clinical trial data, but instead support the TPLC approach to medical product approval and surveillance; they will augment existing mechanisms which are known to have gaps, delays, and deficiencies that are inherent in any system that depends on active reporting by users.

RWE has the potential to inform therapeutic development, outcomes research, patient care, health care systems research, quality improvement, safety surveillance, and well-controlled effectiveness studies. RWE can provide answers to questions relevant to broad populations of patients that may not be possible or intended in the course of a traditional clinical trial and may reduce the number of individuals exposed to a faulty medical product and shorten the period of time before valid performance issues are identified and acted upon. Use of RWD and RWE may also save time and money throughout the TPLC. Additionally, RWE can be used to complement traditional clinical trials, generating more generalizable knowledge from larger, more inclusive populations of patients, providers, and health care delivery systems or settings that reflect actual use in practice. ¹⁶

However, it is important to note that the RWE generated from RWD has limitations and challenges including confidentiality and proprietary concerns, the cost and work required to convert data for use in analyses, and sharing and collaboration considerations.¹⁹

FDA RWE Program Framework

Former FDA Commissioner Scott Gottleib, MD, recently noted that RWD and RWE are a top strategic priority for the FDA and the Agency is "committed to realizing the full potential of these tools in advancing the development of novel therapeutic products and strengthening our regulatory oversight of medical products across the life-cycle continuum." The recently published *Framework for FDA's RWE Program* (framework), issued by the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) is intended to develop a path for ensuring that RWE solutions are an integral part of the drug development and regulatory life cycle. ²⁰

The CDER/CBER framework notes that the FDA's work will be multifaceted and involve demonstration projects, stakeholder engagement, internal processes to promote shared learning and consistency in applying the framework, and the development of guidance documents to assist those using RWD to develop RWE to support FDA regulatory decisions. The framework includes consideration of whether RWD are fit for use; whether the trial or study design used to generate RWE can provide adequate scientific evidence to answer or help answer the regulatory question; and whether the study conduct meets FDA regulatory requirements.

FDA currently uses RWE in safety surveillance and development of drugs for rare diseases, but there are other potential applications. ¹⁸ The FDA program will focus on exploring the potential of RWD/RWE to support regulatory decisions about product effectiveness. Specifically, FDA's RWE Program will evaluate the potential use of RWE to support revisions to drug labeling such as changes in doses, dosing regimen or route of administration, and population or adding comparative effectiveness or safety information. ¹ The framework also includes exploring the use of observational designs to generate RWE.

 The FDA's Center on Devices and Radiological Health (CDRH) recently published guidance on the potential use of RWE for supporting initial decisions to approve or clear devices for use and includes the use a TPLC approach in their current strategic priorities.²¹ The guidance also addresses the use of RWE for post-marketing assurance of medical device safety and performance.⁷ Investigators have noted the high value of post-market evidence in evaluating the performance of modern medical devices outside of the context of a controlled clinical trial and have also noted that RWE can supplement or replace currently required post-approval studies, saving money and time.²²

CDER and CBER routinely use RWE to support post-marketing safety evaluation and, to a limited extent, to evaluate the effectiveness of medical products in certain rare diseases. CDER's and

CBER's experience with Sentinel, a program described in more detail in Appendix A, is informing policy, guidance, frameworks, methods and platforms going forward. Sentinel is leading the way for CDRH to use RWE, from the National Evaluation System for Health Technology (NEST), in its product evaluations in pre- and post-market decisions; NEST is another program described in Appendix A.

Fit for Regulatory Purpose

The FDA states that any RWD/RWE used for regulatory purposes, including drug development and regulatory review, must be fit for purpose – it must be high-quality data that can support regulatory decision making and improve public health. Fit for purpose RWD requires data relevancy and data quality. The process of producing a fit for purpose RWD set begins with selection of one or more data sources, then cleaning, transforming, and linking data. Obtaining curated, high quality, unbiased data is a rate limiting step to obtaining RWE, which is labor intensive and costly.³

The Duke-Margolis Center for Health Policy and FDA published a framework in which they propose that developing RWE fit for regulatory purposes should be guided by the interplay of the regulatory question a sponsor seeks to address, the clinical context within which RWE is being generated, the availability of RWD that is both relevant and of acceptable quality; and the application of trusted methods for turning RWD into actionable evidence.²³

When RWE is identified and intended to be used in regulatory contexts, for example in the FDA's consideration of a new drug indication, labeling revision, safety revision, or risk-benefit profile, there are unique challenges that require careful consideration to characterize it as robust and representative of the population of interest.³ Not all research questions may be suitable for answering with RWE, traditional inferential statistics may be unable to identify clear treatment effects given variations in treatment effect definitions, clinical practice, and partial adherence to treatment, and it remains unclear how regulatory standards and compliance requirements designed for traditional clinical trials apply to RWE.²³ Additional work needs to be done to clarify the types of RWD and RWE that are robust enough to provide information to support regulatory guidance and decisions.²⁴

RWE vs. Traditional Clinical Trials

 RCTs have traditionally served as the gold standard for generating evidence about medical products. RCTs are optimized to control variability and maximize data quality to produce data essential for regulatory approval by answering regulators' questions related to efficacy and safety. 16,25 RCTs are often conducted with a narrowly defined group of patients and many investigators express concern that RCTs may not reflect the broad patient populations that will be exposed to an approved treatment in the real-world, 23 and that specific therapeutic interventions may perform differently in different patient cohorts based on age, gender, race, ethnicity, disease severity, comorbidities, or polypharmacy. 17,25 RCTs are also complex, expensive, time consuming, and cannot answer all questions about a product or intervention. Some estimates state that clinical trials can take as long as seven years and cost more than \$2 billion. The FDA also recognizes that overly complex RCTs and unnecessary data collection can deter patient enrollment and discourage the development of second and third-to-market innovations and reducing competition and lowering prices.

According to the FDA framework, evidence from traditional clinical trials will not be considered RWE, but various hybrid or pragmatic trial designs and observational studies could generate

RWE. 1,14 Traditional RCTs, often referred to as explanatory trials generally measure efficacy – the benefit of a treatment under ideal conditions. Pragmatic trials measure effectiveness – the benefit of treatment in clinical practice. Pragmatic trials can test the same intervention as a traditional RCT, but they are conducted in real-world clinical practice settings, with typical patients and by qualified clinicians who may not have a research background, as detailed in the Salford Lung Study below.²⁶ Augmenting traditional RCTs with data from a broader, more diverse group of patients in different practice settings can increase the generalizability of trials, answer questions about subpopulations for treatments, or demonstrate proof of value to payers and patients, as has been done in some trials conducted within clinical registry populations.^{2,11,17} Many opportunities exist for leveraging RWE during the life cycle of product development (Figure 3).

Benefits of using RWD/RWE to support RCTs includes more efficient and targeted recruitment of patients for RCTs; expediting hypotheses generation to inform RCT design; identification of subpopulations with higher risk-benefit ratios; supporting the identification of drug development tools, such as biomarkers; trial feasibility assessment; supporting geographically distributed research cohorts; and improving the efficiency of studies for drugs approved under the FDA's expedited programs.^{1,17}

PRIVACY, SECURITY, AND ACCESSABILITY

While many opportunities to leverage RWD and RWE to support regulatory efforts related to medical products exist, there are also barriers to their use. The Among the biggest barriers to the use of RWD and RWE are data accessibility, privacy, and security concerns. While increasing the use of patient data is a priority for FDA and national thought leaders, also increasing is public, and AMA, concern about the secondary use of personal information. Noteworthy is a study evaluating RCT participant concerns about the risks of data sharing which found that most participants most were willing to share their data for a wide range of uses provided that adequate security safeguards were in place. The provided that adequate security safeguards are in place.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), safeguards the collection, storage, and disclosure of protected health information for covered entities, which includes health care entities and practitioners that electronically transmit health information, health plans, and clearinghouses. HIPAA rules do not apply to deidentified health data, even as methods to reidentify individuals from other sources proliferate. Privacy conversations related to RWD and RWE focus on ways to decrease risk of reidentifying deidentified data, data minimization, identifiers to remove from data sets, and expanding penalties and civil remedies available for data breaches and misuse, including reidentification attempts. 100 misuse, including reidentification a

Access to RWD requires aggregation of the health data, which are usually stored in multiple silos and can suffer from incompatibility and data quality issues. Increasing the use of these data is challenging for several reasons including confidentiality and proprietary issues, costs and labor associated with raw data transformation, and incentives for data holders to share information that outweigh the disadvantages (for example, unauthorized use and competition).¹⁹

Data enclaves, secure networks through which confidential data can be stored and disseminated, are becoming popular. ^{19,31} Data enclaves address two major barriers related to data sharing: data owners can maintain operational control of their data (granting permissions for analysis requests) and they eliminate the need to construct new, secure systems for each query or study. ¹⁹ Multiple enclaves from different data owners can be linked to create data networks in which the systems format their data identically and execute identical analytic programs on the data. Typically, data

enclaves in a network share aggregate results. Some data enclave networks, such as the FDA's Sentinel System, include the records of more than 100 million individuals.¹⁹

Networks can be centralized (for example, registries), decentralized (for example PCORnet and NEST), or distributed (for example, Sentinel). In a centralized system, all users are connected to a central network owner that stores data for others to access. Decentralized systems do not have one central owner, and instead use multiple central owners, each of which usually stores a copy of the resources users can access. In these models, data owners retain patient-level data behind the firewall of their institution, and issues related to the use and reuse of data resolved by the participants in the network.³² Distributed systems are similar to decentralized and do not have a single, central owner; users have equal access to data and share ownership of the data.

Additionally, patients are taking more control of their own data and creating shareable health records by authorizing data sharing from mobile applications, physician visits, pharmacy records, and more. Patients can share their aggregated data upon request using an application such as Apple's new Health app. Using the Health app, patients and providers can share data and interact on Apple devices.³³ Over 350 health care institutions currently support this type of shareable health information.³⁴ However, substantial concerns remain about the potential for data misuse by third parties, especially when HIPAA does not apply.

DATA NETWORKS

 Many stakeholders, including federal agencies, health systems, payers, and clinicians have made significant progress through investments in the curation, linkage, and analysis of electronic health-related data generated during the course of patient care. Much of these data are housed in clinical data warehouses or enclaves, organized into common data models, refreshed periodically, and subjected to quality assurance checks. Many of the networks are based on voluntary, nonexclusive collaborations in which institutions elect to participate in multi-center studies.

Several independent networks established and active for post-market medical product surveillance are now being leveraged to contribute to public-private collaboration for improved population-based evidence generation related to medical products on a much larger scale. Please see Appendix A for more details about several data networks.

RWE USE CASES

Although currently the most common use of RWE is retrospective analysis of existing data, increasingly, clinical trials are being conducted in real-world settings to improve the generalizability of results and to reduce inefficiencies related to establishing separate research infrastructures. These pragmatic clinical trials are conducted using existing clinical infrastructure to prospectively test interventions in every-day situations. Please see Appendix B for examples of RWE use cases.

CURRENT AMA POLICY

While no AMA policy currently addresses RWD or RWE specifically, AMA has extensive policy on related topics that were developed prior to the propagation of RWD and RWE. The relevant topics include data, registries, post-market surveillance, effectiveness evaluation, and clinical trials/drug approval. Because of the volume of related AMA policies referenced, please see Appendix C for the full text of policies.

Globally, AMA Policy H-100.992, "FDA," supports the principles that an FDA decision to approve a new drug, to withdraw the approval of a drug, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or post-market incident reports.

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Data-related Policy

 AMA Task Force to Address the Release of Physician Information. In 2007, AMA convened a task force to address the release of physician information. This task force was formed in response to physician profiling programs and "efficiency ratings." The task force assisted the AMA in the creation of Principles for the Public Release and Accurate Use of Physician Data, which provides a framework for the AMA to address the appropriate release and use of physical data in evaluating physician performance ("physician-specific data"). The task force also thought it was important for the AMA to specifically craft policy regarding the release and use of physician data by the federal government for all purposes ("physician data"). Board of Trustees (BOT) Report 18-A-09 details this task force and resulting recommendations that address safeguards for the release of physician data and physician profiles. The resulting AMA policy is guided by seven main principles: patient privacy safeguards; data accuracy and security safeguards; transparency requirements; review and appeal requirements; physician profiling requirements; quality measurement requirements; and patient satisfaction measurement requirements (Policies H-406.990, "Work of the Task Force on the Release of Physician Data," H-406.989, "Work of the Task Force on the Release of Physician Data," H-406.991, "Work of the Task Force on the Release of Physician Data," and H-406.996, "Use and Release of Physician-Specific Health Care Data").⁵⁷

Council on Legislation Workgroup on Health Care Data Transparency. In 2014, AMA's Council on Legislation (COL) established a workgroup to focus on health care data transparency. The intent of the workgroup was to develop guiding principles on the data and transparency efforts that should be pursued in order to improve care quality, reduce costs, prioritize the right set of regulatory reforms, and highlight innovative uses of health care data that benefit physicians. BOT Report 6-A-15 provides background on the health care data transparency and details the work of the COL. 58

The workgroup noted that our AMA has extensive policy on physician data transparency; however, it was created at a time when most of this information was not widely available and accordingly, focused on safeguards against releasing this information. The workgroup recognized the work of the 2007 task force, built on their policy recommendations (seven outlined principles) to reflect the new opportunities and potential uses of this information, and identified three components of a data transparency framework: transparency objectives and goals; data transparency resources; and challenges to transparency (Policy H-406.987, "Medical Information and Its Uses").

The framework principles are intended to guide and develop AMA advocacy and policy as more data are sought by stakeholders and new uses of this information emerge. The framework principles recognize the new data environment and the need for physicians to engage in this area. Noteworthy statements in this policy include facilitation of more proactive use of health care data; support of the removal of barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete; supporting definitions of quality based on evidence-based guidelines; promotion of efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility, and reduce barriers that currently limit access to and use of the health care data; and support of improvements in EHRs and other technology to capture and access data in uniform formats.

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- Data Ownership. Informational BOT Report 21-A-18 provided an overview of the current laws and 1 2 regulations at the state and federal levels that address ownership, access, and use of patient data.⁵⁹
- 3 The report notes the importance of patients having appropriate access to their data and physicians
- 4 having the tools and controls they need to be good stewards of their patients' information while at
- 5 the same time having the ability to share information to seamlessly coordinate the best care.
- 6 Additionally, Policy D-315.984, "Ownership of Claims Data," notes that our AMA will continue to
- 7 monitor federal and state activities impacting the exchange of physician-generated health

8 information, including claims data.

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14 15 Additional Data-related Policy. Policy H-406.999, "Goal of Health Care Data Collection," notes the AMA's support for collection of health care data that can be used for education of both consumers and providers and made available to physicians and medical societies. AMA policy supports compliance with HIPAA Privacy and Security Rules and data accessibility to authorized users for purposes of treatment, public health, patient safety, quality improvement, medical liability defense, and research (Policy H-315.973, "Guiding Principles for the Collection, Use and Warehousing of Electronic Medical Records and Claims Data").

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Data Registries Policy

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AMA policy encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs. Additionally, policy encourages physicians and physician groups to participate in efforts to advance the development and use of clinical data registries and provides guidelines to help maximize opportunities for clinical data registries to enhance the quality of care provided to patients. AMA policy also notes that clinical registry data may be used to meet third-party quality reporting requirements with suggested guidelines and encourages a national clinical trial registry to promote subject safety, research quality, and to document previous trial participation (Policies H-450.933, "Clinical Data Registries" and D-460.972, "Creation of a National Registry for Healthy Subjects in Phase I Clinical Trials").

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Post-Market Surveillance/Adverse Event Reporting Policy

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Several polices note our AMA's support of post-market surveillance and adverse event reporting, including Ethical Opinion 8.8, "Required Reporting of Adverse Events," which notes physicians' responsibility to report suspected adverse events resulting from the use of a drug or medical device and Policy H-120.958, "Supporting Safe Medical Products as a Priority Public Health Initiative," which encourages proper reporting of adverse events. Additional policies comment on the utility of manufacturer-conducted post-market surveillance to document long-term safety, effectiveness, and acceptance, encourages manufacturers to better study medication effects in pre- and post-marketing clinical trials, encourages mechanisms for data collection, monitoring, and analysis of medicationrelated problems by age group, and encourages the sharing of post-market surveillance information with the FDA (Policies H-75.990, "Development and Approval of New Contraceptives," and H-100.968, "Improving the Quality of Geriatric Pharmacotherapy").

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Policy D-100.982, "Enhanced Physician Access to Food and Drug Administration Data," urges the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases.

Effectiveness Evaluation Policy

Policy H-110.986, "Incorporating Value into Pharmaceutical Pricing," supports value-based pricing of pharmaceuticals that is evidence-based and the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes.

Clinical Trials/Drug Approval Policy

AMA has long-standing policy supporting clinical trials. Our AMA supports the development of transparent, collaboratively constructed clinical pathways that are implemented in ways that promote administrative efficiencies for both providers and payers; promote access to evidence-based care for patients; recognize medical variability among patients and individual patient autonomy; promote access to clinical trials; and are continuously updated to reflect the rapid development of new scientific knowledge (Policy H-410.948, "Clinical Pathways"). Additional policies include urging access to original source safety data from industry-sponsored trials upon request; support for ample federal funding of medical research, including basic biomedical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research; and support for accounting for the possible role of sex as a biological variable in vertebrate animal and human studies (Policies D-460.970, "Access to Clinical Trial Data," H-460.926, "Funding of Biomedical, Translational, and Clinical Research," and H-525.991, "Inclusion of Women in Clinical Trials").

SUMMARY

Data are more widely collected, available, and accessible than in the past. Evidence and opportunities are mounting on ways to leverage new data sources as RWD and RWE to support regulatory efforts and value-based payment arrangements for medical products, yet privacy accessibility and privacy concerns remain. The FDA is actively engaged in understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations and pursing its integration into drug development and regulatory review, the support of new indications for an approved drug, and its ability to satisfy post-approval study requirements. Advocates note that the use of RWD and RWE is crucial for incorporating patient experiences, currently often a gap in knowledge, into decision-making by drug companies, insurers, providers, and regulators.

In a 2017 Real-World Evidence Benchmark Survey, Deloitte noted that many health care stakeholders, including life sciences companies and others (payers, providers, regulators, and patients) are increasingly making high-impact decisions and attempting to demonstrate value using RWD.⁶⁰ The results of this survey illustrate that with its increasing availability and recognized worth, RWE has the potential to support, improve, and potentially accelerate the delivery of safe and cost-effective medical products.

If RWD and RWE are to be effectively leveraged for public health purposes, then shared learning and collaboration across clinicians, patients, health care systems, pharmaceutical companies, and regulators are necessary. An understanding of the limitations and barriers associated with the use of RWD must also be acknowledged and addressed. Recently, a group of former FDA commissioners offered recommendations and suggested requirements for advancing the generation and use of RWE to evaluate effectiveness and safety of drugs, biologics, and devices including adequate funding, regulatory clarity, access to data, improved data reliability and relevance, assured privacy

and confidentiality, innovative, new models of drug development, and cooperation and collaboration.¹⁷

A component of the AMA's strategic work starting in 2018 and beyond is to provide the physician perspective across health care technology sectors by promoting improved usability of and ready access to data for use in medical decision making and respect for the patient-physician relationship. Although extensive existing policies support the ideas and aims of RWD collection and the development of RWE, no policies specifically address the practice. As a leader in American medicine, our AMA has a unique opportunity to be a part of the evolving conversation related to the use of RWD and RWE for regulatory purposes.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed:

1. Our AMA supports the generation and use of real-world data (RWD) and real-world evidence (RWE) fit for regulatory purpose to: (a) evaluate effectiveness and safety of medical products, while assuring patient privacy and confidentiality; (b) improve regulatory decision-making; (c) decrease medical product costs; (d) increase research efficiency; (e) advance innovative and new models of drug development; and (f) improve clinical care and patient outcomes. (New HOD Policy)

- 2. Our AMA supports the aim of the U.S. Food and Drug Administration (FDA) to expand and clarify the use RWD and RWE in regulatory decision-making including in:
 - a. understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations;
 - b. pursuing the integration of RWE into medical product development and regulatory review;
 - c. utilizing RWE to support new indications for approved medical products, and its ability to satisfy post-approval study requirements. (New HOD Policy)

3. Our AMA supports that there be adequate funding of data infrastructure to allow for transparent data management capabilities, improved access to data by clinicians, especially physicians, as well as researchers and other stakeholders, and improved reliability and relevance of data. (New HOD Policy)

4. Our AMA supports cooperation and collaboration of stakeholders to facilitate the collection and use of RWD and RWE that is deemed fit for regulatory purpose. (New HOD Policy)

5. Our AMA will evaluate and develop a response to the educational needs of physicians seeking to understand the use of fit for purpose RWD and RWE in clinical practice. (New HOD Policy)

6. That Policy H-100.992, "FDA," be amended by addition to read as follows:

H-100.992, "FDA"

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with

- its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit
 analysis or relative safety or efficacy judgments should not be grounds for limiting access
 to or indications for use of a drug unless the weight of the evidence from clinical trials.

 RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
 - (2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
 - (3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history. (Modify Current HOD Policy)
 - 7. That Policy D-100.982, "Enhanced Physician Access to Food and Drug Administration Data," urging the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases, be reaffirmed. (Reaffirm Current HOD Policy)
 - 8. That Policy H-110.986, "Incorporating Value into Pharmaceutical Pricing" supporting value-based pricing of pharmaceuticals that is evidence-based and the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes, be reaffirmed. (Reaffirm Current HOD Policy)
 - 9. That Policy H-406.987, "Medical Information and Its Uses," identifying three components of a data transparency framework, be reaffirmed. (Reaffirm Current HOD Policy)
 - 10. That Policy H-410.948, "Clinical Pathways," supporting the development of transparent, collaboratively constructed clinical pathways that are implemented in ways that promote administrative efficiencies for both providers and payers; promote access to evidence-based care for patients; recognize medical variability among patients and individual patient autonomy; promote access to clinical trials; and are continuously updated to reflect the rapid development of new scientific knowledge, be reaffirmed. (Reaffirm Current HOD Policy)
 - 11. That Policy H-450.933, "Clinical Data Registries," encouraging multi-stakeholder efforts to develop and fund clinical data registries to facilitate quality improvements and research that results in better health care, improved population health, and lower costs be reaffirmed. (Reaffirm Current HOD Policy)
 - 12. That Policy D-460.970, "Access to Clinical Trial Data," urging the FDA to investigate and develop means by which scientific investigators can access original source safety data from industry-sponsored trials upon request; be reaffirmed. (Reaffirm Current HOD Policy)

Fiscal Note: \$50,000

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Figure 1.

Scope of This Report: Where does RWE fit in to Evidence-based Practice?

5 Steps of Evidence-based practice: Acquire the Appraise the Ask a clinical Apply the Assess your best question. evidence. evidence. performance. evidence. Evidence in Health Care Randomized Real-world Controlled Trials Case Reports Experience Others Evidence (RWE) (RCTs) Not Yet Fit for Fit for Purpose Purpose Used in Medical Product Evaluation Used with Augmented Intelligence Used in personalized medicine

Other Uses

Figure 2.

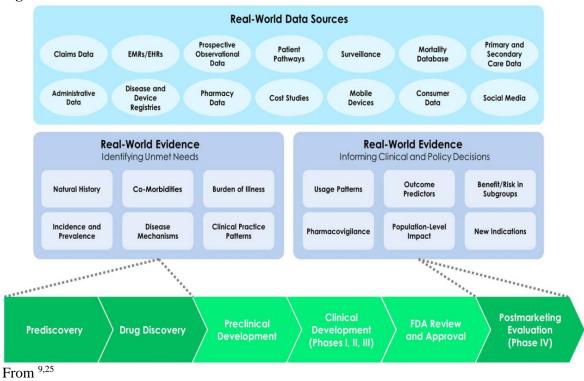
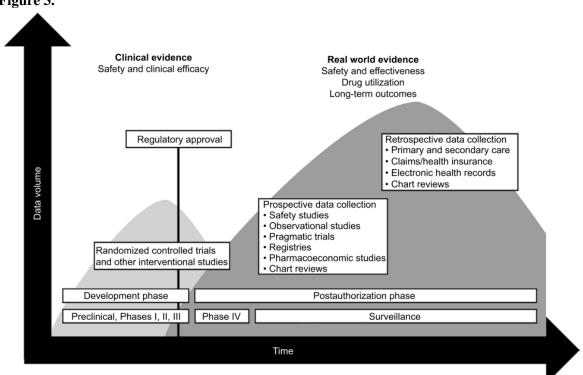


Figure 3.



APPENDIX A

Data Networks

This is a non-comprehensive list of example data networks housing and providing RWD per request. Please see Box 1 for links to more information on the networks.

The Sentinel Initiative

The Sentinel Initiative, launched in 2008, began as a Congressional mandate for the FDA to establish a public-private partnership to develop a medical product safety surveillance system using existing data.³⁵ The FDA partnered with over 200 health systems leaders, pharmacoepidemiologists, clinicians, data scientists, patient representatives, and more from 31 health plans and academic organizations to form the network.¹⁵

The principal component of the Sentinel Initiative is the Sentinel System, a multi-site, privacy-preserving, curated distributed data infrastructure, and suite of analysis tools. The FDA has used Sentinel to conduct more than 250 analyses, and it is now embedded in the regulatory review process through the Active Risk Identification and Analysis (ARIA) process. ARIA is comprised of pre-defined, parameterized, reusable routine querying tools, and undergoes continuous quality checks and refreshes so analyses can be done quickly and efficiently for medical product safety surveillance.

The FDA recognizes the interest in generating effectiveness evidence and is exploring the potential of the Sentinel System to support studies of efficacy. As a part of this effort, the FDA is funding a study to explore whether observational methods can be used to replicate the results of approximately 30 clinical trials designed to provide evidence about the effectiveness of a drug. This project will assist the FDA in understanding how observational methods can be applied to evaluating drug effectiveness and may have the potential to provide evidence to inform regulatory decision-making.²

Additionally, FDA is increasing the scope of safety signals the Sentinel System evaluates by identifying opportunities to improve data, tools, and methods and has completed or has underway several projects related to patient and product safety:

- Sentinel data have informed regulatory decisions made by the FDA's Center for Drug Evaluation and Research and, in the past 2 years, have eliminated the need for post-marketing studies on nine potential safety issues associated with five products, as an example, ustekinumab and serious infections.¹⁵
- To explore how randomized trials can be conducted in real-world settings, the FDA is supporting the first randomized clinical trial in Sentinel. The IMPACT-Afib trial is testing an educational intervention to address underuse of effective medications to reduce the risk of stroke in patients with atrial fibrillation. ^{2,15,39}

FDA released a Sentinel System Five-Year Strategy which details goals for the multi-purpose national data and scientific resource center for evidence-generation that can in inform health care decision-making.⁴⁰ The strategy also details several data improvements FDA plans to prioritize including the following:

- Scaling capabilities related to the mother-infant linkage to evaluate in-utero exposure, medical product usage during pregnancy, and post-natal outcomes.
- Working to integrate national and state registry linkages including the National Death Index (NDI), Surveillance Epidemiology and Ends Results (SEER), and other rare-disease registries.
- Continuing to increase the number of validated Health Outcomes of Interest (HOIs) through medical record review, drawing from increased availability of EHR linkages.
- Expanding linkages to EHR data sources from Sentinel System Data Partners and exploring potential expansion to incorporate other data partners, such as the National Patient-Centered Clinical Research Network (PCORnet).
- Increasing the availability of full medical records, including improved access to the Medicare chart review process, prioritizing electronic sources from integrated delivery systems.

PCORnet

PCORnet originated with, and evolved through funding support from the Patient-Centered Outcomes Research Institute (PCORI) to develop a range of useful resources and partnerships. Currently, PCORnet is a network that supports patient-centered research and answers questions important to patients, caregivers, clinicians, and the broader health care community.⁴¹

PCORnet is a decentralized network that is governed by a steering committee composed of patient representatives and leaders from PCORnet's constituent organizations.⁴² PCORNet supported the largest study of bariatric surgery devices in adolescents.⁴³

MDEpiNet

The Medical Device Epidemiology Network (MDEpiNet) is a global public-private partnership that seeks to advance the collection and use of RWD to improve patient outcomes. ⁴⁴ MDEpiNet brings together stakeholders from across the health ecosystem to develop and improve RWD infrastructure and carry out studies to better understand how devices perform in the real-world. MDEpiNet is also focused on developing better methods and medical device registries for medical device surveillance and post-market data collection.

NEST

In 2016, the FDA awarded the Medical Device Innovation Consortium (MDIC) \$3 million to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). The MDIC was in 2012 as the first public-private partnership created with the objective of advancing medical device regulatory science throughout the total product life cycle.⁴⁵ NESTcc aims to support sustainable generation and use of timely, reliable, and cost-effective RWE throughout the lifecycle of medical devices using RWD to support decision-making for: regulatory purposes, patients and clinicians in clinical situations, health systems purchasing, and payer coverage.^{46,47} NESTcc has established partnerships with twelve network collaborators, including MDEpiNet, that represent more than 195 hospitals and 3,942 outpatient clinics to use high-quality RWD from various sources.

The goals of NESTcc include moving from passive surveillance to active, real-time surveillance, leveraging RWE to support regulatory decisions related to medical devices, making better use of data generated in the course of clinical care or by patients themselves, and moving away from lengthy, one-off, cost-prohibitive studies to an ecosystem that supports more routine evidence generation. NEST is setting data quality and methods standards related to observational and randomized studies; designating demonstration projects to assess feasibility and the ability to capture the data needed to support a range of studies and analyses; and offering value through products and services to key stakeholders in the ecosystem.

Registries

Device-specific and condition-specific registries have played an important role in generating clinical evidence on safety and effectiveness by collecting, curating, and analyzing data related to medical product use in routine practice over time. ³² Registries collect patient-level data from health systems or physician practices through various pathways and are used for many purposes, including short- and long-term surveillance, fulfillment of post-market observational study commitments for regulatory bodies, and comparative safety and effectiveness assessments, including those in under-studied subpopulations. ^{48,49} By linking medical product exposures and long-term outcomes, registries permit follow-up that can span decades. ⁴⁸

Others

The TREND Community data collection platform and PatientsLikeMe are examples of online platforms created that allow for the systematic gathering of patient experience data.^{50,51} These online networks of consented patients and caregivers living with diseases are engaged in community discussions and sharing patient experiences. The communities connect scientists, doctors, therapists, research organizations, patients,

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and caregivers in real time and enable them to directly organize experiments and crowd-source the collection of RWD.

Over the past several years, several companies have emerged that specialize in the collection, curation, analysis of health care technology data. For example, Aetion®, a software platform company delivering the real-world analytics and RWE, recently partnered with the FDA and Brigham and Women's Hospital/Harvard Medical School to use its software platform to re-create RCTs through RWE. The study aims to demonstrate the value of RWE as an accelerant to drug approval, particularly for supplemental indications. ⁵²

Box 1. More information on RWD networks.

- 1. <u>Report an adverse event</u>: Any adverse event experience by patients should be reported to the <u>FDA</u> Adverse Event Reporting System (FAERS)
- 2. Sentinel
- 3. PCORnet
- 4. MDEpiNet
- 5. NEST

APPENDIX B

RWE Use Cases

Salford Lung Study (Pragmatic (hybrid) Clinical Trial)

The Salford Lung Study assessed the effectiveness and safety of fluticasone furoate in patients with chronic obstructive pulmonary disease (COPD). In this 12 month, open-label, phase 3, multicenter study, 2799 patients with COPD were randomized to a once-daily inhaled combination of fluticasone furoate and vilanterol, or to continuation of their existing therapy. This study analyzed EHR data collected during all interactions of consenting patients with physicians, pharmacists and hospitals.⁵³

ADAPTABLE (Pragmatic (hybrid) Clinical Trial)

The ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness) trial compares two commonly used doses of aspirin by randomizing 20,000 patients. The trial is integrated into routine clinical care with minimal inclusion/exclusion criteria and no treatment protocol requirement beyond the assignment to one of the two doses of aspirin. ADAPTABLE is using EHRs and claims data (through PCORnet) to capture primary endpoints such as death, hospitalization for non-fatal myocardial infarction or non-fatal stroke, and secondary endpoints such as coronary revascularization procedures, hospitalization for serious bleeding, and other patient-reported outcomes. 1,54

VALIDATE-SWEDEHEART (Pragmatic (hybrid) Clinical Trial)

The VALIDATE-SWEDEHEART (The Bivalirudin versus Heparin in ST-Segment and Non-ST-Segment Elevation Myocardial Infarction in Patients on Modern Antiplatelet Therapy in the Swedish Web System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies Registry) Trial was a registry-based,

multicenter trial in which patients were randomized to bivalirudin or heparin during percutaneous coronary intervention. The endpoint was myocardial infarction, all-cause mortality, and major bleeding at 6 months. A national population-based Swedish registry platform was used for continuous enrollment, randomization, data collection, and follow up.^{1,55}

PatientsLikeMe – ALS (Patient Generated RWD)

A PatientsLikeMe community of patients with amyotrophic lateral sclerosis (ALS), a progressive and fatal neurodegenerative condition with no effective treatments, crowdsourced an observational study. Many patients with ALS in the community reported using lithium carbonate, which had shown promise in a small study but did not have regulatory approval for use in ALS. An observational study of drug usage and disease progression from quantitative data recorded by members of the community and matched control patients was conducted. No difference in disease progression was observed after 12 months between the two study groups; similar results were reported in a subsequent RCT. Experts note that these types of observational studies are not a substitute for RCTs, but suggest that data reported by patients in online health communities could be useful for accelerating clinical discoveries and evaluating the effectiveness of drugs in use.⁵⁶

APPENDIX C

Related AMA Policy

H-75.990, "Development and Approval of New Contraceptives"

Our AMA (1) supports congressional efforts to increase public funding of contraception and fertility research; (2) urges the FDA to consider the special health care needs of Americans who are not adequately served by existing contraceptive products when considering the safety, effectiveness, risk and benefits of new contraception drugs and devices; and (3) encourages contraceptive manufacturers to conduct post-marketing surveillance studies of contraceptive products to document the latter's long-term safety, effectiveness and acceptance, and to share that information with the FDA. (BOT Rep. O, I-91 Reaffirmed: Sunset Report, I-01 Modified: CSAPH Rep. 1, A-11)

H-100.968, "Improving the Quality of Geriatric Pharmacotherapy"

Our AMA believes that the Food and Drug Administration should encourage manufacturers to develop low dose formulations of medications commonly used by older patients in order to meet the special needs of this group; require geriatric-relevant labeling for over-the-counter medications; provide incentives to pharmaceutical manufacturers to better study medication effects in the frail elderly and oldest-old in pre- and post-marketing clinical trials; and establish mechanisms for data collection, monitoring, and analysis of medication-related problems by age group. (CSA Rep. 5, A-02 Reaffirmation A-10)

D-100.982, "Enhanced Physician Access to Food and Drug Administration Data"

Our AMA will: (1) urge the FDA to collaborate with physician organizations to develop better risk communication vehicles and approaches; (2) urge the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases; (3) monitor the design and implementation of any independent drug safety board that may be instituted within the FDA, or external to the agency, and respond as appropriate; and (4) support adequate funding to implement an improved FDA postmarketing prescription drug surveillance process. (CSA Rep. 6, A-05 Modified: CSAPH Rep. 1, A-15)

H-100.992, "FDA"

- (1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
- (2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
- (3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history. (Res. 119, A-80 Reaffirmed: CLRPD Rep. B, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmation A-06 Appended: Sub. Res. 509, A-06 Reaffirmation I-07 Reaffirmation I-09 Reaffirmation I-10)

H-110.986, "Incorporating Value into Pharmaceutical Pricing"

1. Our AMA supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals

must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

- 2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
- 3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size. (CMS Rep. 05, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: CMS-CSAPH Rep. 01, A-17 Reaffirmed: CMS Rep. 07, A-18)

H-120.958, "Supporting Safe Medical Products as a Priority Public Health Initiative"

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent "look alike-sound alike" errors in giving new drugs generic names;

- (2) continue participation in the National Patient Safety Foundation's efforts to advance the science of safety in the medication use process and likewise work with the National Coordinating Council for Medication Error Reporting and Prevention;
- (3) support the FDA's Medwatch program by working to improve physicians' knowledge and awareness of the program and encouraging proper reporting of adverse events;
- (4) vigorously work to support and encourage efforts to create and expeditiously implement a national machine-readable coding system for prescription medicine packaging in an effort to improve patient safety; (5) participate in and report on the work of the Healthy People 2010 initiative in the area of safe medical products especially as it relates to existing AMA policy; and
- (6) seek opportunities to work collaboratively within the Medicine-Public Health initiative (H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention (CDC) the Agency for Health Care Policy and Research (AHCPR) and the Centers for Medicare & Medicaid Services (CMS) to provide information to individual physicians and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety. (Res. 416, A-99 Appended: Res. 504, I-01 Reaffirmation A-10)

H-315.973, "Guiding Principles for the Collection, Use and Warehousing of Electronic Medical Records and Claims Data"

- 1. It is AMA policy that any payer, clearinghouse, vendor, or other entity that collects and uses electronic medical records and claims data adhere to the following principles: a. Electronic medical records and claims data transmitted for any given purpose to a third party must be the minimum necessary needed to accomplish the intended purpose. b. All covered entities involved in the collection and use of electronic medical records and claims data must comply with the HIPAA Privacy and Security Rules. c. The physician must be informed and provide permission for any analysis undertaken with his/her electronic medical records and claims data, including the data being studied and how the results will be used. d. Any additional work required by the physician practice to collect data beyond the average data collection for the submission of transactions (e.g., claims, eligibility) must be compensated by the entity requesting the data. e. Criteria developed for the analysis of physician claims or medical record data must be open for review and input by relevant outside entities. f. Methods and criteria for analyzing the electronic medical records and claims data must be provided to the physician or an independent third party so re-analysis of the data can be performed. g. An appeals process must be in place for a physician to appeal, prior to public release, any adverse decision derived from an analysis of his/her electronic medical records and claims data. h. Clinical data collected by a data exchange network and searchable by a record locator service must be accessible only for payment and health care operations.
- 2. It is AMA policy that any physician, payer, clearinghouse, vendor, or other entity that warehouses electronic medical records and claims data adhere to the following principles: a. The warehouse vendor must take the necessary steps to ensure the confidentiality, integrity, and availability of electronic medical records and claims data while protecting against threats to the security or integrity and unauthorized uses or disclosure of the information. b. Electronic medical records data must remain accessible to authorized users

for purposes of treatment, public health, patient safety, quality improvement, medical liability defense, and research. c. Physician and patient permission must be obtained for any person or entity other than the physician or patient to access and use individually identifiable clinical data, when the physician is specifically identified. d. Following the request from a physician to transfer his/her data to another data warehouse, the current vendor must transfer the electronic medical records and claims data and must delete/destroy the data from its data warehouse once the transfer has been completed and confirmed. (CMS Rep. 6, I-06 Reaffirmed: BOT Rep. 17, A-13)

D-315.984, "Ownership of Claims Data"

Our AMA will: (1) encourage physicians to include language designed to buttress rights associated with claims data ownership and access when contracting with health plan payers and other third parties; (2) continue to educate physicians on providing public and private health plan payers the "minimum necessary," as defined in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and regulations thereunder, protected health information necessary to achieve the purpose of a disclosure; (3) assist physicians wishing to register a complaint against health plan payers that have used claims data to form a database, or that have permitted access to or sale of the database or its contents without explicit patient and/or physician authorization, beyond the scope permitted by HIPAA with the Department of Health and Human Services Office of Civil Rights; (4) advocate to the Department of Health and Human Services, Office of the National Coordinator of Health Information Technology and/or other appropriate agencies for rules and regulations ensuring appropriate physician ownership and access rights to claims data, and appropriate protection of claims data held by various parties; and (5) continue to monitor federal and state activities impacting the exchange of physician-generated health information, including claims data. (BOT Rep. 19, I-06 Modified: CCB/CLRPD Rep. 2, A-14)

H-406.987, "Medical Information and Its Uses"

DATA TRANSPARENCY PRINCIPLES TO PROMOTE IMPROVEMENTS IN QUALITY AND CARE DELIVERY

Our AMA seeks to help physicians improve the quality reporting of patient care data and adapt to new payment and delivery models to transform our health care system. One means of accomplishing this goal is to increase the transparency of health care data. The principles outlined below ensure that physicians, practices, care systems, physician-led organizations, patients and other relevant stakeholders can access and proactively use meaningful, actionable health care information to achieve care improvements and innovations. These principles do not replace but build upon existing AMA policies H-406.990, H-406.989, H-406.991, and H-406.996 that address safeguards for the release of physician data and physician profiles, expanding these guidelines to reflect the new opportunities and potential uses of this information. Transparency Objectives and Goals

Engaging Physicians - Our AMA encourages greater physician engagement in transparency efforts, including the development of physician-led quality measures to ensure that gaps in measures are minimized and that analyses reflect the knowledge and expertise of physicians.

Promoting New Payment and Delivery Models - Our AMA supports appropriate funding and other support to ensure that the data that are used to inform new payment and delivery models are readily available and do not impose a new cost or additional burden on model participants.

Improving Care Choices and Decisions - Our AMA promotes efforts to present data appropriately depending on the objective and the relevant end-user, including transparently identifying what information is being provided, for what purpose, and how the information can or cannot be used to influence care choices. Informing Physicians - Our AMA encourages the development of user interfaces that allow physicians or their staff to structure simple queries to obtain and track actionable reports related to specific patients, peer comparisons, provider-level resource use, practice patterns, and other relevant information.

Informing Patients - Our AMA encourages patients to consult with physicians to understand and navigate health care transparency and data efforts.

Informing Other Consumers - Our AMA seeks opportunities to engage with other stakeholders to facilitate physician involvement and more proactive use of health care data.

Data Transparency Resources

Data Availability - Our AMA supports removing barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete.

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Access to Timely Data - While some datasets will require more frequent updates than others, our AMA encourages use of the most current information and that governmental reports are made available, at a minimum, from the previous quarter.

Accurate Data - Our AMA supports proper oversight of entities accessing and using health care data, and more stringent safeguards for public reporting, so that information is accurate, transparent, and appropriately used.

Use of Quality Data - Our AMA supports definitions of quality based on evidence-based guidelines, measures developed and supported by specialty societies, and physician-developed metrics that focus on patient outcomes and engagement.

Increasing Data Utility - Our AMA promotes efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility and reduce barriers that currently limit access to and use of the health care data. Challenges to Transparency

Standardization - Our AMA supports improvements in electronic health records (EHRs) and other technology to capture and access data in uniform formats.

Mitigating Administrative Burden - To reduce burdens, data reporting requirements imposed on physicians should be limited to the information proven to improve clinical practice. Collection, reporting, and review of all other data and information should be voluntary.

Data Attribution - Our AMA seeks to ensure that those compiling and using the data avoid attribution errors by working to correctly assign services and patients to the appropriate provider(s) as well as allowing entities to verify who or where procedures, services, and items were performed, ordered, or otherwise provided. Until problems with the current state of episode of care and attribution methodologies are resolved, our AMA encourages public data and analyses primarily focused at the system-level instead of on individual physicians or providers. (BOT Rep. 6, A-15)

H-406.989, "Work of the Task Force on the Release of Physician Data"

1. Our AMA Council on Legislation will use the Release of Claims and Payment Data from Governmental Programs as a basis for draft model legislation. 2. Our AMA will create additional tools to assist physicians in dealing with the release of physician data. 3. Our AMA will continue to monitor the status of, and take appropriate action on, any legislative or regulatory opportunities regarding the appropriate release and use of physician data and its use in physician profiling programs. 4. Our AMA will monitor new and existing Web sites and programs that collect and use data on patient satisfaction and take appropriate action when safeguards are not in place to ensure the validity of the results. 5. Our AMA will continue and intensify its extensive efforts to educate employers, healthcare coalitions and the public about the potential risks and liabilities of pay-for-performance and public reporting programs that are not consistent with AMA policies, principles, and guidelines. 6. Our AMA: A) opposes the public reporting of individual physician performance data collected by certification and licensure boards for purposes of MOC and MOL; and B) supports the principle that individual physician performance data collected by certification and licensure boards should only be used for the purposes of helping physicians to improve their practice and patient care, unless specifically approved by the physician. (BOT Rep. 18, A-09 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmed in lieu of Res. 808, I-10 Appended: Res. 327, A-11 Modified: CCB/CLRPD Rep. 2, A-14)

H-406.990, "Work of the Task Force on the Release of Physician Data"

Release of Claims and Payment Data from Governmental Programs

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments.

Raw claims data used in isolation have significant limitations. The release of such data from government programs must be subject to safeguards to ensure that neither false nor misleading conclusions are derived that could undermine the delivery of appropriate and quality care. If not addressed, the limitations of such data are significant. The foregoing limitations may include, but are not limited to, failure to consider factors that impact care such as specialty, geographic location, patient mix and demographics, plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution.

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Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare and Medicaid programs should only be released:

- 1. when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations;
- 2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided;
- 3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency's investigation or prosecution of a possible violation;
- 4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities];
- 5. to other entities only if the data do not identify specific physicians [or their practice entities]; or 6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria: (a) the publication or release of this information is deemed imperative to safeguard the public welfare; (b) the raw data regarding physician claims from governmental healthcare programs is: (i) published in conjunction with appropriate disclosures and/or explanatory statements as to the limitations of the data that raise the potential for specific misinterpretation of such data. These statements should include disclosure or explanation of factors that influence the provision of care including geographic location, specialty, patient mix and demographics, health plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution, in addition to other relevant factors. (ii) safeguarded to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.
- (c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following: (i) the data are used to profile physicians based on quality of care provided never on utilization of resources alone and the degree to which profiling is based on utilization of resources is clearly identified. (ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties. (iii) the data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians. (d) any governmental healthcare data shall be protected and shared with physicians before it is released or used, to ensure that physicians are provided with an adequate and timely opportunity to review, respond and appeal the accuracy of the raw data (and its attribution to individual physicians) and any physician profiling results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release. (BOT Rep. 18, A-09 Reaffirmed: BOT Rep. 09, A-19 Modified: Speakers Rep., A-19)

H-406.991, "Work of the Task Force on the Release of Physician Data"

Principles for the Public Release and Accurate Use of Physician Data

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data when it is used in conjunction with program(s) designed to improve or maintain the quality of, and access to, medical care for all patients and is used to provide accurate physician performance assessments in concert with the following Principles:

- 1. Patient Privacy Safeguards
- All entities involved in the collection, use and release of claims data comply with the HIPAA Privacy and Security Rules (H-315.972, H-315.973, H-315.983, H-315.984, H-315.989, H-450.947).

- Disclosures made without patient authorization are generally limited to claims data, as that is generally the only information necessary to accomplish the intended purpose of the task (H-315.973, H-315.975, H-315.983).
- 2. Data Accuracy and Security Safeguards
- Effective safeguards are established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data (H-406.996, H-450.947, H-450.961).
- Reliable administrative, technical, and physical safeguards provide security to prevent the unauthorized use or disclosure of patient or physician-specific health care data and physician profiles (H-406.996, H-450.947, H-450.961).
- Physician-specific medical practice data, and all analyses, proceedings, records and minutes from quality review activities are not subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent (H-406.996, H-450.947, H-450.961).
- 3. Transparency Requirements
- When data are collected and analyzed for the purpose of creating physician profiles, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure (H-315.973, H-406.993, H-406.994, H-450.947, H-450.961).
- The limitations of the data sources used to create physician profiles are clearly identified and acknowledged in terms understandable to consumers (H-406.994, H-450.947).
- The capabilities and limitations of the methodologies and reporting systems applied to the data to profile and rank physicians are publicly revealed in understandable terms to consumers (H-315.973, H-406.994, H-406.997, H-450.961).
- Case-matched, risk-adjusted resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients (H-285.931).
- 4. Review and Appeal Requirements
- Physicians are provided with an adequate and timely opportunity to review, respond and appeal the results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release (H-315.973, H-406.996, H-406.998, H-450.941, H-450.947, H-450.961).
- When the physician and the rater cannot reach agreement, physician comments are appended to the report at the physician's request (H-450.947).
- 5. Physician Profiling Requirements
- The data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians (H-406.994, H-406.997, H-450.947, H-450.961).
- Data reporting programs only use accurate and balanced data sources to create physician profiles and do not use these profiles to create tiered or narrow network programs that are used to steer patients towards certain physicians primarily on cost of care factors (450.951).
- When a single set of claims data includes a sample of patients that are skewed or not representative of the physicians' entire patient population, multiple sources of claims data are used.
- Physician efficiency of care ratings use physician data for services, procedures, tests and prescriptions that are based on physicians' patient utilization of resources so that the focus is on comparative physicians' patient utilization and not on the actual charges for services.
- Physician-profiling programs may rank individual physician members of a medical group but do not use those individual rankings for placement in a network or for reimbursement purposes.
- 6. Quality Measurement Requirements
- The data are used to profile physicians based on quality of care provided never on utilization of resources alone -- and the degree to which profiling is based on utilization of resources is clearly identified (H-450.947).
- Data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the Physician Consortium for Performance Improvement. (H-406.994, H-406.998, H-450.947, H-450.961).
- These evidence-based measures are endorsed by the National Quality Forum (NQF) and/or the AQA and HQA, when available. When unavailable, scientifically valid measures developed in conjunction with appropriate medical specialty societies and practicing physicians are used to evaluate the data.

- 7. Patient Satisfaction Measurement Requirements
- Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians to better meet patient needs particularly as they relate to favorable patient outcomes and other criteria of high quality care (H-450.982).
- Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of the performance of a physician or physician office, or the result of the demands or restrictions of health insurers or other factors out of the control of the physician, the use of patient satisfaction data is not appropriate for incentive or tiering mechanisms.
- As in physician profiling programs, it is important that programs that publicly rate physicians on patient satisfaction notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication. (BOT Rep. 18, A-09 Reaffirmation A-10 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmation I-10 Reaffirmed in lieu of Res. 808, I-10 Reaffirmed in lieu of Res. 824, I-10 Reaffirmation A-11 Reaffirmed: BOT Rep. 17, A-13 Reaffirmed: Res. 806, I-13 Reaffirmation: A-19)

H-406.996, "Use and Release of Physician-Specific Health Care Data"

- (1) Our AMA advocates that third party payers, government entities and others that use and release physician-specific health care data adhere to the following principles: (a) Physicians under review and relevant physician organizations shall be provided with an adequate opportunity to review and respond to proposed physician-specific health care data interpretations and disclosures prior to their publication or release. (b) Effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate or subjective physician-specific health care data shall be established. (c) Reliable administrative, technical, and physical safeguards to prevent the unauthorized use or disclosure of physician-specific health care data shall be developed. (d) Such safeguards shall treat all underlying physician-specific health care data and all analyses, proceedings, records, and minutes from quality review activities on physician-specific health care data as confidential, and provide that none of these documents shall be subject to discovery, or admitted into evidence in any judicial or administrative proceeding.
- (2) Our AMA supports release of severity-adjusted physician-specific health care data from carefully selected pilot projects where the data may be deemed accurate, reliable, and meaningful to physicians, consumers, and purchaser;
- (3) Our AMA urges that any published physician-specific health care data be limited to appropriate data concerning the quality of health care, access to health care, and the cost of health care;
- (4) Our AMA opposes the publication of physician-specific health care data collected outside of carefully selected pilot studies or where the data are not deemed accurate, reliable, or meaningful;
- (5) Our AMA urges that a copy of the information in any such profile be forwarded to the subject physician, and that the physician be given the right to review and certify adequacy of the information prior to any profile being distributed, including being placed on the Internet; and
- (6) Our AMA urges that the costs associated with creation of any such profiling system should not be paid for by physicians licensure fees. (BOT Rep. Q, I-92 BOT Rep. W, A-92 Reaffirmed: Res. 719, A-93 CMS Rep. 10, A-96 Appended: Res. 316, I-97 Reaffirmation A-01 Reaffirmation A-02 Reaffirmation A-05 Reaffirmed in lieu of Res. 724, A-05 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10)

H-406.999, "Goal of Health Care Data Collection"

The AMA (1) continues to advocate that health care data collected by government and third party payers be used for education of both consumers and providers; and (2) believes that government, third party payers and self-insured companies should make physician-specific utilization information available to medical societies. (BOT Rep. W, A-92 Reaffirmed: Res. 719, A-93 BOT Rep. Y, I-85 Reaffirmed CLRPD Rep. 2, I-95 CMS Rep. 10, A-96 Reaffirmed: CMS Rep. 8, A-06 Reaffirmed: CMS Rep. 01, A-16)

H-410.948, "Clinical Pathways"

Our AMA supports the development of transparent, collaboratively constructed clinical pathways that: (1) are implemented in ways that promote administrative efficiencies for both providers and payers; (2) promote access to evidence-based care for patients; (3) recognize medical variability among patients and individual patient autonomy; (4) promote access to clinical trials; and (5) are continuously updated to reflect the rapid development of new scientific knowledge. (Res. 708, A-16 Reaffirmed: CMS Rep. 06, A-18)

H-450.933, "Clinical Data Registries"

- 1. Our AMA encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs.
- 2. Our AMA encourages national medical specialty societies, state medical associations, and other physician groups to join the National Quality Registry Network and to participate in efforts to advance the development and use of clinical data registries.
- 3. Our AMA supports flexibility in the development and implementation of clinical data registries. The following guidelines can help maximize opportunities for clinical data registries to enhance the quality of care provided to patients: a. Practicing physicians must be actively involved in decisions related to the development, maintenance and use of clinical data registries and registry data. b. Data elements, risk-adjustment models and measures used in the registry should be fully transparent. c. Registries should provide timely, actionable feedback reports to individual physicians or entities reporting at the organizational level. d. Registries and electronic health records should be interoperable, and should be capable of sharing and integrating information across registries and with other data sources in a HIPAA-compliant and confidential manner. e. Registry stewards should establish a formal process to facilitate the modification, expansion, or dissolution of the registry in order to accommodate advances in technology and changing clinical data needs to ensure continued utility of their registry.
- 4. Our AMA encourages physicians to participate in clinical data registries, and will encourage efforts that help physicians identify existing registries suitable for and of benefit to their patient populations and their practices.
- 5. Our AMA will continue to advocate for and support initiatives that minimize the costs and maximize the benefits of physician practice participation in clinical data registries.
- 6. Our AMA supports that, with the consent of the participating physician, physician-specific clinical registry data may be used to meet third-party quality reporting requirements, in accordance with the following principles: a. Data should be used to improve the quality of patient care and the efficient use of resources in the delivery of health care services. b. Data related to resource use and cost of care must be evaluated and reported in conjunction with quality of care information. c. Effective safeguards must be established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data. d. Case-matched, risk-adjusted quality measure and resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients. e. When data are collected and analyzed for the purpose of meeting quality reporting requirements, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians, and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure. (CMS Rep. 8, A-14 Reaffirmed: CMS Rep. 05, I-16 Reaffirmed: CMS Rep. 10, A-17)

H-460.926, "Funding of Biomedical, Translational, and Clinical Research"

Our AMA: (1) reaffirms its long-standing support for ample federal funding of medical research, including basic biomedical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research; and (2) encourages the National Institutes of Health, the Agency for Healthcare Research and Quality and other appropriate bodies to develop a mechanism for the continued funding of translational research. (Sub. Res. 507, I-97 Reaffirmed: CSA Rep. 13, I-99 Modified: Res. 503, and Reaffirmation A-00 Modified: CSAPH Rep. 1, A-10)

H-460.943, "Potential Impact of Health System Reform Legislative Reform Proposals on Biomedical Research and Clinical Investigation"

The AMA, to encourage and support the continuing development of new advances in science and medicine and the development and implementation of meaningful quality assurance programs essential to improving the delivery of medical and health care in the United States, advocates:

- (1) Strong support and funding for medical education programs at all levels to attract and stimulate gifted students and physicians to receive training and experience in, and to participate in, basic science or clinically-oriented research programs.
- (2) Strong financial and policy support for all aspects of biomedical science and research, including: basic science research (investigator initiated grant-funded research) in a wide variety of fields; laboratory-based

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clinical studies (including surgical studies); clinical studies and therapy trials; clinical outcomes research; behavioral science research, including studies to assess implementation of health promotion and/or disease prevention activities; and technology transfer research, with an emphasis on diffusing information about, training personnel in, and encouraging appropriate use of new technologies.

- (3) Adequate federal funding for biomedical science programs, including an appropriate balance of funding for basic, clinical, health service, and public health/prevention research.
- (4) Support and funding for evaluation and implementation research, including drug and technology assessment, medical device review, and developing and setting standards for computerized medical records. (CSA Rep. 10, A-94 Reaffirmed: CSA Rep. 8, A-05 Reaffirmed: CSAPH Rep. 1, A-15)

D-460.970, "Access to Clinical Trial Data"

Our AMA: (1) urges the Food and Drug Administration to investigate and develop means by which scientific investigators can access original source safety data from industry-sponsored trials upon request; and (2) supports the adoption of universal policy by medical journals requiring participating investigators to have independent access to all study data from industry-sponsored trials. (Res. 503, A-14 Reaffirmed: Res. 907, I-15)

D-460.972, "Creation of a National Registry for Healthy Subjects in Phase I Clinical Trials"

Our AMA encourages the development and implementation of a national registry, with minimally identifiable information, for healthy subjects in Phase 1 trials by the US Food and Drug Administration or other appropriate organizations to promote subject safety, research quality, and to document previous trial participation. (Res. 913, I-11)

H-525.991, "Inclusion of Women in Clinical Trials"

Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice. (Res. 183, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 05, A-16 Reaffirmed: Res. 909, I-16)

8.8 Required Reporting of Adverse Events

Physicians' professional commitment to advance scientific knowledge and make relevant information available to patients, colleagues, and the public carries with it the responsibility to report suspected adverse events resulting from the use of a drug or medical device.

Mandated pre- and post-marketing studies provide basic safeguards for public health, but are inherently limited in their ability to detect rare or unexpected consequences of use of a drug or medical device. Thus spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations are irreplaceable as a source of information about the safety of drugs and devices. As the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events.

Cases in which there is clearly a causal relationship between use of a drug/device and an adverse event, especially a serious event, will be rare. Physicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship, to suspect that an adverse event has occurred. A physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to: (a) Communicate that information to the professional community through established reporting mechanisms. (b) Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention to the appropriate regulatory agency.

AMA Principles of Medical Ethics: I,V,VII

Issued: 2016

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-I-19

Subject: Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in

Hospitals (Resolution 414-A-19)

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

Resolution 414-A-19, introduced by the Oklahoma Delegation and referred by the House of Delegates asks:

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That our American Medical Association offer guidance to medical staffs regarding patient use of non-US Food and Drug Administration approved medical marijuana and cannabinoids on hospital property, including product use, storage in patient rooms, nursing areas and/or pharmacy, with report back to the House of Delegates at the 2019 Interim Meeting.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2009 to August 2019 using the search terms: "hospital policies" and cannabis; "hospital policies" and marijuana. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and applicable professional organizations, including hospital associations, were reviewed for relevant information.

 The Council on Science and Public Health acknowledges that the use of non-FDA approved cannabis and cannabinoid products presents challenges in health care facilities beyond hospitals (e.g., long-term care facilities, mental health and addiction facilities) and patients (e.g., visitors and employees), but those issues were deemed outside of the scope of this report.

CURRENT AMA POLICY

 The AMA believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use. Furthermore, cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process. The AMA also supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws and believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions (D-95.969, "Cannabis Legalization for Medicinal Use").

The AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-

based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product (H-95.952, "Cannabis and Cannabinoid Research").

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STATUS OF CANNABIS UNDER FEDERAL LAW

Under the U.S. Controlled Substances Act (CSA) of 1970, cannabis is classified as a Schedule I controlled substance, meaning it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. This means that the cultivation, manufacture, sale distribution, and use of medical cannabis violates the CSA and constitutes a federal felony.

Cannabis is not FDA-approved as a safe and effective drug for any indication. However, the agency has approved three drug products containing synthetic versions of the main psychoactive ingredient of cannabis, delta-9 tetrahydrocannabinol (THC). Marinol® and SyndrosTM, which include the active ingredient dronabinol, are indicated for nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS.³ Cesamet®, which contains the active ingredient nabilone, is also indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy.²

The Agriculture Improvement Act of 2018 (Farm Bill) removed hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.² However, the law explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds.² The FDA has approved one cannabis-derived product, Epidiolex®, which contains a purified form of the drug substance cannabidiol (CBD) for the treatment of seizures associated with Lennox-Gastaut or Dravet syndrome.³ The FDA has expressed concern at the proliferation of products asserting to contain CBD that are being marketed for therapeutic or medical uses that have not been approved by FDA.³ Since CBD has been studied as a new drug, it cannot be legally included in foods or dietary supplements. The FDA is currently considering potential regulatory frameworks for CBD.

STATUS OF CANNABIS UNDER STATE LAW

At the state level, trends in law have moved from decriminalization, to the legalization of medical use of cannabis, to cannabis regulated for adult use. California was the first jurisdiction in the United States to legalize the medical use of cannabis. Today, 33 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have legalized the medical use of cannabis through either the legislative process or ballot measures. These laws vary greatly by jurisdiction, from how patients access the product (home cultivated or dispensary), to qualifying conditions, product safety and testing requirements, packaging and labeling requirements, and consumption method (some states prohibit smoking the product). In jurisdictions that have legalized cannabis for medicinal use, physicians can "certify" or "recommend" a qualifying patient for the medicinal use of cannabis, but physicians cannot prescribe cannabis for medical purposes because it is illegal under federal law. In recent years, an additional 17 states have enacted laws allowing access to low THC/high CBD products for children with epilepsy.

In 2012, Colorado and Washington were the first U.S. jurisdictions to legalize the adult use of cannabis for recreational purposes. Today, a total of 11 states and the District of Columbia have legalized cannabis for adult use. Most of these jurisdictions have created for-profit, commercial cannabis production and distribution markets where the product is sold and taxed.

DISCUSSION

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The AMA does not approve of state-based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. Hospitals are being encouraged to accommodate patient use of cannabis. The primary argument for allowing patients to use cannabis in hospitals is focused on continuity of care. If patients have had success using cannabis for medicinal purposes, ending that treatment due to a hospital admission disrupts treatment and could lead to worse outcomes.⁵

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Risks to Hospitals in Allowing Patient Use of Cannabis Products

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Hospitals are subject to federal law because they receive reimbursement from federal programs. Since cannabis is a Schedule 1 controlled substance, its manufacture, distribution, or possession is a criminal offense. Hospitals that allow patient use of cannabis are at risk of violating federal law, losing their deemed status from Centers for Medicare and Medicaid Services (CMS), exposing themselves to possible penalties or sanctions, and losing federal funding.⁶⁻⁸

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Physicians who maintain DEA licensure are also subject to federal law and are not permitted to prescribe a Schedule I substance. In addition to the prohibition on prescribing, the DEA also prohibits a practitioner from administering a Schedule I substance, which means that physicians and other clinicians with DEA licenses cannot administer cannabis. Doing so may jeopardize a clinician's federal DEA registration and their ability to prescribe controlled substances.

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26 27 In addition to federal law, hospitals must also meet standards for pharmacies and medication management such as those established by hospital accreditation bodies.⁸ For example, The Joint Commission Standard MM.03.01.05 on Medication Management requires that: "[t]he hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners."8,9

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This standard includes the following elements of performance:

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The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.⁹

Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.9 The hospital informs the prescriber and patient if the medication brought into the hospital

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One of the biggest challenges for hospitals in meeting this standard for cannabis would likely be identifying the medication and visually evaluating the medication's integrity.8 Depending on state law, the patient may be enrolled in the state's cannabis for "medicinal use" program and have their own supply from a state licensed manufacturer. However, the hospital would likely not want to assume responsibility for vetting the substance or any adverse effects the patient experiences as a result of the product.

by patients, their families, or licensed independent practitioners is not permitted.⁹

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49 50 Hospitals would also have to address medication storage concerns, particularly if cannabis products should be stored with the pharmacy department and treated as a controlled substance, by security personnel, or with the patient. 10 There are also complicated logistics for self-administration of cannabis by the patient or caregiver. Many hospitals have policies on self-administration of

medicines that permit patients to use their own medications only after identification and labeling by pharmacy personnel.

Since many hospitals have policies prohibiting smoking on facility grounds, hospitals would have to determine what preparations of cannabis would be allowed (e.g., oils or edibles). Hospitals should also be prepared to provide information to their medical staffs on cannabis withdrawal symptoms as well as possible cannabis or cannabinoid contraindications, drug interactions, or possible adverse effects.

State Laws Addressing Cannabis Use in Hospitals

Some states have tried to address cannabis use in hospital facilities by amending their state laws. Connecticut and Maine permit the use of cannabis by hospitalized patients and give some state-level legal protection for clinicians who administer it. Connecticut law provides that a nurse shall not be subject to arrest or prosecution, or penalized in any manner for administering cannabis to a qualifying patient or research program subject in a hospital or health care facility licensed by the Department of Public Health.¹¹

Maine has enacted protection for hospitals and long-term care facilities for use of edible cannabis products, tinctures, and salves by an admitted patient who has been certified for use of cannabis products under state law.¹² The law provides that hospitals and long-term care facilities are not subject to prosecution, search, seizure or penalty in any manner, including but not limited to a civil penalty or disciplinary action by an occupational or professional licensing board or entity, and may not be denied any license, registration, right or privilege solely because the admitted patient lawfully engages in conduct involving the medical use of cannabis.¹² These protections also apply to officers or directors, employees or agents of a hospital or long-term care facility.¹²

 Minnesota law provides that hospitals may adopt reasonable restrictions on use and storage of cannabis. The restrictions may include a provision that the provider will not store or maintain the patient's supply of cannabis, that the provider is not responsible for providing cannabis for patients, and that cannabis be used only in a place specified by the provider. Under Minnesota state law, employees of these facilities are not subject to violations under the statutes for possession while carrying out employment duties, such as providing or supervising care to a registered patient, or distribution of cannabis to a registered patient.

The Minnesota Hospital Association (MHA) convened a broad group of stakeholders to discuss the impact of the state's cannabis law on hospital workflows as well as policies and procedures. The group produced template policies on cannabis for MHA members. The policies can be summarized as follows: (1) the hospital will not allow patient use of cannabis, (2) the hospital will allow inpatients to continue use while inpatient in the hospital and cannabis will be treated as self-administered home therapy, and (3) the hospital will allow inpatients to continue while inpatient in the hospital and cannabis will be treated as a medication and integrated within the hospital medical workflows. The templates provide hospitals with a helpful list of issues for consideration.

CONCLUSION

It is the AMA's position that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use. The AMA does not believe cannabis for medicinal use should be legalized through the state legislative, ballot initiative, or referendum process. Given the growing number of states that have legalized cannabis use, hospitals

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1 are increasingly likely to encounter patients who are taking cannabis or cannabis-related products. 2 It has been argued that patients should be allowed to use non-FDA approved cannabis-related 3 products to ensure continuity of care if they are admitted to the hospital. However, hospitals and 4 physicians face legal risks in doing so given cannabis' status as a Schedule I controlled substance. 5 Hospitals should consider the risks associated with allowing the use of non-FDA approved 6 cannabis or cannabis-derived products by patients and develop policies to address this issue so 7 patients and clinicians have clarity on what is permitted. Hospitals that decide to allow the use of 8 non-FDA approved cannabis or cannabis-derived products should provide information to their 9 medical staffs on cannabis withdrawal symptoms as well as possible cannabis or cannabinoid 10 contraindications, drug interactions, or possible adverse effects.

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RECOMMENDATIONS

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The Council recommends that the following recommendation be adopted in lieu of Resolution 414-A-19, and the remainder of the report be filed.

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The AMA encourages hospitals and health systems to: (1) engage stakeholders, including, but not limited to physicians, nurses, pharmacists, legal counsel, experts in controlled substance diversion prevention, as well as relevant state and federal agencies in developing policies for addressing patient use of non-FDA approved cannabis or cannabis-derived products for use within their facilities and (2) communicate their policy on patient use of non-FDA approved cannabis or cannabis-derived products within their facilities, to ensure clinicians are prepared to treat patients in accordance with policy. (New HOD Policy)

Fiscal Note: less than \$500

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 901

(I-19)

Introduced by: Medical Student Section

Subject: Health Impact of Per- and Polyfluoroalkyl Substances (PFAS) Contamination

in Drinking Water

Referred to: Reference Committee K

Whereas, The Environmental Protection Agency (EPA) determines whether a contaminant should have an enforceable regulatory standard for water contamination based on three criteria including: a) adverse effect on the health of persons, b) the contaminant is known to occur in public water often enough at levels of concern, c) regulation provides a meaningful opportunity for health risk reductions¹; and

for health risk reductions¹; and

Whereas, Polyfluoroalkyl chemicals (PFAS) are chemicals used in the manufacturing of thousands of industrial and consumer products and are recognized by the Centers for Disease Control and Prevention (CDC) as substances toxic to human health²; and

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Whereas, PFAS are non-biodegradable chemicals that accumulate in the human body with elimination half-lives up to 12 years and as of July 2018 PFAS have been detected at 172 sites in 40 states and have resulted in more than 3000 environmental and health related publications since 2000^{2–6}; and

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Whereas, PFAS' negative health effects include but are not limited to increased risk of hypertension, pre-eclampsia, and low birth weight during pregnancy, endocrine disruption, increased risk of thyroid and kidney disease, and association with various cancers^{2,7,8}; and

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Whereas, PFAS cross the placental barrier, are detected in cord blood, are transmitted through breast milk, and are negatively associated with fetal and postnatal growth, immune function, and reproductive health^{9–12}; and

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Whereas, Children are particularly at risk due to differences in PFAS dosimetry, impact on physical and cognitive development, and in particular, dose-dependent immunomodulatory effects which dampen responses to vaccines^{9,13,14}; and

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Whereas, The EPA found PFAS in water and soil nationwide, labeled PFAS an "emerging contaminant," and in May 2016 released non-enforceable lifetime health advisories for two specific PFAS chemicals: perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) of 70 ppt, above this level the EPA recommends that drinking water systems takes steps to assess contamination, inform consumers, and limit exposure^{15,16}: and

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Page 2 of 6

Whereas, In November 2016, the American Public Health Association stated that all exposures to PFAS should be reduced, and in June 2018, the CDC's Agency for Toxic Substances and Disease Registry (ATSDR) recommended reducing the minimum risk levels of PFAS ten-fold, from 70 ppt to 7 ppt due to the chemicals' significant negative health effects^{2,17}; and

Whereas, The International Agency for Research on Cancer (IARC), a part of the World Health Organization (WHO) has classified PFOA as possibly carcinogenic to humans¹⁸; and

Whereas, The EPA sets Maximum Contaminant Level Goals (MCLG) at zero for contaminants that may cause cancer¹; and

Whereas, The EPA maintains the Integrated Risk Information System (IRIS), an electronic database that contains information on human health effects from exposure to various substances in the environment, in which PFOA is not classified as to its carcinogenicity^{19,20}; and

Whereas, In February 2019, the EPA published its PFAS Action Plan which included as priorities initiating processes for listing PFOA and PFOS as hazardous substances and organizing efforts for water supply clean-up, but does not commit to setting maximum contaminant levels (MCLs)^{21,22}; and

Whereas, A Congressional PFAS Task Force was established in January 2019 to educate and draft policies on PFAS based on the latest research, and a Senate bill in March 2019, calls for PFAS to be designated as a hazardous chemical within a year and require cleanup of contaminated sites^{23,24}; and

Whereas, Despite the CDC's recommendations, urging from various U.S. senators, and examples from various states which have established their own PFAS water guidelines, no federal PFAS drinking water standards have yet been implemented^{16,25–28}; and

Whereas, The CDC blood lead level limits are based on a reference blood lead level based on the 97.5th percentile of the blood lead level distribution among children 1-5 years old in the United States, which is currently a 5 ug/dL lead level in children²⁹; and

Whereas, A similar reference blood PFAS level to aim to reduce average PFAS blood levels in US children to as low a level as possible could be based on the 95th percentile of total serum concentration of PFAS in U.S. children, which as per the most recent study of National Health and Nutritional Examination Survey would be 11 ng/dL (0.11 μ g/L) with a limit of detection is 0.1 ng/dL (0.001 μ g/L) in children ages 3-11 from 2013-14³⁰; and

Whereas, In 2006, the EPA announced a Product Stewardship agreement with 8 global manufacturing companies who pledged to reduce PFOA emissions and product content by 95% in 2010 and work towards its elimination by 2015, and as of February 2017 all participating companies state they met the PFOA Stewardship Program goals^{31,32}; and

Whereas, The European Union has phased out contamination from PFAS by severely limiting the use of PFAS and PFAS derivatives in manufacturing via the REACH Regulation³³; and

Page 3 of 6

Whereas, Existing AMA policy addresses water contamination by lead (H-135.928, H-60.918), pharmaceuticals (D-135.993), and chlorine (H-135.956), but does not address contamination of drinking water by PFAS chemicals specifically: and

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Whereas, Blood screening for water contamination is supported by H-60.924, but no similar policy exists for PFAS; therefore be it

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8 RESOLVED, That our American Medical Association support legislation and regulation seeking 9 to address contamination, exposure, classification, and clean-up of Per- and Polyfluoroalkyl 10 substances. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Safe Drinking Water H-135.928

Our AMA supports updates to the U.S. Environmental Protection Agency's Lead and Copper Rule as well as other state and federal laws to eliminate exposure to lead through drinking water by:

- (1) Removing, in a timely manner, lead service lines and other leaded plumbing materials that come into contact with drinking water;
- (2) Requiring public water systems to establish a mechanism for consumers to access information on lead service line locations:
- (3) Informing consumers about the health-risks of partial lead service line replacement:
- (4) Requiring the inclusion of schools, licensed daycare, and health care settings among the sites routinely tested by municipal water quality assurance systems;
- (5) Creating and implementing standardized protocols and regulations pertaining to water quality testing, reporting and remediation to ensure the safety of water in schools and child care centers;
- (6) Improving public access to testing data on water lead levels by requiring testing results from public water systems to be posted on a publicly available website in a reasonable timeframe thereby allowing consumers to take precautions to protect their health;
- (7) Establishing more robust and frequent public education efforts and outreach to consumers that have lead service lines, including vulnerable populations:
- (8) Requiring public water systems to notify public health agencies and health care providers when local water samples test above the action level for lead;
- (9) Seeking to shorten and streamline the compliance deadline requirements in the Safe Drinking Water Act: and
- (10) Actively pursuing changes to the federal lead and copper rules consistent with this policy. Citation: Res. 409, A-16; Modified: Res. 422, A-18; Reaffirmed: BOT Rep. 29, A-19

Chemical Analysis Report of Public and Commercial Water D-440.999

Our AMA: (1) requests the appropriate federal agency to require analysis and appropriate labeling of the chemical content, including fluoride, of commercially bottled water, as well as of the water supplies of cities or towns; (2) urges the FDA to require that annual water quality reports from bottled water manufacturers be publicly accessible in a readily available format; and (3) urges the FDA to evaluate bottled water for changes in quality after typical storage conditions.

Citation: (Res. 427, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 3, A-12)

Lead Contamination in Municipal Water Systems as Exemplified by Flint, Michigan H-60.918

- 1. Our AMA will advocate for biologic (including hematological) and neurodevelopmental monitoring at established intervals for children exposed to lead contaminated water with resulting elevated blood lead levels (EBLL) so that they do not suffer delay in diagnosis of adverse consequences of their lead exposure.
- 2. Our AMA will urge existing federal and state-funded programs to evaluate at-risk children to expand services to provide automatic entry into early-intervention screening programs to assist in the neurodevelopmental monitoring of exposed children with EBLL.
- 3. Our AMA will advocate for appropriate nutritional support for all people exposed to lead contaminated water with resulting elevated blood lead levels, but especially exposed pregnant women, lactating mothers and exposed children. Support should include Vitamin C, green leafy vegetables and other

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calcium resources so that their bodies will not be forced to substitute lead for missing calcium as the children grow.

4. Our AMA promotes screening, diagnosis and acceptable treatment of lead exposure and iron deficiency in all people exposed to lead contaminated water.

Citation: Res. 428, A-16

The Health Risks of Hydraulic Fracturing H-135.931

- 1. Our AMA encourages appropriate agencies and organizations to study the potential human and environmental health risks and impacts of hydraulic fracturing.
- 2. Our AMA: (A) supports the full disclosure of chemicals placed into the natural environment during the petroleum, oil and natural gas exploration and extraction process; and (B) supports the requirement that government agencies record and monitor the chemicals placed into the natural environment for petroleum oil and natural gas extraction and the chemicals found in flowback fluids, to monitor for human exposures in well water and surface water, and to share this information with physicians and the public.
- 3. Our AMA supports research on the implementation of buffer zones or well set-backs between oil and gas development sites and residences, schools, hospitals, and religious institutions, to determine the distance necessary to ensure public health and safety.

Citation: Res. 405, A-13; Appended: Sub. Res. 508, A-15; Appended: Res. 908, I-17

Contamination of Drinking Water by Pharmaceuticals and Personal Care Products D-135.993

Our AMA supports the EPA and other federal agencies in engaging relevant stakeholders, which may

include, but is not limited to the AMA, pharmaceutical companies, pharmaceutical retailers, state and specialty societies, and public health organizations in the development of guidelines for physicians and the public for the proper disposal of pharmaceuticals and personal care products to prevent contamination of drinking water systems.

Citation: (Sub. Res. 42, I-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10

Reducing Lead Poisoning H-60.924

- 1. Our AMA: (a) supports regulations and policies designed to protect young children from exposure to lead; (b) urges the Centers for Disease Control and Prevention to give priority to examining the current weight of scientific evidence regarding the range of adverse health effects associated with blood lead concentrations below the current "level of concern" in order to provide appropriate guidance for physicians and public health policy, and encourage the identification of exposure pathways for children who have low blood lead concentrations, as well as effective and innovative strategies to reduce overall childhood lead exposure; (c) encourages physicians and public health departments to screen children based on current recommendations and guidelines and to report all children with elevated blood levels to the appropriate health department in their state or community in order to fully assess the burden of lead exposure in children. In some cases this will be done by the physician, and in other communities by the laboratories; (d) promotes community awareness of the hazard of lead-based paints; and (e) urges paint removal product manufacturers to print precautions about the removal of lead paint to be included with their products where and when sold.
- 2. Our AMA will call on the United States government to establish national goals to: (a) ensure that no child has a blood lead level >5 μ g/dL (>50 ppb) by 2021, and (b) eliminate lead exposures to pregnant women and children, so that by 2030, no child would have a blood lead level >1 μ g/dL (10 ppb).
- 3. Our AMA will call on the United States government in all its agencies to pursue the following strategies to achieve these goals: (a) adopt health-based standards and action levels for lead that rely on the most up-to-date scientific knowledge to prevent and reduce human exposure to lead, and assure prompt implementation of the strongest available measures to protect pregnant women and children from lead toxicity and neurodevelopmental impairment; (b) identify and remediate current and potential new sources of lead exposure (in dust, air, soil, water and consumer products) to protect children before they are exposed; (c) continue targeted screening of children to identify those who already have elevated blood lead levels for case management, as well as educational and other services; (d) eliminate new sources of lead introduced or released into the environment, which may entail banning or phasing out all remaining uses of lead in products (aviation gas, cosmetics, wheel weights, industrial paints, batteries, lubricants, and other sources), and the export of products containing lead, and setting more protective limits on emissions from battery recyclers and other sources of lead emissions; (e) provide a dedicated funding stream to enhance the resources available to identify and eliminate sources of lead exposure, and

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provide educational, social and clinical services to mitigate the harms of lead toxicity, particularly to protect and improve the lives of children in communities that are disproportionately exposed to lead; and (f) establish an independent expert advisory committee to develop a long-term national strategy, including recommendations for funding and implementation, to achieve the national goal of eliminating lead toxicity in pregnant women and children, defined as blood lead levels above 1 µg/dL (10 ppb).

4. Our AMA supports requiring an environmental assessment of dwellings, residential buildings, or child care facilities following the notification that a child occupant or frequent inhabitant has a confirmed elevated blood lead level, to determine the potential source of lead poisoning, including testing the water supply.

Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 926, I-16; Appended: Res. 412, A-17

Expansion of Hazardous Waste Landfills Over Aquifers H-135.943

- (1) recognizes that the expansion of hazardous waste landfills or the construction of new hazardous waste landfills over principal aquifers represents a potential health risk for the public water supply and is inconsistent with sound principles of public health policy, and therefore should be opposed;
- (2) will advocate for the continued monitoring of groundwater sources, including principal aquifers, that may be contaminated by hazardous waste landfill or other landfill leachate; and
- (3) supports efforts to improve hazardous waste treatment, recycling, and disposal methods in order to reduce the public health burden.

Citation: CSAPH Rep. 4, A-07; Reaffirmed: CSAPH Rep. 01, A-17

Human and Environmental Health Impacts of Chlorinated Chemicals H-135.956

- (1) Our AMA encourages the Environmental Protection Agency to base its evaluations of the potential public health and environmental risks posed by exposure to an individual chlorinated organic compound, other industrial compound, or manufacturing process on reliable data specific to that compound or process;
- (2) encourages the chemical industry to increase knowledge of the environmental behavior, bioaccumulation potential, and toxicology of their products and by-products; and
- (3) supports the implementation of risk reduction practices by the chemical and manufacturing industries. Citation: Sub. Res. 503, A-94; Reaffirmation I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmation I-16

EPA and Green House Gas Regulation H-135.934

- 1. Our AMA supports the Environmental Protection Agency's authority to promulgate rules to regulate and control green house gas emissions in the United States.
- 2. Our AMA: (a) strongly supports evidence-based environmental statutes and regulations intended to regulate air and water pollution and to reduce greenhouse gas emissions; and (b) will advocate that environmental health regulations should only be modified or rescinded with scientific justification. Citation: Res. 925, I-10; Reaffirmed in lieu of Res. 526, A-12; Reaffirmed: Res. 421, A-14; Appended: Res. 523, A-17

Guidance for Worldwide Conservation of Potable Water H-135.947

Our AMA favors scientific and cultural development of a plan for worldwide potable water conservation, especially in countries affected by natural disasters or other events that disrupt the potable water supply. Citation: (Res. 406, A-04; Modified in lieu of Res. 906, I-11)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 902

(I-19)

Introduced by: Medical Student Section

Subject: Amending H-490.913, "Smoke-Free Environments and Workplaces," and

H-490.907, "Tobacco Smoke Exposure of Children in Multi-Unit Housing," to

Include E-Cigarettes

Referred to: Reference Committee K

Whereas, The use of e-cigarettes, otherwise known as vaping, has become increasingly popular for nicotine usage among youth, new smokers, and those seeking smoking cessation options^{1,2}; and

Whereas, Among middle school students, current e-cigarette use increased by 48% during 2017-2018³; and

Whereas, Among high school students, current e-cigarette use increased from 1.5% in 2011 to 20.8% in 2018³; and

Whereas, In 2018, more than 3.6 million U.S. youth, including 1 in 5 high school students and 1 in 20 middle school students currently used e-cigarettes, resulting in a different population exposed to the toxic effects of secondhand smoke due to e-cigarette use than due to cigarette use³; and

Whereas, College students who use electronic nicotine delivery systems (ENDS) are more than twice as likely to initiate cigarette use⁴; and

Whereas, During an assessment of indoor air quality at an e-cigarette (vaping) convention, it was found that e-cigarette use was a major source of particulate matter, air nicotine, and real-time total volatile organic compounds, impairing indoor air quality⁵; and

Whereas, E-cigarette use indoors increased particulate matter concentrations 160-fold at 0.5m and 103-fold at 1m, showing that particulate matter increases as proximity to the e-cigarette increases⁶; and

Whereas, When characterizing nicotine persistence on surfaces over a 72-hr period, residual nicotine concentrations persisted on both terry cloth and glass surfaces for 72 hours, and was found to persist long enough to pose a potential third hand nicotine exposure risk⁷; and

Whereas, It has been shown that vaping worsens indoor air quality by increasing the concentration of nicotine, particulate matter, polycyclic aromatic hydrocarbons, and aluminum-all substances associated with increased risk for lung and cardiovascular disease and cancer⁸; and

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Whereas, Oxidants and reactive oxygen species reactivity in e-cigarette aerosols was similar to that in traditional cigarette smoke, with copper levels being found at much higher levels in e-cigarettes⁹; and

Whereas, A systematic review found that e-cigarette vapor may lead to adverse health effects, such as an increased risk of cardiovascular and respiratory diseases and certain cancers^{10,11}; and

Whereas, These adverse health effects may extend to non-users due to secondhand vapor exposure, especially those who are pregnant or children^{11,12}; and

Whereas, Nicotine exposure during adolescence can harm the developing brain, impacting learning, memory, and attention as well as increasing risk for future addiction to other drugs²; and

Whereas, Smoke-free policies were designed to protect non-smokers from toxic irritants, incentivize smoking cessation, and denormalize smoking¹³; and

Whereas, The use of e-cigarettes where smoke-free policies are implemented increases exposure risk to non-user bystanders, reduces cessation initiatives, and may promote the renormalization of smoking¹³; and

Whereas, Users who were not able to vape indoors would use less frequently and were less dependent on e-cigarettes¹⁴; and

Whereas, 26.1% (n=1034) of users reported not being able to vape in places where smoking is typically banned, while 73.9% (n=2926) reported being able to vape in places where smoking is typically banned¹⁴; and

Whereas, 15 states and 814 municipalities have currently prohibited the use of e-cigarettes in the same places where cigarette smoking is prohibited, which means that approximately 70% of states remain unprotected 15,16; and

Whereas, Our AMA recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and is actively working to counteract the marketing and use of addictive e-cigarette and vaping devices (AMA policy H-495.986); therefore be it

RESOLVED, That our American Medical Association amend policy H-490.913, "Smoke-Free Environments and Workplaces," by addition and deletion to read as follows:

Smoke-Free and Vape-Free Environments and Workplaces, H-490.913

On the issue of the health effects of environmental tobacco smoke (ETS), and passive smoke, and vape exposure in the workplace and other public facilities, our AMA: (1)(a) supports classification of ETS as a known human carcinogen; (b) concludes that passive smoke exposure is associated with increased risk of sudden infant death syndrome and of cardiovascular disease; (c) encourages physicians and medical societies to take a leadership role in defending the health of the public from ETS risks and from political assaults by the tobacco industry; and (d) encourages the concept of establishing smoke-free and vape-free campuses for business, labor, education, and government; (2) (a) honors companies and governmental workplaces that go smoke-free and vape-free; (b) will petition the Occupational Safety and Health Administration (OSHA) to adopt regulations prohibiting smoking and vaping in the

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workplace, and will use active political means to encourage the Secretary of Labor to swiftly promulgate an OSHA standard to protect American workers from the toxic effects of ETS in the workplace, preferably by banning smoking and vaping in the workplace; (c) encourages state medical societies (in collaboration with other antitobacco organizations) to support the introduction of local and state legislation that prohibits smoking and vaping around the public entrances to buildings and in all indoor public places, restaurants, bars, and workplaces; and (d) will update draft model state legislation to prohibit smoking and vaping in public places and businesses, which would include language that would prohibit preemption of stronger local laws. (3) (a) encourages state medical societies to: (i) support legislation for states and counties mandating smoke-free and vape-free schools and eliminating smoking and vaping in public places and businesses and on any public transportation; (ii) enlist the aid of county medical societies in local anti-smoking and anti-vaping campaigns; and (iii) through an advisory to state, county, and local medical societies, urge county medical societies to join or to increase their commitment to local and state anti-smoking and anti-vaping coalitions and to reach out to local chapters of national voluntary health agencies to participate in the promotion of anti-smoking and anti-vaping control measures; (b) urges all restaurants, particularly fast food restaurants, and convenience stores to immediately create a smoke-free and vapefree environment; (c) strongly encourages the owners of family-oriented theme parks to make their parks smoke-free and vape-free for the greater enjoyment of all guests and to further promote their commitment to a happy, healthy life style for children; (d) encourages state or local legislation or regulations that prohibit smoking and vaping in stadia and encourages other ball clubs to follow the example of banning smoking in the interest of the health and comfort of baseball fans as implemented by the owner and management of the Oakland Athletics and others: (e) urges eliminating cigarette. pipe, cigar, and e-cigarette smoking in any indoor area where children live or play, or where another person's health could be adversely affected through passive smoking inhalation; (f) urges state and county medical societies and local health professionals to be especially prepared to alert communities to the possible role of the tobacco industry whenever a petition to suspend a nonsmoking or non-vaping ordinance is introduced and to become directly involved in community tobacco control activities: and (g) will report annually to its membership about significant anti-smoking and antivaping efforts in the prohibition of smoking and vaping in open and closed stadia; (4) calls on corporate headquarters of fast-food franchisers to require that one of the standards of operation of such franchises be a no smoking and no vaping policy for such restaurants, and endorses the passage of laws, ordinances and regulations that prohibit smoking and vaping in fast-food restaurants and other entertainment and food outlets that target children in their marketing efforts; (5) advocates that all American hospitals ban tobacco and supports working toward legislation and policies to promote a ban on smoking, vaping, and use of tobacco products in, or on the campuses of, hospitals, health care institutions, retail health clinics, and educational institutions, including medical schools; (6) will work with the Department of Defense to explore ways to encourage a smoke-free and vape-free environment in the military through the use of mechanisms such as health education, smoking and vaping cessation programs, and the elimination of discounted prices for tobacco products in military resale facilities; and (7) encourages and supports local and state medical societies and tobacco control coalitions to work with (a) Native American casino and tribal leadership to voluntarily prohibit smoking and vaping in their casinos; and (b) legislators and the gaming industry to support the prohibition of smoking and vaping in all casinos and gaming venues (Modify Current HOD Policy); and be it further

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1 RESOLVED, That our AMA amend Policy H-490.907, "Tobacco Smoke Exposure of Children in Multi-Unit Housing," to include e-cigarettes and vaping by addition to read as follows:

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Tobacco Smoke <u>and Vaping</u> Exposure of Children in Multi-Unit Housing, H-490.907

6 7 Our AMA: (1) encourages federal, state and local housing authorities and 8 governments to adopt policies that protect children and non-smoking or non-vaping 9 adults from tobacco smoke and vaping exposure by prohibiting smoking and vaping in multi-unit housing; and (2) encourages state and local medical societies, chapters, 10 11 and other health organizations to support and advocate for changes in existing state 12 and local laws and policies that protect children and non-smoking or non-vaping 13 adults from tobacco smoke and vaping exposure by prohibiting smoking and vaping in 14 multi-unit housing. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Smoke-Free Environments and Workplaces H-490.913

On the issue of the health effects of environmental tobacco smoke (ETS) and passive smoke exposure in the workplace and other public facilities, our AMA:

- (1) (a) supports classification of ETS as a known human carcinogen; (b) concludes that passive smoke exposure is associated with increased risk of sudden infant death syndrome and of cardiovascular disease; (c) encourages physicians and medical societies to take a leadership role in defending the health of the public from ETS risks and from political assaults by the tobacco industry; and (d) encourages the concept of establishing smoke-free campuses for business, labor, education, and government:
- (2) (a) honors companies and governmental workplaces that go smoke-free; (b) will petition the Occupational Safety and Health Administration (OSHA) to adopt regulations prohibiting smoking in the workplace, and will use active political means to encourage the Secretary of Labor to swiftly promulgate an OSHA standard to protect American workers from the toxic effects of ETS in the workplace, preferably by banning smoking in the workplace: (c) encourages state medical societies (in collaboration with other anti-tobacco organizations) to support the introduction of local and state legislation that prohibits smoking around the public entrances to buildings and in all indoor public places, restaurants, bars, and workplaces; and (d) will update draft model state legislation to prohibit smoking in public places and businesses, which would include language that would prohibit preemption of stronger local laws. (3) (a) encourages state medical societies to: (i) support legislation for states and counties mandating smoke-free schools and eliminating smoking in public places and businesses and on any public transportation; (ii) enlist the aid of county medical societies in local anti-smoking campaigns; and (iii) through an advisory to state, county, and local medical societies, urge county medical societies to join or to increase their commitment to local and state anti-smoking coalitions and to reach out to local chapters of national voluntary health agencies to participate in the promotion of anti-smoking control measures; (b) urges all restaurants, particularly fast food restaurants, and convenience stores to immediately create a smoke-free environment; (c) strongly encourages the owners of family-oriented theme parks to make their parks smoke-free for the greater enjoyment of all guests and to further promote their commitment to a happy, healthy life style for children: (d) encourages state or local legislation or regulations that prohibit smoking in stadia and encourages other ball clubs to follow the example of banning smoking in the interest of the health and comfort of baseball fans as implemented by the owner and management of the Oakland Athletics and others; (e) urges eliminating cigarette, pipe, and cigar smoking in any indoor area where children live or play, or where another person's health could be adversely affected through passive smoking; (f) urges state and county medical societies and local health professionals to be especially prepared to alert communities to the possible role of the tobacco industry whenever a petition to suspend a nonsmoking ordinance is introduced and to become directly involved in community tobacco control activities; and (g) will report annually to its membership about significant anti-smoking efforts in the prohibition of smoking in open and closed stadia:
- (4) calls on corporate headquarters of fast-food franchisers to require that one of the standards of operation of such franchises be a no smoking policy for such restaurants, and endorses the passage of laws, ordinances and regulations that prohibit smoking in fast-food restaurants and other entertainment and food outlets that target children in their marketing efforts;
- (5) advocates that all American hospitals ban tobacco and supports working toward legislation and policies to promote a ban on smoking and use of tobacco products in, or on the campuses of, hospitals, health care institutions, retail health clinics, and educational institutions, including medical schools;
- (6) will work with the Department of Defense to explore ways to encourage a smoke-free environment in the military through the use of mechanisms such as health education, smoking cessation programs, and the elimination of discounted prices for tobacco products in military resale facilities; and
- (7) encourages and supports local and state medical societies and tobacco control coalitions to work with
- (a) Native American casino and tribal leadership to voluntarily prohibit smoking in their casinos; and (b) legislators and the gaming industry to support the prohibition of smoking in all casinos and gaming venues.

Citation: (CSA Rep. 3, A-04; Appended: Sub. Res. 426, A-04; Modified: CSAPH Rep. 1, I-07; Reaffirmation I-14; Reaffirmation I-15)

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Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

Our AMA:

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21:
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;
- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and
- (9) opposes the sale of tobacco at any facility where health services are provided; and
- (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18

Electronic Cigarettes, Vaping, and Health H-495.972

- 1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.
- 2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.
- 3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.

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Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19; Appended: Res. 428, A-19;

FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products H-495.973

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of 21; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth; and (3) urges federal officials, including but not limited to the U.S. Food and Drug Administration to: (a) prohibit the sale of any e-cigarette cartridges and e-liquid refills that do not include a complete list of ingredients on its packaging, in the order of prevalence (similar to food labeling); and (b) require that an accurate nicotine content of e-cigarettes, e-cigarette cartridges, and e-liquid refills be prominently displayed on the product alongside a warning of the addictive quality of nicotine.

Citation: Res. 206, I-13; Modified in lieu of Res. 511, A-14; Modified in lieu of Res. 518, A-14; Modified in lieu of Res. 519, A-14; Modified in lieu of Res. 521, A-14; Modified: CSAPH Rep. 2, I-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 412, A-15; Reaffirmed in lieu of Res. 421, A-15; Reaffirmation A-16; Appended: Res. 429, A-18; Modified: CSAPH Rep. 05, A-18

FDA Regulation of Tobacco Products H-495.988

- 1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes: (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does. and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges Congress to pass legislation to phase in the production of reduced nicotine content tobacco products and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products.
- 2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with

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physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.

3. Our AMA: (A) will continue to monitor the FDA's progress towards establishing a low nicotine product standard for tobacco products and will submit comments on the proposed rule that are in line with the current scientific evidence and (B) recognizes that rigorous and comprehensive post-market surveillance and product testing to monitor for unintended tobacco use patterns will be critical to the success of a nicotine reduction policy.

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19

Secondhand Smoke H-490.910

- 1. Our AMA urges the President of the United States to issue an Executive Order making all federal workplaces, including buildings and campuses, entirely smoke free and urges its federation members to do the same.
- 2. Our AMA supports legislation that prohibits smoking while operating or riding in a vehicle that contains children.

Citation: (Res. 417, A-09; Appended: Res. 202, A-14)

Tobacco Smoke Exposure of Children in Multi-Unit Housing H-490.907

Our AMA: (1) encourages federal, state and local housing authorities and governments to adopt policies that protect children and non-smoking adults from tobacco smoke exposure by prohibiting smoking in multi-unit housing; and (2) encourages state and local medical societies, chapters, and other health organizations to support and advocate for changes in existing state and local laws and policies that protect children and non-smoking adults from tobacco smoke exposure by prohibiting smoking in multi-unit housing.

Tobacco-Free School Environment H-490.908

Our AMA: (1) supports and advocates for a tobacco-free school environment (as defined by the CDC) as the cornerstone of a comprehensive policy intended to prevent and reduce tobacco use and addiction in young people; (2) supports the adoption of tobacco-free school laws or policies that incorporate the guidelines developed by the Centers for Disease Control and Prevention for school-based health programs to prevent tobacco use and addiction; (3) will provide a link on its website of existing resources to assist those at the state and local levels who are interested in pursuing tobacco free school environments; and (4) urges its Federation members to collaborate with students, parents, school officials and members of the community to establish tobacco free schools.

Citation: (Res. 418, A-10)

Oppose Efforts to Stop, Weaken or Delay FDA's Authority to Regulate All Tobacco Products D-495.993

- 1. Our AMA encourages Congress to oppose any legislation that would stop, weaken, or delay FDA's authority to fully regulate all tobacco products.
- 2. Our AMA will write a letter to the Administration expressing our strong opposition to the decision to strike from the Food and Drug Administration's deeming rule on tobacco products, the restriction of flavored electronic nicotine delivery systems.

Citation: Res. 425, A-16

Banning Smoking in All Workplaces D-490.979

Our AMA will (1) actively support national, state, and local legislation and actively pursue regulations banning smoking in all workplaces; and (2) work to ensure that federal legislation banning smoking in all workplaces does not prohibit or weaken more strict state or local regulations.

Citation: Res. 903, I-05; Modified: Res. 401, A-06; Reaffirmed: CSAPH 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 903

(I-19)

Introduced by: Medical Student Section

Subject: Encouraging the Development of Multi-Language, Culturally Informed Mobile

Health Applications

Referred to: Reference Committee K

Whereas, There is a scarcity of mobile health applications addressing the needs of patients receiving costly care, in poor health, or of low English literacy¹; and

Whereas, Longstanding disparities in health burden minority and low-income communities and persist at all levels of health care, from access to health insurance, preventive services, and high-quality care to condition-specific burden, morbidity, and mortality^{2,3}; and

Whereas, Concern has been raised that current mobile health technologies may exacerbate existing disparities by precluding individuals of low socioeconomic status from potential financial rewards or health benefits^{3,4}; and

Whereas, Existing national policy fails to address barriers to equal access to mobile health technologies for vulnerable, culturally diverse, and low-income communities^{2,5}; and

Whereas, The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care, published by the U.S. Department of Health and Human Services, do not contain provisions relating to mobile health application development⁶; and

Whereas, English language fluency varies widely among cultural subgroups, from 31% of Hispanics to 51% of Vietnamese Americans who report non-fluency²; and

Whereas, A study of Hispanic migrant farm workers, a patient population with high burden of chronic disease and limited access to healthcare, found 81% of this population has access to mobile devices and the majority are receptive to using mobile health platforms for facilitation of medication adherence and management of chronic conditions⁷; and

Whereas, A 2018 study noted that a uniquely designed mobile health app could facilitate smoking cessation in LGBTQ+ young adults, who engage in tobacco use at much higher rates than the general population⁸; and

Whereas, The pervasiveness of smartphone use may serve as a means to deliver health-related interventions to racial and ethnic minority groups⁹; and

Whereas, The timely and convenient interventions offered by mobile devices, such as personalized medication reminders, have the potential to enhance the health of minority and low-income individuals, to reduce the costs of their medical care, and to close health gaps between populations^{7,10}; and

Resolution: 903 (I-19)

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Whereas, Our AMA has resolved to "identify and incorporate strategies specific to the elimination of minority health disparities in its ongoing advocacy and public health efforts" (D-350.996); therefore be it

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RESOLVED, That American Medical Association amend policy D-480.972 by addition to read as follows:

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- Guidelines for Mobile Medical Applications and Devices, D-480.972
- 1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
- 2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
- 3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based.
- 4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
- 5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
- 6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
- 7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.
- 8. Our AMA encourages the development of mobile health applications that employ linguistically appropriate and culturally informed content catered to underserved and low-income populations. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY:

Integration of Mobile Health Applications and Devices into Practice D-480.967

Our AMA will: (1) assess the potential liability risks to physicians for using, recommending, or prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws; and (2) assess the feasibility of state and federal legislation, as well as other innovative alternatives, in an effort to mitigate the physician's potential risk of liability from the use or recommendation of mHealth apps.

Citation: CMS Rep. 06, I-16

Guidelines for Mobile Medical Applications and Devices D-480.972

- 1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
- 2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
- 3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based.
- 4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
- 5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
- 6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
- 7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.

Citation: CSAPH Rep. 5, A-14; Appended: Res. 201, A-15; Appended: Res. 305, I-16

Integration of Mobile Health Applications and Devices into Practice H-480.943

1. Our AMA supports the establishment of coverage, payment and financial incentive mechanisms to support the use of mobile health applications (mHealth apps) and associated devices, trackers and sensors by patients, physicians and other providers that: (a) support the establishment or continuation of a valid patient-physician relationship; (b) have a high-quality clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness; (c) follow evidence-based practice guidelines, especially those developed and produced by national medical specialty societies and based on systematic reviews, to ensure patient safety, quality of care and positive health outcomes; (d) support care delivery that is patient-centered, promotes care coordination and facilitates team-based communication; (e) support data portability and interoperability in order to promote care coordination through medical home and accountable care models; (f) abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services facilitated by the app; (g) require that physicians and other health practitioners delivering services through the

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app be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board; and (h) ensure that the delivery of any services via the app be consistent with state scope of practice laws.

- 2. Our AMA supports that mHealth apps and associated devices, trackers and sensors must abide by applicable laws addressing the privacy and security of patients' medical information.
- 3. Our AMA encourages the mobile app industry and other relevant stakeholders to conduct industry-wide outreach and provide necessary educational materials to patients to promote increased awareness of the varying levels of privacy and security of their information and data afforded by mHealth apps, and how their information and data can potentially be collected and used.
- 4. Our AMA encourages the mHealth app community to work with the AMA, national medical specialty societies, and other interested physician groups to develop app transparency principles, including the provision of a standard privacy notice to patients if apps collect, store and/or transmit protected health information.
- 5. Our AMA encourages physicians to consult with qualified legal counsel if unsure of whether an mHealth app meets Health Insurance Portability and Accountability Act standards and also inquire about any applicable state privacy and security laws.
- 6. Our AMA encourages physicians to alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks
- 7. Our AMA supports further development of research and evidence regarding the impact that mHealth apps have on quality, costs, patient safety and patient privacy.
- 8. Our AMA encourages national medical specialty societies to develop guidelines for the integration of mHealth apps and associated devices into care delivery. Citation: CMS Rep. 06, I-16; Reaffirmation: A-17

Resolution: 904

(I-19)

Introduced by: Medical Student Section

Subject: Amendment to AMA Policy H-150.949, "Healthy Food Options in Hospitals"

Referred to: Reference Committee K

Whereas, Medical care facilities include hospitals, skilled nursing facilities, intermediate care facilities, and correctional treatment facilities such as prisons^{1,2}; and

Whereas, Current AMA policy H-150.949 encourages healthy, plant-based options to be provided within hospitals, but does not explicitly encourage the same of other medical care facilities; and

Whereas, There is a lack of consistency in food safety and option regulations among prisons at the local and state level³⁻⁶; and

Whereas, Centers for Medicare & Medicaid Services regulations require nursing facilities to provide a "nourishing, palatable, well-balanced diet that meets ... daily nutritional and special dietary needs", but does not explicitly address plant-based diets⁷; and

Whereas, A study found 65% of nursing home residents expressed complaints about their food service and the presence of complaints was related to poor food intake⁸; and

Whereas, Plant-based diets have been shown to improve health in all people, not just hospitalized patients⁹⁻¹⁴; and

Whereas, Plant-based options also have the potential to be cheaper than alternatives depending on the decisions made by individual facilities regarding costs for purchase, storage and preparation¹⁷⁻¹⁹; therefore be it

RESOLVED, That our American Medical Association encourage the availability of healthy, plant-based options at medical care facilities by amending AMA Policy H-150.949, "Healthy Food Options in Hospitals," by addition and deletion to read as follows:

Healthy Food Options in Hospitals Medical Care Facilities, H-150.949

- 1. Our AMA encourages healthy food options be available, at reasonable prices and easily accessible, on hospital the premises of Medical Care Facilities.
- 2. Our AMA hereby calls on US hospitals <u>all Medical Care Facilities and Correctional Facilities</u> to improve the health of patients, staff, and visitors by: (a) providing a variety of healthy food, including plant-based meals, and meals that are low in fat, sodium, and added sugars; (b) eliminating processed meats from menus; and (c) providing and promoting healthy beverages.
- 3. Our AMA hereby calls for hospital Medical Care Facility cafeterias and inpatient meal menus to publish nutrition information. (Modify Current HOD Policy)

Resolution: 904 (I-19)

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Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY:

Dietary Intake of Incarcerated Populations D-430.995

Our AMA: 1) urges the National Commission on Correctional Health Care, the American Correctional Association, and individual states to mandate adherence to the current Dietary Reference Intakes and Dietary Guidelines for Americans (with adjustments, as needed, for special populations) as a criterion for accreditation and/or standards compliance, until national dietary guidelines specific for adolescent and adult incarcerated populations becomes available; and 2) urges the Food and Nutrition Board of the Institute of Medicine to examine the nutrient status and dietary requirements of incarcerated populations and issue guidelines on menu planning for adolescent and adult incarcerated populations.

Citation: (CSAPH Rep. 4, A-11)

Nutrition Labeling and Nutritionally Improved Menu Offerings in Fast-Food and Other Chain Restaurants H-150.945

Our AMA:

- 1. supports federal, state, and local policies to require fast-food and other chain restaurants with 10 or more units (smaller, neighborhood restaurants could be exempt) to provide consumers with nutrition information on menus and menu boards;
- 2. recommends that nutrition information in fast-food and other chain restaurants include calorie, fat, saturated fat and trans fat, and sodium labeling on printed menus, and, at a minimum,

Resolution: 904 (I-19)

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calories on menu boards, since they have limited space, and that all nutrition information be conspicuous and easily legible;

- 3. urges federal, state, and local health agencies, health organizations, and physicians and other health professionals to educate people how to use the nutrition information provided in restaurants to make healthier food choices for themselves and their families; and
- 4. urges restaurants to improve the nutritional quality of their menu offerings--for example, by reducing caloric content; offering smaller portions; offering more fruits, vegetables, and wholegrain items; using less sodium; using cooking fats lower in saturated and trans fats; and using less added sugars/sweeteners.

Citation: Res. 419, A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09; Reaffirmed: CSAPH Rep. 01, A-19

H-150.944 Increasing Healthy Food Options in School Lunches for Elementary and Middle School Students

Our AMA supports efforts to: (1) reduce health disparities by basing food assistance programs on the health needs of their constituents; (2) provide vegetables, fruits, legumes, grains, vegetarian foods, and healthful dairy and nondairy beverages in school lunches and food assistance programs; and (3) ensure that federal subsidies encourage the consumption of foods and beverages low in fat, added sugars, and cholesterol.

Citation: Res. 413, A-07; Reaffirmation A-12; Reaffirmation A-13; Modified: CSAPH Rep. 03, A-17

H-150.949 Health Food Options in Hospitals

- 1. Our AMA encourages healthy food options be available, at reasonable prices and easily accessible, on hospital premises.
- 2. Our AMA hereby calls on US hospitals to improve the health of patients, staff, and visitors by: (a) providing a variety of healthy food, including plant-based meals, and meals that are low in fat, sodium, and added sugars; (b) eliminating processed meats from menus; and (c) providing and promoting healthy beverages.
- 3. Our AMA hereby calls for hospital cafeterias and inpatient meal menus to publish nutrition information.

Citation: Res. 410, A-04; Reaffirmed: CSAPH Rep. 1, A-14; Appended: Res. 406, A-17; Modified: Res. 425, A-18

Resolution: 905

(I-19)

Introduced by: Medical Student Section

Subject: Sunscreen Dispensers in Public Spaces as a Public Health Measure

Referred to: Reference Committee K

Whereas, One in five Americans will develop skin cancer in their lifetime, and five million Americans will be treated for skin cancer this year alone¹; and

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Whereas, The annual cost of treating skin cancers in the United States is estimated to be \$8.1 billion^{1,2}; and

Whereas, Most skin cancers are a direct result of exposure to the UV rays in sunlight³; and

Whereas, One bad sunburn can demonstrably increase the chances of developing skin cancer later in life⁴; and

Whereas, Sunscreen has been conclusively shown to protect from a variety of skin cancers^{5,6}; and

 Whereas, Patients of lower socioeconomic status are less likely to engage in sun-protective behaviors such as sunscreen use, present with later stages of disease, and experience greater mortality from skin cancers linked tightly with sun exposure including melanoma and nonmelanoma cancers^{7,8,9}; and

Whereas, Studies have shown that those of low SES who require year-round protection from the sun, such as the homeless and those who spend a significant part of any given day outdoors, may require financial assistance to allow adherence to sun protection guidelines¹⁰; and

Whereas, The provision of free public sunscreen has been shown to lead to increased systematic application of sunscreen and decrease sunburn occurrence in sun-sensitive individuals ^{11, 12}; and

Whereas, Clear educational labels placed in areas with sunscreen availability regarding sunburn protection and likely long-term effects of UV also increases adoption of sun-protective behaviors and helps reduce social differentiation of sun-protection behaviors^{13,14,15}; and

Whereas, Free public sunscreen programs have been suggested to be partially responsible for the declining rates of melanoma in the northeastern United States compared to the increasing rates nationally ^{1,16,27}; and

Whereas, Public sunscreen programs are beginning to gain ground on a local level in the United States^{17,18,19,20}; and

Resolution: 905 (I-19) Page 2 of 3

Whereas, The CDC supports "interventions in outdoor occupational settings and outdoor 1 2 recreational and tourism settings to promote sun protective behaviors" such as "providing sunscreen or shade"21: and 3

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Whereas, National policy makers support free public sunscreen programs, including the Surgeon General's Office of the United States²²; and

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Whereas, The American Society for Dermatologic Surgery, the American Academy of Dermatology, and the American Cancer Society each support free public sunscreen programs as a public safety measure^{23,24,25,26}: and

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12 Whereas, Current AMA policy H-440.839 supports broad-spectrum sunscreen protection and education programs about the dangers of UV radiation, and AMA policy H-440.841 supports 13 14 public health intervention programs to reduce population cancer risk; therefore be it

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16 RESOLVED, That our American Medical Association support free public sunscreen programs in 17 public spaces where the population would have a high risk of sun exposure. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Protecting the Public from Dangers of Ultraviolet Radiation H-440.839

1. Our AMA encourages physicians to counsel their patients on sun-protective behavior.

Tanning Parlors: Our AMA supports: (1) educational campaigns on the hazards of tanning parlors, as well as the development of local tanning parlor ordinances to protect our patients and the general public from improper and dangerous exposure to ultraviolet radiation; (2) legislation to strengthen state laws to make the consumer as informed and safe as possible; (3) dissemination of information to physicians and the public about the dangers of ultraviolet light from sun exposure and the possible harmful effects of the ultraviolet light used in commercial tanning centers; (4) collaboration between medical societies and schools to achieve the inclusion of information in the health curricula on the hazards of exposure to tanning rays; (5) the enactment of federal legislation to: (a) prohibit access to the use of indoor tanning equipment (as defined in 21 CFR ?1040.20 [a][9]) by anyone under the age of 18; and (b) require a United States Surgeon General warning be prominently posted, detailing the positive correlation between ultraviolet radiation, the use of indoor tanning equipment, and the incidence of skin cancer: (6) warning the public of the risks of ultraviolet A radiation (UVA) exposure by skin tanning units, particularly the FDA's findings warning Americans that the use of UVA tanning booths and sun beds pose potentially significant health risks to users and should be discouraged; (7) working with the FDA to ensure that state and local authorities implement legislation, rules, and regulations regarding UVA exposure, including posted warnings in commercial tanning salons and spas; (8) an educational campaign in conjunction with various concerned national specialty societies to secure appropriate state regulatory and oversight activities for tanning parlor facilities, to reduce improper and dangerous exposure to ultraviolet light by patients and general public consumers; and (9) intensified efforts to enforce current regulations. Sunscreens. Our AMA supports: (1) the development of sunscreens that will protect the skin from a broad spectrum of ultraviolet radiation, including both UVA and UVB; and (2) the labeling of sunscreen products with a standardized ultraviolet (UV) logo, inclusive of ratings for UVA and UVB, so that consumers will know whether these products protect against both types of UV radiation. Terms such as low, medium. high and very high protection should be defined depending on standardized sun protection factor level. 2. Our AMA supports sun shade structures (such as trees, awnings, gazebos and other structures providing shade) in the planning of public and private spaces, as well as in zoning matters and variances in recognition of the critical important of sun protection as a public health measure.

Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 403, A-14; Appended: Res. 404, A-19

Permitting Sunscreen in Schools H-440.841

- 1. Our AMA supports the exemption of sunscreen from over-the-counter medication possession bans in schools and encourages all schools to allow students to bring and possess sunscreen at school without restriction and without requiring physician authorization.
- 2. Our AMA will work with state and specialty medical societies and patient advocacy groups to provide advocacy resources and model legislation for use in state advocacy campaigns seeking the removal of sunscreen-related bans at schools and summer camp programs.

Citation: Res. 403, A-13; Appended: Res. 422, A-16

Resolution: 906

(I-19)

Introduced by: Medical Student Section

Subject: Ensuring the Best In-School Care for Children with Sickle Cell Disease

Referred to: Reference Committee K

Whereas, Sickle cell disease (SCD) affects approximately 1 in 100,000 Americans, particularly in communities of color where the incidence is 1 in 365 African Americans and 1 in 16,300 Hispanics in the U.S.¹; and

Whereas, 1 in 13 African Americans are born with sickle cell trait, making this autosomal recessive disease commonly inherited and highly prevalent in African American families and communities¹; and

Whereas, Youth with SCD miss on average 20-30 school days per year because of symptoms or complications of the disease²; and

Whereas, Adolescents with SCD report having important academic goals, and school absenteeism becomes an impediment of reaching these goals resulting in worse standardized test scores and history of repeated grade levels³: and

Whereas, Due to impaired kidney functions, those with SCD need constant access to hydration and liberal access to the bathroom, both of which are frequently monitored and restricted in the classroom⁴⁻⁷; and

Whereas, SCD can limit students' abilities to engage in the same intensity of aerobic physical activities as those not impacted by SCD due to increased fatigue and further, exercise-induced acidosis promotes red blood cell sickling⁴⁻⁸; and

Whereas, Educators' poor understanding of physical limitations and students' needs for accommodations, such as adequate hydration, can result in increased pain crises or stroke⁴⁻⁷; and

Whereas, In a study assessing the needs of educators working with students with chronic illnesses, researchers found that educators felt least supported and trained to work with students suffering from sickle cell disease, cystic fibrosis, and epilepsy⁹; and

Whereas, Studies show that teachers who understand medical conditions such as ADHD, asthma, and allergy tend to use more evidence-based approaches to accommodating students' classroom needs¹⁰⁻¹¹; and

Whereas, 25.2% of schools in the United States lack a school nurse, thus recognition and monitoring of potentially emergent medical complications, such as stroke, fall on teachers and non-healthcare staff in many schools¹²; and

Resolution: 906 (I-19) Page 2 of 3

Whereas, According to the American School Health Association, school professionals suggested a need for more support when working with students with conditions such as sickle cell disease, cystic fibrosis, and epilepsy⁹; and

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> Whereas, Existing AMA policy currently "recognizes sickle cell disease (SCD) as a chronic illness, (2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD" (H-350.973); and

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Whereas, Existing AMA policy currently urges "physicians, physicians-in-training, and medical students to serve as advocates for pediatric patients with diabetes to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections" (H-60.932); and

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Whereas, Existing AMA policy currently "(1) urges all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans" for children at risk for anaphylactic reactions; and "(5) urges physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan" (D-60.976); therefore be it

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RESOLVED. That our American Medical Association support the development of an individualized sickle cell emergency care plan by physicians for in-school use, especially during sickle cell crises (New HOD Policy); and be it further

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RESOLVED, That our AMA support the education of teachers and school officials on policies and protocols, encouraging best practices for children with sickle cell disease, such as adequate access to the restroom and water, physical education modifications, seat accommodations during extreme temperature conditions, access to medications, and policies to support continuity of education during prolonged absences from school, in order to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Sickle Cell Disease H-350.973

Our AMA: (1) recognizes sickle cell disease (SCD) as a chronic illness, (2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD; (3) supports the inclusion of SCD in newborn screening programs and encourages genetic counseling for parents of SCD patients and for young adults who are affected, carriers, or at risk of being carriers; (4) supports ongoing and new research designed to speed the clinical implementation of new SCD treatments; and (5) recommends that SCD research programs have input in the planning stage from the local African American community, SCD patient advocacy groups, and others affected by SCD.

Citation: (CLRPD Rep. 3, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Modified: BOT Rep. 12, A-11)

Ensuring the Best In-School Care for Children with Diabetes H-60.932

Our AMA policy is that physicians, physicians-in-training, and medical students should serve as advocates for pediatric patients with diabetes to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections. Citation: CSAPH Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18

Childhood Anaphylactic Reactions D-60.976

Our AMA will: (1) urge all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans (MERP); (b) practice these plans in order to identify potential barriers and strategies for improvement; (c) ensure that school campuses have a direct communication link with an emergency medical system (EMS); (d) identify students at risk for life-threatening emergencies and ensure these children have an individual emergency care plan that is formulated with input by a physician; (e) designate roles and responsibilities among school staff for handling potential life-threatening emergencies, including administering medications, working with EMS and local emergency departments, and contacting families; (f) train school personnel in cardiopulmonary resuscitation; (g) adopt the School Guidelines for Managing Students with Food Allergies distributed by FARE (Food Allergy Research & Education); and (h) ensure that appropriate emergency equipment to deal with anaphylaxis and acute asthmatic reactions is available and that assigned staff are familiar with using this equipment; (2) work to expand to all states laws permitting students to carry prescribed epinephrine or other medications prescribed by their physician for asthma or anaphylaxis; (3) support increased research to better understand the causes, epidemiology, and effective treatment of anaphylaxis; (4) urge the Centers for Disease Control and Prevention to study the adequacy of school personnel and services to address asthma and anaphylactic emergencies; (5) urge physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan; and (6) work to allow all first responders to carry and administer epinephrine in suspected cases of anaphylaxis.

Citation: (CSAPH Rep. 1, A-07; Modified: CCB/CLRPD Rep. 2, A-14)

Resolution: 907

(I-19)

Introduced by: Medical Student Section

Subject: Increasing Access to Gang-Related Laser Tattoo Removal in Prison and

Community Settings

Referred to: Reference Committee K

Whereas, Between 2007 and 2012, gang-related homicides were estimated to be approximately 13% of all homicides in the United States¹ and, while national rates of violent crime have been experiencing historic lows, gang-related homicide rates have stagnated or risen²; and

Whereas, Violent crime results in enormous health care costs, criminal justice system expenditures, and productivity losses, with estimated total costs of \$5.7 million per murder and \$89,250 per aggravated assault³; and

Whereas, Public health insurance programs reimburse the majority of insurance claims pertaining to firearm-related injuries and, by extension, taxpayers bear most of the healthcare costs relating to these injuries⁴; and

Whereas, Gang tattoos present significant barriers to gang detachment and social reintegration⁵; and

Whereas, Gang tattoos increase risk of violent victimization⁶; and

Whereas, The AMA Code of Medical Ethics Opinion 8.10 states that "physicians have an ethical obligation to take actions to aver the harms caused by violence and abuse" for their patients; and

Whereas, Visible⁷ and prison⁸ tattoos are associated with higher risk for recidivism, putting exoffenders at risk for wide-ranging negative health outcomes strongly associated with incarceration⁹; and

Whereas, Visual markers of gang affiliation are stigmatizing and can lead to discrimination in employment and legal¹⁰ settings; and

Whereas, Everyday discrimination mediates the association between former incarceration and poor mental health outcomes¹¹; and

Whereas, Tattoo removal can have profound social, psychological, and economic benefits for formerly incarcerated and gang-affiliated individuals^{12,13}; and

Whereas, Removal of "branding" tattoos for victims of gang-related human trafficking facilitates psychosocial healing¹⁵⁻¹⁷; and

Resolution: 907 (I-19) Page 2 of 4

Whereas, Demand for tattoo removal is reflected in the creation of free and low cost communitybased tattoo removal programs¹⁸, including one gang rehabilitation program that performed 11.834 tattoo removal procedures in 2017¹⁹: and

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Whereas, The average national cost for one session of laser tattoo removal procedure in a private physician's office is \$401²⁰ and an average of 7-10 sessions are required for full removal of one tattoo²¹; and

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Whereas, High cost of tattoo removal has led to proliferation of an unregulated market of more inexpensive techniques which pose risks such as burns, dyspigmentation, and scarring²²; and

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Whereas, Tattoo removal services can serve as a bridge to other rehabilitative social, psychological, and educational services and opportunities²³⁻²⁵; and

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Whereas, There is public support for government-subsidized tattoo removal services for incarcerated and gang-affiliated populations²⁶; and

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Whereas, Local law enforcement agencies have recognized the value of tattoo removal services for inmates and created prison-based tattoo removal programs^{27, 28}; and

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Whereas, The AMA has supported expansion of health services in prisons, such as substance abuse treatment (H-430.994, H-430.987) and infant bonding programs (H-430.990), that enable a more successful transition from prison to community settings; therefore be it

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RESOLVED, That our American Medical Association support increased access to gang-related tattoo removal in prison and community settings. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

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RELEVANT AMA POLICY

Definitions of "Cosmetic" and "Reconstructive" Surgery H-475.992

Our AMA: (1) supports the following definitions of "cosmetic" and "reconstructive" surgery:

Cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem. Reconstructive surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance. (2) Our AMA encourages third party payers to use these definitions in determining services eligible for coverage under the plans they offer or administer. Citation: (CMS Rep. F, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed, A-03; Reaffirmed: CMS Rep. 4, A-13)

Preventing, Identifying and Treating Violence and Abuse E-8.10

All patients may be at risk for interpersonal violence and abuse, which may adversely affect their health or ability to adhere to medical recommendations. In light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to avert the harms caused by violence and abuse.

To protect patients' well-being, physicians individually should:

- (a) Become familiar with:
- (i) how to detect violence or abuse, including cultural variations in response to abuse;
- (ii) community and health resources available to abused or vulnerable persons;
- (iii) public health measures that are effective in preventing violence and abuse;
- (iv) legal requirements for reporting violence or abuse.
- (b) Consider abuse as a possible factor in the presentation of medical complaints.
- (c) Routinely inquire about physical, sexual, and psychological abuse as part of the medical history.
- (d) Not allow diagnosis or treatment to be influenced by misconceptions about abuse, including beliefs that abuse is rare, does not occur in "normal" families, is a private matter best resolved without outside interference, or is caused by victims' own actions.
- (e) Treat the immediate symptoms and sequelae of violence and abuse and provide ongoing care for patients to address long-term consequences that may arise from being exposed to violence and abuse.
- (f) Discuss any suspicion of abuse sensitively with the patient, whether or not reporting is legally mandated, and direct the patient to appropriate community resources.
- (g) Report suspected violence and abuse in keeping with applicable requirements. Before doing so, physicians should:
- (i) inform patients about requirements to report;
- (ii) obtain the patient's informed consent when reporting is not required by law. Exceptions can be made if a physician reasonably believes that a patient's refusal to authorize reporting is coerced and therefore does not constitute a valid informed treatment decision.
- (h) Protect patient privacy when reporting by disclosing only the minimum necessary information.

Resolution: 907 (I-19)

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Collectively, physicians should:

- (i) Advocate for comprehensive training in matters pertaining to violence and abuse across the continuum of professional education.
- (j) Provide leadership in raising awareness about the need to assess and identify signs of abuse, including advocating for guidelines and policies to reduce the volume of unidentified cases and help ensure that all patients are appropriately assessed.
- (k) Advocate for mechanisms to direct physicians to community or private resources that might be available to aid their patients.
- (I) Support research in the prevention of violence and abuse and collaborate with public health and community organizations to reduce violence and abuse.
- (m) Advocate for change in mandatory reporting laws if evidence indicates that such reporting is not in the best interests of patients.

Issued: 2016

Laser Surgery H-475.988

The AMA supports the position that revision, destruction, incision or other structural alteration of human tissue using laser is surgery.

Citation: (Res. 316, A-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: BOT Rep. 16, A-13)

Prison-Based Treatment Programs for Drug Abuse H-430.994

Our AMA: (1) encourages the increased application to the prison setting of the principles, precepts and processes derived from drug-free residential therapeutic community experience; and (2) urges state health departments or other appropriate agencies to take the lead in working with correction and substance abuse agencies for the expansion of such prison-based drug-free treatment programs.

Citation: (Sub. Res. 124, I-89; Reaffirmed: Sunset Report, A-00; Modified: CSAPH Rep. 1, A-10; Reaffirmation: I-12)

Opiate Replacement Therapy Programs in Correctional Facilities H-430.987

- 1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (b) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.
- 2. Our AMA advocates for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy in conjunction with counseling, in correctional facilities within the United States and that this apply to all incarcerated individuals including pregnant women.
- 3. Our AMA supports legislation, standards, policies, and funding that encourage correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including pregnant women, are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths and help ensure post-incarceration medical coverage and accessibility to medication assisted therapy.

Citation: Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17

Bonding Programs for Women Prisoners and their Newborn Children H-430.990

Because there are insufficient data at this time to draw conclusions about the long-term effects of prison nursery programs on mothers and their children, the AMA supports and encourages further research on the impact of infant bonding programs on incarcerated women and their children. The AMA recognizes the prevalence of mental health and substance abuse problems among incarcerated women and continues to support access to appropriate services for women in prisons. The AMA recognizes that a large majority of female inmates who may not have developed appropriate parenting skills are mothers of children under the age of 18. The AMA encourages correctional facilities to provide parenting skills training to all female inmates in preparation for their release from prison and return to their children. The AMA supports and encourages further investigation into the long-term effects of prison nurseries on mothers and their children.

Citation: CSA Rep. 3, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17

Resolution: 908

(I-19)

Introduced by: Medical Student Section

Subject: Request for Benzodiazepine-Specific Prescribing Guidelines for Physicians

Referred to: Reference Committee K

Whereas, Benzodiazepines are highly addictive and may cause physical dependence¹; and

Whereas, From 1999-2016 there has been an almost eightfold rise in mortality rates from benzodiazepine overdoses²; and

Whereas, Benzodiazepine overdose rates increased 830% in women aged 30-64 from 1999 to 2017³; and

Whereas, The use of benzodiazepines has almost doubled in ambulatory care visits from 2003-2015⁴; and

Whereas, The FDA requires black boxed warnings for the co-prescription of benzodiazepines, opioid analgesics, and opioid-containing cough products⁵; and

Whereas, The rate of co-prescribing benzodiazepines and opioids quadrupled from 2003-2015⁴; and

Whereas, The rate of co-prescribing benzodiazepines and other sedative medications more than doubled from 2003 to 2015⁴: and

Whereas, Some states and cities, such as Texas, Pennsylvania, and New York City, have established guidelines for prescribing benzodiazepines⁶⁻⁸; and

Whereas, Some national medical associations, such as the American Family Physician, have various articles about guidelines⁹; and

Whereas, The select state and national medical associations that do have guidelines lack consistency and completeness¹⁰; and

Whereas, No national guidelines exist to unify overall benzodiazepine prescription guidelines; and

Whereas, The passage of CDC guidelines on opioid prescribing in March 2016 marked a steeper decline in the rate of overall opioid prescriptions¹¹; and

Whereas, While the CDC has guidelines for opioid prescriptions it currently does not have any guidelines for benzodiazepine prescriptions¹²; therefore be it

Resolution: 908 (I-19)

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1 RESOLVED, That our American Medical Association support the creation of national

2 benzodiazepine-specific prescribing guidelines for physicians. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

References:

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- 11. Bohnert, A.S.B. et al. Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention's 2016 Opioid Guideline. Ann Intern Med. 2018; 169(6):367-375. CDC.

RELEVANT AMA POLICY

Informing the Public & Physicians about Health Risks of Sedative Hypnotics, Especially Rohypnol H-515.968

The AMA re-emphasizes to physicians and public health officials the fact that Rohypnol (a benzodiazepine), other benzodiazepines, and other sedatives and hypnotics carry the risk of misuse, morbidity and mortality. The AMA supports public education and public health initiatives regarding the dangers of the use of sedatives and hypnotics in sexual abuse and rape, especially when mixed with ethanol ingestion.

Citation: Sub. Res. 408, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17

Benzodiazepine Education H-100.976

Our AMA encourages physicians interested in the addictive nature of benzodiazepines and their rational use to seek information from appropriate sources.

Citation: (CSA Rep. E, A-92; Amended: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)

Inappropriate Use of CDC Guidelines for Prescribing Opioids D-120.932

- 1. Our AMA applauds the Centers for Disease Control and Prevention (CDC) for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths.
- 2. Our AMA will actively continue to communicate and engage with the nation's largest pharmacy chains, pharmacy benefit managers, National Association of Insurance Commissioners, Federation of State Medical Boards, and National Association of Boards of Pharmacy in opposition to communications being sent to physicians that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care. A report is due back to the House of Delegates at the 2019 Annual Meeting.
- 3. Our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for

Resolution: 908 (I-19)

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Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate.

- 4. Our AMA will advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients' medical access to opioid analgesia.
- 5. Our AMA will advocate that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.
- 6. Our AMA: (a) supports balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements; (b) opposes the use of "high prescriber" lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice; and (c) will incorporate into its advocacy that clinical practice guidelines specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC's Guideline for Prescribing Opioids for Chronic Pain as per the CDC's clarifying recommendation.

Citation: Res. 235, I-18; Appended: BOT Rep. 22, A-19

A More Uniform Approach to Assessing and Treating Patients for Controlled Substances for Pain Relief D-120.947

- 1. Our AMA will consult with relevant Federation partners and consider developing by consensus a set of best practices to help inform the appropriate clinical use of opioid analgesics, including risk assessment and monitoring for substance use disorders, in the management of persistent pain.
- 2. Our AMA will urge the Centers for Disease Control and Prevention to take the lead in promoting a standard approach to documenting and assessing unintentional poisonings and deaths involving prescription opioids, including obtaining more complete information on other contributing factors in such individuals, in order to develop the most appropriate solutions to prevent these incidents.
- 3. Our AMA will work diligently with the Centers for Disease Control and Prevention and other regulatory agencies to provide increased leeway in the interpretation of the new guidelines for appropriate prescription of opioid medications in long-term care facilities and in the care of patients with cancer and cancer-related pain, in much the same way as is being done for hospice and palliative care.

Citation: BOT Rep. 3, I-13; Appended: Res. 522, A-16; Modified: Res. 918, I-16; Reaffirmed in lieu of: Res. 803, I-16; Reaffirmation: A-19

Resolution: 909

(1-19)

Introduced by: Resident and Fellow Section

Subject: Decreasing the Use of Oximetry Monitors for the Prevention of Sudden Infant

Death Syndrome

Referred to: Reference Committee K

Whereas, A causal relationship between prolonged apnea and sudden infant death syndrome has not been established; and

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Whereas, Studies have failed to document any impact of home cardiorespiratory monitoring for apnea and/or bradycardia on the incidence of sudden infant death syndrome; and

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Whereas, Home cardiorespiratory monitoring with medical-grade pulse oximeters may be warranted for infants who have unstable airways, rare medical conditions affecting regulation of breathing, symptomatic chronic lung disease, or require respiratory support; and

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Whereas, Home apnea monitors cause unnecessary worry due to false alarms; and

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Whereas, Parents may actually feel more fear and anxiety if they often use medical equipment to check on their healthy baby, which can lead to increased parental depression; and

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Whereas, The most effective ways to reduce the risk of sudden infant death syndrome is to place baby prone on a firm crib mattress with nothing else in the crib; and

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Whereas, A recent study in JAMA found that non-FDA regulated oximetry monitors, such as the Owlet Sock and Baby Vida, performed inconsistently in detecting hypoxemia and also displayed falsely low pulse rates; and

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Whereas, False readings from these commercially-available, non-FDA regulated, pulse oximetry monitors can lead to increased unnecessary use of the medical system; and

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Whereas, Commercial monitors, such as the Owlet Smart Sock, retails for over \$200, and is often a recommended baby item by most store baby registries; therefore be it

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RESOLVED, That our American Medical Association oppose the sale and use of oximetry monitors to prevent sudden infant death syndrome. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 09/04/19

Resolution: 909 (I-19)

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References:

1 American Academy of Pediatrics. Apnea, sudden infant death syndrome, and home monitoring. Committee on Fetus and Newborn. *Pediatrics* 2003; 111(4): 914-916.

2 Bonafide CP, Localio AR, Ferro DF, Orenstein EW, Jamison DT, Lavanchy C, Foglia EE. Accuracy of pulse oximetry-based home baby monitors. *JAMA* 2018; 320(97):717-719.

3 Eichenwald EC. Apnea of prematurity. Pediatrics 2016; 137(1).

4 "The truth about home apnea monitors for SIDs." Healthy Children. 22 August 2017

https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Home-Apnea-Monitors-for-SIDs.aspx.

RELEVANT AMA POLICY

Standardization of Newborn Screening Programs H-245.973

Our AMA: (1) recognizes the need for uniform minimum newborn screening (NBS) recommendations; and (2) encourages continued research and discussions on the potential benefits and harms of NBS for certain diseases. (CSAPH Rep. 9, A-06; Reaffirmed in lieu of Res. 502, A-09)

Early Hearing Detection and Intervention H-245.970

Our AMA: 1) supports early hearing detection and intervention to ensure that every infant receives proper hearing screening, diagnostic evaluation, intervention, and follow-up in a timely manner; and 2) supports federal legislation that provides for the development and monitoring of statewide programs and systems for hearing screening of newborns and infants, prompt evaluation and diagnosis of children referred from screening programs, and appropriate medical, educational, and audiological interventions and follow-up for children identified with hearing loss.

Citation: (Res. 514, A-11; Reaffirmed: CMS Rep. 6, I-15)

Sudden Infant Death Syndrome H-245.977

- 1. The AMA encourages the education of parents, physicians and all other health care professionals involved in newborn care regarding methods to eliminate known Sudden Infant Death Syndrome (SIDS) risk factors, such as prone sleeping, soft bedding and parental smoking.
- 2. Our AMA will advocate for the appropriate labeling of all infant sleep products, not in compliance with the Safe Infant Sleeping Environment Guidelines, as adopted by the AAP, to adequately warn consumers of the risks of product use and prevent sudden unexpected infant death.
- 3. Our AMA encourages consumers to avoid commercial devices marketed to reduce the risk of SIDS, including: wedges, positioners, special mattresses, and special sleep surfaces.
- 4. Our AMA encourages media and manufacturers to follow safe-sleep guidelines in their messaging and advertising.
- 5. Our AMA encourages further research of infant safe sleeping environment programs, including, but not limited to, the study of the safety and efficacy of boxes.

Citation: (Res. 414, A-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 429, A-16; Appended: Res. 407, A-18)

Infant Mortality D-245.994

- 1. Our AMA will work with appropriate agencies and organizations towards reducing infant mortality by providing information on safe sleep positions and preterm birth risk factors to physicians, other health professionals, parents, and child care givers.
- 2. Our AMA will work with Congress and the Department of Health and Human Services to improve maternal outcomes through: (a) maternal/infant health research at the NIH to reduce the prevalence of premature births and to focus on obesity research, treatment and prevention; (b) maternal/infant health research and surveillance at the CDC to assist states in setting up maternal mortality reviews; modernize state birth and death records systems to the 2003-recommended guidelines; and improve the Safe Motherhood Program; (c) maternal/infant health programs at HRSA to improve the Maternal Child Health Block grant; (d) comparative effectiveness research into the interventions for preterm birth; (e) disparities research into maternal outcomes, preterm birth and pregnancy-related depression; and (f) the development, testing and implementation of quality improvement measures and initiatives. Citation: (Res. 410, A-10)

Resolution: 910

(I-19)

Introduced by: Minority Affairs Section

Subject: Ban on Electronic Nicotine Delivery System (ENDS) Products

Referred to: Reference Committee K

Whereas, Vaping or e-cigarettes are common terms--describing products that produce an aerosolized mixture of nicotine and flavored liquids--that do not encompass all of the products in this rapidly evolving market. Electronic Nicotine Delivery Systems (ENDS) is a more accurate term to include personal vaporizers, vape pens, e-cigarettes, e-cigars, e-hookah, vaping devices, mod systems or pod systems, and whatever new terms might be used for these incendiary nicotine devices; and

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Whereas, On December 18, 2018, the U.S. Surgeon General declared e-cigarettes or ENDS an epidemic, stating, "current e-cigarette use increased 78% among high school students during the past year, from 11.7% in 2017... In 2018, more than 3.6 million U.S. youth, including 1 in 5 high school students and 1 in 20 middle school students, currently use e-cigarettes"; and

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Whereas, Two deaths and 215 cases of severe pulmonary disease in 25 states are suspected to be caused by ENDS product use; prompting the CDC to state, "if you are concerned about these specific health risks, consider not using e-cigarette products"; and

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Whereas, The City of San Francisco banned ENDS products, including online sales, citing safety concerns, in spite of the fact that JUUL, the company with the market share of ENDS products, is based in San Francisco; and

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Whereas, Tobacco is a sacred plant to American Indians that has been highly modified from its original form to increase the nicotine content. JUUL has approached Tribes, some of the poorest communities in the U.S., with the offer of hundreds of thousands of dollars to "switch" their smokers to JUUL products; therefore be it

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26 RESOLVED, That our American Medical Association advocate for regulatory, and/or legislative, 27 and/or legal action at the federal and/or state levels to ban all Electronic Nicotine Delivery 28 Systems (ENDS) products. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/25/19

Resolution: 910 (I-19)

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RELEVANT AMA POLICY

Electronic Cigarettes, Vaping, and Health H-495.972

- 1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.
- 2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.
- 3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.

 Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19; Appended: Res. 428, A-19;

Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution Our AMA:

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;
- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and

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(9) opposes the sale of tobacco at any facility where health services are provided; and (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18;

FDA Regulation of Tobacco Products H-495.988

- 1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges Congress to pass legislation to phase in the production of reduced nicotine content tobacco products and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco
- 2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.
- 3. Our AMA: (A) will continue to monitor the FDA's progress towards establishing a low nicotine product standard for tobacco products and will submit comments on the proposed rule that are in line with the current scientific evidence and (B) recognizes that rigorous and comprehensive post-market surveillance and product testing to monitor for unintended tobacco use patterns will be critical to the success of a nicotine reduction policy.

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19;

References:

https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf

https://www.cnn.com/2019/09/03/health/ecigarettes-vaping-death-lung-disease-oregon-bn/index.html

https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

https://www.npr.org/sections/health-shots/2019/06/25/735714009/san-francisco-poised-to-ban-sales-of-e-cigarettes

^{*} https://www.cbsnews.com/news/juul-came-to-a-9th-grade-classroom-and-told-teens-their-products-were-totally-safe-according-to-teens-testimonies/

Resolution: 911

(I-19)

Introduced by: Young Physicians Section

Subject: Basic Courses in Nutrition

Referred to: Reference Committee K

Whereas, A 2018 burden of disease collaborators report showed evidence that poor quality diet has been identified as the leading cause of death in the United States¹; and

Whereas, Health care has shifted from disease management to health promotion and
 prevention; and

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Whereas, "Beginning with medical school the time devoted to nutrition is limited, with an average of 19 total hours over 4 years, and is focused largely on biochemistry and vitamin deficiency states" and nutritional deficiencies (for example, scurvy and beriberi) are not a major problem in the United States²: and

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Whereas The latest Accreditation Council for Graduate Medical Education common program requirement for residency and fellowship training lack a requirement for physician trainees to learn about nutrition or diet³; and

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Whereas, Clinical nutrition might not only serve to improve patient health, but also resident and physician wellness through "greater awareness and knowledge of the dietary influences on well-being" and

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Whereas, Clinicians with a foundation in nutrition will be more likely to recognize the importance of diet and make more effective referrals⁵; therefore be it

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RESOLVED, That our American Medical Association amend Policy H-150.995, "Basic Courses in Nutrition," by addition to read as follows:

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Basic Courses in Nutrition H-150.995

1. Our AMA encourages effective education in nutrition at the undergraduate, graduate, and postgraduate levels.

2. Our AMA encourages collaboration with appropriate entities to develop and promote relevant nutrition education to enhance patient care and medical trainee education and wellbeing.

3. Our AMA encourages alignment with evidence-based dietary guidelines for food served in medical trainings and medical conferences. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 09/26/19

Resolution: 911 (I-19)

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RELEVANT AMA POLICY

Basic Courses in Nutrition H-150.995

Our AMA encourages effective education **in nutrition** at the undergraduate, graduate, and postgraduate levels.

Sub. Res. 116, A-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report, A-00 Reaffirmed: CME Rep. 2, A-11 Reaffirmation: A-19

References:

- 1. Mokdad AH, Ballestros K, Echko M, et al. US Burden of Disease Collaborators. The state of US health, 1990-2016: burden of diseases, injuries, and risk factors among US states. *JAMA*. 2018;319(14):1444-1472. doi:10.1001/jama.2018.0158
- 2. Devries S, Willett W, and Bonow RO. Nutrition Education in Medical School, Residency Training, and Practice. *JAMA*. Published online March 21, 2019. doi:10.1001/jama.2019.1581
- 3. Accreditation Council for Graduate Medical Education. ACGME Common Program Requirements (Residency). Chicago, IL: Accreditation Council for Graduate Medical Education;2018. Available at http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2019.pdf. Accessed February 4, 2019.
- 4. U.S. Department of Health and Human Services. US Department of Agriculture. 2015-2020 Dietary Guidelines for Americans. 8th Ed. Washington, DC: Office of Disease Prevention and Health Promotion; 2015. Available at http://health.gov/dietrayguidelines/2015/guidelines/. Accessed March 23, 2019.
- 5. Adams KMBW, Kohlmeier M, and Zeisel S. The state of nutrition education at US medical schools. *J Biomed Educ*. 2015;2015:1-7. doi:10.1155/2015/357627

Resolution: 912

(I-19)

Introduced by: Young Physicians Section

Subject: Improved Emergency Response Planning for Infectious Disease

Outbreaks

Referred to: Reference Committee K

Whereas, In the Blueprint list of priority diseases released by the World Health Organization in February 2018, a "Disease X", or an unexpected infectious disease, was added representing an unknown pathogen with a serious international epidemic potential¹; and

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Whereas, The Centers for Disease Control and Prevention has faced budget cuts of 1.525 billion dollars over the last three fiscal years²; and

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Whereas, Continued public health funding is fundamental to maintaining essential services to the general population in prevention, outbreak investigation, and emergency response; and

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Whereas, Availability of funding for an unexpected infectious disease prior to its clinical presentation would allow for patterned syndromic surveillance; and

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Whereas, Early identification of a potential infectious disease outbreak reduces transmission, morbidity, mortality; and

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Whereas, Early identification and public health messaging provides education for the general public; therefore be it

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RESOLVED, That our American Medical Association encourage hospitals and other entities that collect patient encounter data to report syndromic (i.e., symptoms that appear together and characterize a disease or medical condition) data to public health departments in order to facilitate syndromic surveillance, assess risks of local populations for disease, and develop comprehensive plans with stakeholders to enact actions for mitigation, preparedness, response, and recovery (Directive to Take Action); and be it further

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RESOLVED, That our AMA support flexible funding in public health for unexpected infectious disease to improve timely response to emerging outbreaks and build public health infrastructure at the local level with attention to medically underserved areas (Directive to Take Action); and be it further

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RESOLVED, That our AMA encourage health departments to develop public health messaging to provide education on unexpected infectious disease. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 09/26/19

Resolution: 912 (I-19)

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RELEVANT AMA POLICY

programs.

Federal Block Grants and Public Health H-440.912

(1) Our AMA should collaborate with national public health organizations to explore ways in which public health and clinical medicine can become better integrated; such efforts may include the development of a common core of knowledge for public health and medical professionals, as well as educational vehicles to disseminate this information.

- (2) Our AMA urges Congress and responsible federal agencies to: (a) establish set-asides or stable funding to states and localities for essential public health programs and services, (b) provide for flexibility in funding but ensure that states and localities are held accountable for the appropriate use of the funds; and (c) involve national medical and public health organizations in deliberations on proposed changes in funding of public health programs.
- (3) Our AMA will work with and through state and county medical societies to: (a) improve understanding of public health, including the distinction between publicly funded medical care and public health; (b) determine the roles and responsibilities of private physicians in public health, particularly in the delivery of personal medical care to underserved populations; (c) advocate for essential public health programs and services; (d) monitor legislative proposals that affect the nation's public health system; (e) monitor the growing influence of managed care organizations and other third party payers and assess the roles and responsibilities of these organizations for providing preventive services in communities; and (f) effectively communicate with practicing physicians and the general public about important public health issues.

 (4) Our AMA urges state and county medical societies to: (a) establish more collegial relationships with public health agencies and increase interactions between private practice and public health physicians to develop mutual support of public health and clinical medicine; and (b) monitor and, to the extent possible, participate in state deliberations to ensure that block grant funds are used appropriately for health-related
- (5) Our AMA urges physicians and medical societies to establish community partnerships comprised of concerned citizens, community groups, managed care organizations, hospitals, and public health agencies to: (a) assess the health status of their communities and determine the scope and quality of population- and personal-based health services in their respective regions; and (b) develop performance objectives that reflect the public health needs of their states and communities.
- 6. Our AMA: (a) supports the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, in order to assure preservation of many critical public health programs for chronic disease prevention and health promotion in California and nationwide, and to maintain training of the public health physician workforce; and (b) will communicate support of the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, to the US Congress.

Citation: CSA Rep. 3, A-96; Reaffirmation A-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmed in lieu of Res. 424, A-11; Appended: Res. 935, I-11; Reaffirmation A-15; Reaffirmed in lieu of: Res. 419, A-19;

Pandemic Preparedness for Influenza H-440.847

In order to prepare for a potential influenza pandemic, our AMA: (1) urges the Department of Health and Human Services Emergency Care Coordination Center, in collaboration with the leadership of the Centers for Disease Control and Prevention (CDC), state and local health departments, and the national organizations representing them, to urgently assess the shortfall in funding, staffing, vaccine, drug, and data management capacity to prepare for and respond to an influenza pandemic or other serious public health emergency; (2) urges Congress and the Administration to work to ensure adequate funding and other resources: (a) for the CDC, the National Institutes of Health (NIH) and other appropriate federal agencies, to support implementation of an expanded capacity to produce the necessary vaccines and anti-viral drugs and to continue development of the nation's capacity to rapidly vaccinate the entire population and care for large numbers of seriously ill people; and (b) to bolster the infrastructure and capacity of state and local health department to effectively prepare for, respond to, and protect the population from illness and death in an influenza pandemic or other serious public health emergency; (3) urges the CDC to develop and disseminate electronic instructional resources on procedures to follow in an influenza epidemic, pandemic, or other serious public health emergency, which are tailored to the needs of physicians and medical office staff in ambulatory care settings; (4) supports the position that: (a) relevant national and state agencies (such as the CDC, NIH, and the state departments of health) take immediate action to assure that physicians, nurses, other health care professionals, and first responders having direct patient contact, receive any appropriate vaccination in a timely and efficient manner, in order to reassure them that they will have first priority in the event of such a pandemic; and (b) such

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agencies should publicize now, in advance of any such pandemic, what the plan will be to provide immunization to health care providers; (6) will monitor progress in developing a contingency plan that addresses future influenza vaccine production or distribution problems and in developing a plan to respond to an influenza pandemic in the United States.

Citation: (CSAPH Rep. 5, I-12; Reaffirmation A-15)

Next Generation Infectious Diseases Diagnostics H-440.834

- 1. Our American Medical Association supports strong federal efforts to stimulate early research and development of emerging rapid ID (infectious disease) diagnostic technologies through increased funding for appropriate agencies.
- 2. Our AMA supports the reduction of regulatory barriers to allow for safe and effective emerging rapid diagnostic tests, particularly those that address unmet medical needs, to more rapidly reach laboratories for use in patient care.
- 3. Our AMA supports improving the clinical integration of new diagnostic technologies into patient care through outcomes research that demonstrates the impact of diagnostics on patient care and outcomes, educational programs and clinical practice guidelines for health care providers on the appropriate use of diagnostics, and integration of diagnostic tests results into electronic medical records.
- 4. Our AMA supports efforts to overcome reimbursement barriers to ensure coverage of the cost of emerging diagnostics.

Citation: (Res. 507, A-15; Reaffirmed: CSAPH Rep. 3, I-15)

Public and Private Funding of Prevention Research D-425.999

Our AMA seeks to work in partnership with the Centers for Disease Control and Prevention, the National Institutes of Health, and other Federal Agencies, the Public Health Community, and the managed care community to ensure that there is a national prevention research agenda.

Citation: Res. 418, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18;

AMA Leadership in the Medical Response to Terrorism and Other Disasters H-130.946

Our AMA: (1) Condemns terrorism in all its forms and provide leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters.

- (2) Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Program, to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts.
- (3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma. (4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the

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role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems. (5) Believes that physicians and other health professionals who have direct involvement in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and sanitation; (f) public health laws; and (g) state and federal resources that contribute to emergency management and response at the local level.

(6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including

- (6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues.
- (7) Believes physicians and medical societies should participate directly with state, local, and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters.
- (8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive agent detection and defense capabilities.

Citation: (BOT Rep. 26, I-01; Reaffirmed: BOT Rep. 3, I-02; Modified: CSA Rep. 1, I-03; Reaffirmed: CME Rep. 1, I-11; Reaffirmation A-15)

Fund for Public Health Emergency Response H-440.825

Our AMA supports the reauthorization and appropriation of sufficient funds to a public health emergency fund within the Department of Health and Human Services to facilitate adequate responses to public health emergencies without redistributing funds from established public health accounts. Citation: Res. 420, A-16;

Global Tracking System of Zoonotic Diseases D-440.940

Our AMA will work with the American Veterinary Medical Association and other relevant stakeholders to encourage the US Departments of Health and Human Services, Agriculture, Interior, and other appropriate federal and state agencies to take the lead in establishing a robust, coordinated, and effective global surveillance system of zoonotic diseases in humans and syndromic outbreaks in animals, thereby enhancing collaboration of human and animal health sectors and resulting in improved early detection and response.

Citation: Sub. Res. 519, A-10; Reaffirmed: CSAPH Rep. 04, A-19;

References:

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- 7. H.R.3590 Patient Protection and Affordable Care Act. Available at www.congress.gov/bill/111th-congress/house-bill/3590. Accessed March 2019.
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- 9. H.R.1892 Bipartisan Budget Act of 2018. Available at www.congress.gov/bill/115th-congress/house-bill/1892. Accessed March 2019

Resolution: 913

(I-19)

Introduced by: Young Physicians Section

Subject: Public Health Impacts and Unintended Consequences of Legalization and

Decriminalization of Cannabis for Medicinal and Recreational Use

Referred to: Reference Committee K

Whereas, AMA Policy D-95.969, "Cannabis Legalization for Medicinal Use," states, in part, that our AMA: "(2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process;" and

Whereas, AMA Policy H-95.924, "Cannabis Legalization for Recreational Use," states, in part, that our AMA: "(5) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis use;" and

 Whereas, AMA Policy H-95.923, "Taxes on Cannabis Products," states that "our AMA encourages states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts;" and

Whereas, AMA Policy H-95.952, "Cannabis and Cannabinoid Research," states, in part, that our AMA: "(4) supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding; and (5) urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic and social consequences of its use;" and

Whereas, Despite existing AMA policies, "ten states and the District of Columbia have full legalization [of recreational cannabis], and another 23 states permit medicinal uses with permission from a doctor, according to the National Conference of State Legislatures;" and

Whereas, Legalization of both hemp and cannabis have bipartisan support in Congress;² and

Whereas, Emerging research in Colorado has shown that "marijuana use during pregnancy, concerns related to marijuana in homes with children, and adolescent use should continue to guide public health education and prevention efforts:

 The percentage of women who use marijuana in pregnancy...is higher among younger women, women with less education, and women with unintended pregnancies.

 Marijuana exposure in pregnancy is associated with decreased cognitive function and attention problems in childhood.

 Unintentional marijuana consumption among children under age 9 continues a slow upward trend, as do emergency visits due to marijuana. Additionally, an estimated 23,000 homes with children in Colorado have marijuana stored potentially unsafely. Marijuana exposures in children can lead to significant clinical effects that require medical attention;"³ and

Whereas, Dr. Tista Ghosh of the Colorado Department of Public Health and Environment states that "it's critical we continue to monitor use in all populations and work to minimize harms that could result from a variety of causes including unintended poisoning, unsafe driving, and mental health issues that may be associated with long-term, habitual use;" and

Whereas, In Washington State, where recreational marijuana use was decriminalized, "between 2011 and 2013, there was an average of 155 marijuana-related calls per year to the Poison Control Center; from 2014 to 2016 the average number of calls was 268, a 73% increase;" and

Whereas, the Rocky Mountain High Intensity Drug Trafficking Area has been tracking the impact of marijuana legalization in the state of Colorado, finding that:

- "Marijuana-related traffic deaths increased 48% in the three-year average (2013-2015) since Colorado legalized recreational marijuana compared to the three-year average (2010-2012) prior to legalization;
 - o During the same time, all traffic deaths increased 11%;

 Marijuana-related traffic deaths increased 62% from 71 to 115 persons after recreational marijuana was legalized in 2013;

 In 2009, Colorado marijuana-related traffic deaths involving operators testing positive for marijuana represented 10% of all traffic fatalities. By 2015, that number doubled to 21%;

 Emergency department rates likely related to marijuana increased 49% in the two-year average (2013-2014) since Colorado legalized recreational marijuana compared to the twoyear average prior to legalization (2011-2012);

 Hospital[ization] rates likely related to marijuana increased 32% in the three-year average (2013-2015) since Colorado legalized recreational marijuana compared to the three-year average prior to legalization (2010-2012);

Of the 394 seizures in 2015, there were 36 different states destined to receive marijuana from Colorado. The most common destinations identified were Missouri, Illinois, Texas, Iowa, and Florida;"5 and

Whereas, States sharing a border with states that have legalized recreational marijuana may have increased public health and public safety impacts, with no potential benefits from the tax revenues associated with that legalization; and

Whereas, The AMA Council on Science and Public Health Report 5-I-17, "Clinical Implications and Policy Consideration of Cannabis Use," states that "ongoing surveillance to determine the impact of cannabis legalization and commercialization on public health and safety will be critical. Surveillance should include but not be limited to the impact on patterns of use, traffic fatalities and injuries, emergency department visits and hospitalizations, unintentional exposures, exposure to second-hand smoke, and cannabis-related treatment admissions. At-risk populations, including pregnant women and children, should be a focus of attention. Continued evaluation of the effectiveness of regulations developed to ensure public health and safety in states that have legalized the medical and/or recreational use of cannabis is necessary;" therefore be it

RESOLVED, That our American Medical Association work with interested organizations to collate existing worldwide data on the public health impacts, societal impacts, and unintended consequences of legalization and/or decriminalization of cannabis for recreational and medicinal use, with a report back at the 2020 Interim Meeting (Directive to Take Action); and be it further

RESOLVED, That our AMA continue to encourage research on the unintended consequences of legalization and decriminalization of cannabis for recreational and medicinal use in an effort to promote public health and public safety (Directive to Take Action); and be it further

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RESOLVED, That our AMA encourage dissemination of information on the public health impacts of legalization and decriminalization of cannabis for recreational and medicinal use, with consideration of making links to that information available on the AMA website (Directive to Take Action); and be it further

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- 10 RESOLVED, That our AMA work with interested organizations to lobby Congress to allow more
- 11 sites to conduct research on the risks and benefits of cannabinoid products. (Directive to Take
- 12 Action)

Fiscal Note: Modest – between \$1,000 - \$5,000.

Received: 09/26/19

RELEVANT AMA POLICY

Cannabis Warnings for Pregnant and Breastfeeding Women H-95.936

Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed.

Citation: Res. 922, I-15; Reaffirmed: CSAPH Rep. 05, I-17;

Taxes on Cannabis Products H-95.923

Our AMA encourages states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts.

Citation: CSAPH Rep. 05, I-17;

Cannabis and Cannabinoid Research H-95.952

- 1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
- 2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
- 3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
- 4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
- 5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

Citation: CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19;

Cannabis Legalization for Recreational Use H-95.924

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for recreational use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (3) believes states that have already legalized cannabis (for medical or recreational use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (5) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis use; and (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. Citation: CSAPH Rep. 05, I-17;

Cannabis Legalization for Medicinal Use D-95.969

Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; and (6)will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians.

Citation: CSAPH Rep. 05, I-17; Appended: Res. 211, A-18;

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Resolution: 914

(I-19)

Introduced by: Indiana

Subject: Nicotine Replacement Therapy for Minors

Referred to: Reference Committee K

Whereas, The number of children and adolescents under the age of 18 who are using, as well as experiencing exposure to and addiction to tobacco and nicotine, is increasing at an alarming rate; and

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Whereas, Most current evidence-based nicotine cessation treatment options are available only to those 18 and older; and

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Whereas, Additional treatment options are needed to help young patients; therefore be it

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RESOLVED, That our American Medical Association seek immediate and thorough study of the use of all forms of nicotine delivery, as well as all nicotine addiction treatment options in populations under the age of 18 (Directive to Take Action); and be it further

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14 RESOLVED, That our AMA support federal regulation that encourages manufacturers of 15 nicotine addiction treatment therapy approved for adults to examine their products' effects in 16 populations under age 18. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 09/27/19

RELEVANT AMA POLICY

Health Insurance and Reimbursement for Tobacco Cessation and Counseling H-490.916 Our AMA:

(1) (a) continues to support development of an infrastructure for tobacco dependence treatment; (b) will work with the U.S. Public Health Service, particularly the Agency for Health Research and Quality, health insurers, and others to develop recommendations for third party payment for the treatment of nicotine addiction; (c) urges third party payers and governmental agencies involved in medical care to regard and treat nicotine addiction counseling and/or treatment by physicians as an important and legitimate medical service; and (d) supports the ready availability of health insurance coverage and reimbursement for pharmacologic and behavioral treatment of nicotine dependence and smoking cessation efforts; (2) (a) requests Congress to provide matching funds for Medicaid coverage for evidence-based programs and Food and Drug Administration (FDA)-approved products that lead to smoking cessation; and (b) seeks the requirement that state Medicaid programs, prepaid health plans, and insurance companies provide evidence-based approaches for smoking cessation and nicotine withdrawal, including FDA-approved pharmacotherapy, as part of their standard benefit packages.

CSA Rep. 3, A-04 Reaffirmed: BOT Rep. 8, A-08 Reaffirmation A-11

Resolution: 915

(I-19)

Introduced by: American College of Cardiology

Heart Rhythm Society

Subject: Preventing Death and Disability Due to Particulate Matter Produced by

Automobiles

Referred to: Reference Committee K

Whereas, Environmental pollution is the largest cause of premature and preventable death and disability in the world today (Landrigan PJ, Fuller R, Acosta NJR, et al. The Lancet Commission on pollution and health. Lancet 2018;391:462-512); and

Whereas, Inextricable evidence documents the adverse health effects of air pollution on climate change and the global environment; and

 Whereas, Robust scientific evidence indicates that environmental exposure to toxic nanoparticles (fine particulate matter <2.5 pm), is a direct causal factor in the development of cardiovascular disease, (Rajagopalan S, Al-Kindi SG, Brook RD. Air Pollution and Cardiovascular Disease. JACC 2018;72:2054-70. Chen CL, Sera F, Vicedo-Cabrera AM, et al. Ambient Particulate Air Pollution and Daily Mortality in 652 Cities. N Engl J Ned 2019;381:705-

12 Ambient F 13 715); and

Whereas, Air pollution and global warming are multi-factorial, longstanding, multinational problems that require comprehensive, widely collaborative solutions; and

Whereas, Gasoline and diesel combustion powered vehicles are a primary source of environmental exposure to these nanoparticles and other disease-causing pollutants including noise (Luscher TF. Noise, pollution, food, or medication: what really matters in primary prevention? Eur Heart J 2019;40:563-566), Heritier H, Vienneau D, Foraster M, et al. A systematic analysis of natural effects of transportation noise and air pollution exposure on myocardial infarction mortality: a nationwide cohort study in Switzerland. Dur Heart J 2019;40:598-603); and

Whereas, Regulation, reduction and future elimination of gasoline and diesel combustion vehicles has been proposed as a near term, readily achievable means for prevention of cardiovascular diseases which can be implemented while additional comprehensive approaches to reducing air pollution from all sources are developed (Burch I, Gilchrist J. Survey of Global Activity to Phase Out Internal Combustion Engine Vehicles https://climateprotection.org/wp-conten/uploads/2018/09/Survey-in-Global-Activities-to-Phase-Out-ICE-Vehicles-FINAL.pdf, Schnell J, Naik V, Horowitz LW, et al. Air quality impacts from the electrification of light-duty passenger vehicles in the United States. *Atmospheric Environment*, 2019;208:95); and

Whereas, Automobile manufacturers are aggressively developing electric powered vehicles, and alternatives for quiet, non-polluting, efficient public transportation exist, but funding for these

Resolution: 915 (I-19) Page 2 of 2

services competes for funding for freeway construction, air travel and the fossil fuel industry; and

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Whereas, Reduced exposure to nanoparticles produced by combustion engines may have a beneficial effect in reducing heart disease and cancer of a magnitude similar to that produced by public health programs which reduced tobacco smoking; and

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Whereas, Current AMA policy (H-135-998 "Governmental control programs should be implemented primarily at those local, regional, or state levels which have jurisdiction over the respective sources of air pollution and the population and areas immediately affected, and which possess the resources to bring about equitable and effective control," H-135-999" ...this may be done by federal grants for (1) the development of research activity and (2) the encouragement of local programs for the prevention and control of air pollutants" and D-135-985 "...declare the need for authorities in all states to expeditiously adopt, and implement effective air pollution control strategies to reduce emissions, and this position will be disseminated to state and specialty societies"} should be updated to address urgent policy issues related to environmental exposure to nanoparticles that transcend local, regional and national governmental authority); and

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Whereas, Our AMA is responsible for informing our colleagues, our patients and responsible authorities at all levels of society and government as to the medical evidence supporting the direct link between exposure to particulate matter produced by gasoline and diesel powered vehicles to heart and lung disease and cancer, (Dunk JH, Jones DS, Capon A, et al. Human Health on an Ailing Plants – Historical Perspective on Our Future. N Engl J Med 2019;381:778-781); therefore be it

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RESOLVED, That our American Medical Association promote policies at all levels of society and government that educate and encourage policy makers to limit or eliminate disease causing contamination of the environment by gasoline and diesel combustion-powered automobiles, advocating for the development of alternative means for automobile propulsion and public transportation. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/01/19

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- Woodward NC, Pakbin P, Saffari A, Shirmohammadi F, Haghani A, Sioutas C, Cacciottolo M, Morgan TE, Finch CE. Traffic-related air pollution impact on mouse brain accelerates myelin and neuritic aging changes with specificity for CA1 neurons. Neurobiol Aging. 2017 05; 53:48-58. PMID: 28212893

Resolution: 916

(I-19)

Introduced by: American College of Cardiology

Subject: Sale of Tobacco in Retail Pharmacies

Referred to: Reference Committee K

Whereas, Smoking tobacco causes heart disease; and

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Whereas, Ongoing public health efforts to limit tobacco use have had major impact in reducing the incidence of heart disease; and

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Whereas, Tobacco smoking continues to be a major cause of heart disease, cancer and lung disease; and

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Whereas, Addiction to tobacco smoking often begins in youth; and

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Whereas, The sale of tobacco products to minors is legally prohibited; and

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Whereas, The U.S. Food and Drug Administration has identified high rates of sales of tobacco products to minors by several prominent national retailers, including those who also sell prescription pharmaceuticals and other healthcare services in their stores; and

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Whereas, Healthcare providers have a special responsibility to promote the public health and should not sell addictive products known to cause disease; and

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Whereas, AMA policy H-500.975 calls for AMA to "...use appropriate lobbying resources to support programs of anti-tobacco health...."; therefore be it

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RESOLVED, That our American Medical Association widely publicize opposition to pharmacies

selling tobacco products, especially to minors, and seek active collaboration with other healthcare professionals through their professional organizations, especially pharmacists, but

including all healthcare team members, to persuade all retailers of prescription pharmaceuticals

to immediately cease selling tobacco products, with a report back at the 2020 Annual Meeting.

28 (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/01/19

Resolution: 916 (I-19)

Page 2 of 2

RELEVANT AMA POLICY

AMA Corporate Policies on Tobacco H-500.975

- (1) Our AMA: (a) continues to urge the federal government to reduce and control the use of tobacco and tobacco products; (b) supports developing an appropriate body for coordinating and centralizing the Association's efforts toward a tobacco-free society; and (c) will defend vigorously all attacks by the tobacco industry on the scientific integrity of AMA publications. (2) It is the policy of our AMA to continue to use appropriate lobbying resources to support programs of anti-tobacco health promotion and advertising.
- (3) Our AMA's House of Delegates endorses the April 24, 1996, statement by the AMA Secretary-Treasurer that all physicians, health professionals, medical schools, hospitals, public health advocates, and citizens interested in the health and welfare of our children should review their personal and institutional investments and divest of any tobacco holdings (including mutual funds that include tobacco holdings); and specifically calls on all life and health insurance companies and HMOs to divest of any tobacco holdings.
- (4) Our AMA defines the Tobacco Industry as companies or corporate divisions that directly produce or purchase tobacco for production or market tobacco products, along with their research and lobbying groups, including the Council for Tobacco Research and the Smokeless Tobacco Research Council. A company or corporate division that does not produce or market tobacco products but that has a tobacco producing company as or among its owners will not be considered a prohibited part of the tobacco industry as long as it does not promote or contribute to the promotion, sale and/or use of tobacco products. If such promotional practices begin, the company will be placed on an "unacceptable for support" list.
- (5) Accordingly, it is the policy of our AMA (a) not to invest in tobacco stocks or accept financial support from the tobacco industry; (b) to urge medical schools and their parent universities to eliminate their investments in corporations that produce or promote the use of tobacco and discourage them from accepting research funding from the tobacco industry; (c) to likewise urge all scientific publications to decline such funded research for publication; and (d) to encourage state and county medical societies and members to divest of any and all tobacco stocks.
- (6) Our AMA (a) encourages state and local medical societies to determine whether candidates for federal, state and local offices accept gifts or contributions of any kind from the tobacco industry, and publicize their findings to both their members and the public; and (b) urges state and county medical societies and local health professionals along with their allies to support efforts to strengthen state and local laws that require public disclosure of direct and indirect expenditures to influence legislation or ordinances, given recent allegations about tobacco industry strategies.

Citation: (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

Resolution: 917

(I-19)

Introduced by: Medical Student Section

Subject: Supporting Research into the Therapeutic Potential of Psychedelics

Referred to: Reference Committee K

Whereas, There is a complex cultural and political history regarding psychedelic drugs, which include, among others, mescaline, lysergic acid diethylamide (LSD), psilocybin, and NN-dimethyltryptamine (DMT); and

Whereas, The first legislative limitation of psychedelic use occurred through amendments to the Federal Food, Drug and Cosmetic Act in 1965; and

Whereas, Following this, the Controlled Substances Act (CSA) of 1970 was passed, which places "all substances which were in some manner regulated under existing federal law into one of five schedules" and

Whereas, Congress established Schedule I for drugs with (1) a high potential for abuse, (2) no accepted medical use in treatment in the United States, and (3) a lack of accepted safety for use under medical supervision¹⁰; and

Whereas, The major factor distinguishing substances in Schedule I from the others is established and accepted medical use in treatment in the United States⁶; and

Whereas, There is a D.C. Circuit Court precedent stating that a substance or drug with "no currently accepted medical use" should not automatically be placed into Schedule I⁹; and

Whereas, Despite finding in this court ruling, no changes were made as the ruling was filed in dicta, in other words, as an opinion from an authoritative body and not binding, exemplifying the power the Drug Enforcement Agency (DEA) holds over scheduling of substances and an explanation as to why and how the DEA has refused rescheduling of certain substances⁶; and

 Whereas, It is argued that scheduling criteria that cannot be consistently followed and that is open to interpretation is fundamentally flawed, making the scheduling of substances by a political law enforcement agency at odds with those that want to study substances for their medical or scientific benefit⁶: and

Whereas, Upon close look at the socio-political environment in the United States at the time of passing the Controlled Substances Act, there is concern over the intention of the law and the consequences that result in limiting the study of psychotropics for medical and scientific purposes; and

Whereas, There is a large amount of evidence that psychedelics exhibit promise as therapeutics for a number of disorders including mood disorders, substance use disorders and headaches, among others; and

Resolution: 917 (I-19) Page 2 of 4

Whereas, One such study of more than 900 marginalized women who were at an increased risk of suicide, showed that subjects who used psychedelic drugs were at no significant hazard for suicidal ideation or attempt, while subjects with regular opioid use were at a three times great risk of suicidal ideation¹; and

Whereas, A systematic review of published clinical treatment studies using psychedelics showed that unipolar mood disorders, the current treatment for which is often suboptimal, can be improved by the psychedelic drugs lysergic acid diethylamide and psilocybin; and

Whereas, Other studies have shown, for example, that long-term ayahuasca use improves a subject's positive percept of health and correlates with health lifestyles, increased personal values, and reduced prescription drug use¹¹; and

Whereas, Both psilocybin and ayahuasca may be effective in treating treatment-resistant depression^{13,14}; and

Whereas, Ketamine psychedelic therapy may help with alcohol use disorder treatment⁷; and

Whereas, Cluster headaches may be effectively treated by both psilocybin and LSD¹⁸; and

Whereas, There is evidence that "micro-dosing" of psychedelics led to improved physical functions of connection, contemplation, focus, happiness, productivity and wellness¹⁵; and

Whereas, It should be noted that the preliminary results surrounding the therapeutic uses of psychedelics are promising, however, the studies done so far have had a limited number of subjects and have not been conducted over long enough time periods to firmly conclude the benefits of these substances; and

Whereas, Major concerns exist over the potential dangers associated with using these substances in research or patient treatment; and

Whereas, Symptoms of using these substances could include increased blood pressure, heart rate, body temperature, pupil size, cortisol, prolactin, oxytocin and epinephrine¹⁷; and

Whereas, Under current legal and procedural regulations, it is difficult to register to study psychedelic substances through the Drug Enforcement Agency (DEA); and

Whereas, Researchers must submit research protocols to conduct research on Schedule I drugs, and in this manner the DEA continues to be the authority on whether a substance maintains its classification and whether the researchers are allowed to conduct the studies outlined in their protocol pursuant to meeting certain criteria; and

Whereas, As the system currently stands, we are caught in an impasse even though investigators have published evidence to suggest that psychedelics are substances with (1) low potential for abuse, (2) measurable medical use in treatment in the United States, and (3) proven safety while used in clinical trials under medical supervision; therefore be it

RESOLVED, That our American Medical Association call for the status of psychedelics as Schedule I substances be reclassified into a lower schedule class with the goal of facilitating clinical research and developing psychedelic-based medicines (Directive to Take Action); and be it further

Resolution: 917 (I-19)

Page 3 of 4

- 1 RESOLVED, That our AMA explicitly support and promote research into the therapeutic
- 2 potential of psychedelics to help make a more conducive environment for research, given the
 - high regulatory and cultural barriers (Directive to Take Action); and be it further

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- 5 RESOLVED, That our AMA support and promote research to determine the benefits and
- 6 adverse effects of long-term psychedelic use. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Date Received: 10/01/19

References:

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RELEVANT AMA POLICY

FDA Recommendation on Scheduling of Hydrocodone Combination Products D-120.948Our AMA will issue a public statement to the US Food and Drug Administration urging the FDA to maintain hydrocodone combination products as Schedule III of the Controlled Substances Act.

Citation: Res. 518, A-13;

Cannabis and Cannabinoid Research H-95.952

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.

Resolution: 917 (I-19)

Page 4 of 4

2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.

- 3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
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 Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

Citation: CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19;

Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976 Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). Citation: Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13; Reaffirmation I-16;

Resolution: 918

(1-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island,

Vermont, Washington

Subject: Banning Flavors, Including Menthol and Mint, in Combustible and Electronic

Cigarettes and Other Nicotine Products

Referred to: Reference Committee K

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Whereas, In the United States, tobacco use remains the leading cause of preventable death and disease. Combustible cigarettes, when used as intended, cause the overwhelming majority of tobacco-related disease and are responsible for the death of half of all long-term users; 1 and

Whereas, Menthol cigarettes are at least as dangerous as other cigarettes; and

Whereas, Menthol includes mint, spearmint, and wintergreen; and

Whereas, There are menthol e-cigarette products, including e-cigarette products sold by the major tobacco manufacturers;² and

Whereas, The 2018 *National Youth Tobacco Survey*, a representative survey conducted of middle and high school students, showed a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students from 2017 to 2018. The total number of middle and high school students currently using e-cigarettes rose to 3.6 million,1.5 million more children than the previous year. Additionally, 27.7% of high school current e-cigarette users are using the product regularly (on 20 or more days in the past month) and 67.8% are using flavored e-cigarettes;³ and

Whereas, A state-of-the-art review article on e-cigarette use published in August 2019 by the American Academy of Pediatrics describes that "[t]here are an estimated 15,000 e-cigarette flavors, including products with labels enticing to children and adolescents that imitate cookies, whipped cream, alcoholic beverages, and other dessert flavors" and recommends "[b]an all flavored tobacco products, including mint and menthol;" and

Whereas, Menthol is associated with higher youth initiation rates and lower quit rates;^{5,6} and

¹ Food and Drug Administration. Press announcement. Nov. 15, 2018. Available online: <u>www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm</u>. Accessed Mar 15, 2019. ² Ibid

³ Food and Drug Administration. Press announcement. Nov. 15, 2018. Available online: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm. Accessed Mar 15, 2019.

⁴ Walley, S, Wilson, K, et.al. "A Public Health Crisis: Electronic Cigarettes, Vape, and JUUL." *Pediatrics* Vol 143 (6). August 2019. https://pediatrics.aappublications.org/content/143/6/e20182741

⁵ Campaign for Tobacco Free Kids; Impact of menthol cigarettes on youth smoking initiation and health disparities. Available online: www.tobaccofreekids.org/assets/factsheets/0390.pdf. Accessed Mar 17, 2019.

⁶ Truth Initiative: facts, stats, and regulations. Available online: https://truthinitiative.org/news/menthol-facts-stats-and-regulations. Accessed Mar 17, 2019.

Resolution: 918 (I-19) Page 2 of 6

Whereas, The United States Food and Drug Administration (FDA) materials state "Menthol is a flavor additive with a minty taste and aroma that is widely used in consumer and medicinal products due to its reported cooling or painkilling properties. When used in cigarettes, menthol may reduce the irritation and harshness of smoking. However, research suggests menthol cigarettes may be harder to quit than non-menthol cigarettes, particularly among African American smokers. Menthol is also used in other tobacco products, such as cigars, hookah (waterpipe) tobacco, smokeless tobacco (dip, chew, snuff, and snus), and e-cigarettes and other electronic nicotine delivery systems (ENDS)":8

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Whereas, The FDA states that "In the United States:

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- More than 19.5 million people are current smokers of menthol cigarettes.
- 85.8 percent of African American smokers, 46 percent of Hispanic smokers, 39 percent of Asian smokers, and 28.7 percent of White smokers smoke menthol cigarettes.
- Youth who smoke are more likely to smoke menthol cigarettes than older smokers.
- More than half of smokers ages 12–17 smoke menthols.";9 and

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Whereas, Tobacco company marketing has targeted by race, with a focus on the black community for decades, which appears to have caused higher smoking rates of menthol tobacco products in the black community;¹⁰ and

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Whereas, The NAACP passed a resolution in 2016 that supports restrictions on menthol sales;¹¹ and

232425

Whereas, Tobacco companies also focus marketing on the lesbian, gay, bisexual, transgender, and queer/questioning community: and

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Whereas, In 2009, tobacco companies successfully lobbied to have menthol excluded from the Family Smoking Prevention and Tobacco Control Act which bans flavor cigarettes;¹³ and

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Whereas, The U.S. First and Second Circuit Courts have ruled that the Food and Drug Administration has broad preemption language to allow for state and local regulation of flavors;¹⁴ and

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⁷ Ibid

⁸ Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS). U.S. Food and Drug Administration Website. www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm. Updated March 13, 2019. Accessed March 17, 2019.

⁹ Menthol and other flavors in tobacco products. U.S. Food and Drug Administration Website. <u>www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm2019416.htm#reference</u>. Updated March 13, 2019. Accessed March 18, 2019.

¹⁰ Ibid

NCAAP delegates endorse push to say no to menthols. Truth Initiative Website. https://truthinitiative.org/news/naacp-delegates-endorse-push-say-no-menthols. Published July 21, 2016. Accessed March 18, 2019.
 BIG TOBACCO TARGETS LGBT COMMUNITY WITH MENTHOL CIGARETTES AND PREDATORY ADVERTISING. THINK

PROGRESS WEBSITE. https://thinkprogress.org/blg-tobacco-targets-lgbt-community-with-menthol-clgarettes-and-predatory-advertising-18059e4e1cde/. PUBLISHED MAY 12, 2011. ACCESSED MARCH 16, 2019.

13 Public Law 111-31 Congress (2009-2010) Family smoking prevention and tobacco control and federal retirement reform. Congress Website. https://www.congress.gov/bill/111th-congress/house-bill/1256/text?overview=closed. Published June 22, 2009. Accessed March 18. 2019.

¹⁴ Preemption: The biggest challenge to tobacco control. Tobacco Control Legal Consortium Website. https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-preemption-tobacco-control-challenge-2014.pdf.Published
October 2014. Accessed March 17, 2019.

Resolution: 918 (I-19) Page 3 of 6

Whereas, According to the Campaign for Tobacco Free Kids, at least two states and over 200 localities have passed restrictions on the sale of flavored tobacco products, some of which include restrictions on sales of menthol cigarettes;¹⁵ and

Whereas, Last year the FDA issued an advance notice of proposed rulemaking (ANPRM) and called upon all stakeholders to share data, research, and information to inform their process for examining the role that flavors--including menthol--play in initiation, use, and cessation of tobacco products, but fell short of recommending banning all flavors in electronic cigarettes; 16 and

Whereas, According to draft guidance issued in March 2019, the FDA expects manufacturers of all flavored ENDS products (other than tobacco-, mint-, and menthol-flavored) that remain on the market under these new conditions to submit premarket applications to the agency by Aug. 8, 2021;¹⁷ and

Whereas, A genetic variant found only in people of African descent significantly increases a smoker's preference for cigarettes containing menthol, an FDA and NIH-funded study found. The variant of the specific gene is five to eight times more frequent among smokers who use menthol cigarettes than other smokers;¹⁸ and

Whereas, The American Academy of Pediatrics policy statement dated February 2019 recommends that the FDA "Ban all characterizing flavors, including menthol, in e-cigarettes; ¹⁹ and

 Whereas, Our AMA has consistent policy advocating FDA regulation of tobacco products (FDA Regulation of Tobacco Products, H-495.988) and policy that "recognizes the use of e-cigarettes and vaping as an urgent public health epidemic" and "will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices "(Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes, H-495.986); and

Whereas, Our AMA's policy on FDA Regulatory Jurisdiction over tobacco products (FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products, H-495.973) and Opposition to Addition of Flavors to Tobacco Products (H-495.971) lack sufficient breadth, specificity and urgency to accomplish the goal of removing all flavors from all tobacco products, including ENDS immediately; therefore be it

¹⁵ States and localities that have restricted the sale of flavored tobacco products. Campaign for Tobacco Free Kids, August 14, 2019. https://www.tobaccofreekids.org/assets/factsheets/0398.pdf.

¹⁶ Regulation of flavors in tobacco products. Federal Register. The Daily Journal of the United States Government Website. https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products. Published March 15, 2018. Accessed March 17, 2019.

 $^{^{\}rm 17}$ MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS. US FOOD AND DRUG ADMINISTRATION WEBSITE.

<u>WWW.FDA.GOV/TOBACCOPRODUCTS/LABELING/RULESREGULATIONSGUIDANCE/UCM633280.HTM</u>. PUBLISHED MARCH 2019. ACCESSED MARCH 17, 2019.

¹⁸ Kozlitina et al, "An African-specific haplotype in *MRGPRX4* is associated with menthol cigarette smoking." *PLOS Genetics*. February 15, 2019 https://doi.org/10.1371/journal.pgen.1007916. Accessed March 16, 2019.

¹⁹ Jennsen and Walley, "E-Cigarettes and Similar Devices." *Pediatrics* Vol143(2). February 2019. https://doi.org/10.1542/peds.2018-3652.

Resolution: 918 (I-19)

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RESOLVED, That our American Medical Association amend Policy H-495.971, "Opposition to Addition of Flavors to Tobacco Products," by addition as follows:

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Our AMA: (1) supports state and local legislation to prohibit the sale or distribution of <u>all</u> flavored tobacco products, <u>including menthol</u>, <u>mint and wintergreen flavors</u>; (2) urges local and state medical societies and federation members to support state and local legislation to prohibit the sale or distribution of <u>all</u> flavored tobacco products; and (3) encourages the FDA to prohibit the use of <u>all</u> flavoring agents in tobacco products, which includes electronic nicotine delivery systems <u>as well as combustible cigarettes</u>, <u>cigars and smokeless tobacco</u>. (Modify Current HOD Policy); and be it further

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RESOLVED, That our AMA amend Policy H-495.976, "Opposition to Exempting the Addition of Menthol to Cigarettes," by addition and deletion as follows:

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Our AMA: (1) will continue to support a ban on the use and marketing of menthol in cigarettes all tobacco products as a harmful additive; and (2) encourages and will assist its members to seek state bans on the sale of menthol cigarettes, electronic nicotine delivery devices and other tobacco products. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/02/19

RELEVANT AMA POLICY

Opposition to Addition of Flavors to Tobacco Products H-495.971

Our AMA: (1) supports state and local legislation to prohibit the sale or distribution of flavored tobacco products; (2) urges local and state medical societies and federation members to support state and local legislation to prohibit the sale or distribution of flavored tobacco products; and (3) encourages the FDA to prohibit the use of flavoring agents in tobacco products, which includes electronic nicotine delivery systems.

Citation: CSAPH Rep. 01, A-18; Modified: Res. 916, I-18;

Opposition to Exempting the Addition of Menthol to Cigarettes H-495.976

Our AMA: (1) will continue to support a ban on the use and marketing of menthol in cigarettes as a harmful additive; and (2) encourages and will assist its members to seek state bans on the sale of menthol cigarettes.

Citation: BOT Action in response to referred for decision Res. 436, A-08; Modified: CSAPH Rep. 01, A-18;

FDA Regulation of Tobacco Products H-495.988

1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges

Resolution: 918 (I-19) Page 5 of 6

Congress to pass legislation to phase in the production of reduced nicotine content tobacco products and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state

delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco

- 2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.
- 3. Our AMA: (A) will continue to monitor the FDA's progress towards establishing a low nicotine product standard for tobacco products and will submit comments on the proposed rule that are in line with the current scientific evidence and (B) recognizes that rigorous and comprehensive post-market surveillance and product testing to monitor for unintended tobacco use patterns will be critical to the success of a nicotine reduction policy.

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19;

Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution Our AMA:

products.

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors:
- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and

Resolution: 918 (I-19)

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(9) opposes the sale of tobacco at any facility where health services are provided; and (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18;

FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products H-495.973

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of 21; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth; and (3) urges federal officials, including but not limited to the U.S. Food and Drug Administration to: (a) prohibit the sale of any e-cigarette cartridges and e-liquid refills that do not include a complete list of ingredients on its packaging, in the order of prevalence (similar to food labeling); and (b) require that an accurate nicotine content of e-cigarettes, e-cigarette cartridges, and e-liquid refills be prominently displayed on the product alongside a warning of the addictive quality of nicotine.

Citation: Res. 206, I-13; Modified in lieu of Res. 511, A-14; Modified in lieu of Res. 518, A-14; Modified in lieu of Res. 519, A-14; Modified in lieu of Res. 521, A-14; Modified: CSAPH Rep. 2, I-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 412, A-15; Reaffirmed in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Reaffirmation A-16; Appended: Res. 429, A-18; Modified: CSAPH Rep. 05, A-18;

Resolution: 919

(I-19)

Introduced by: American Thoracic Society

Subject: Raising Awareness of the Health Impact of Cannabis

Referred to: Reference Committee K

Whereas, As of October 2019, there are 11 states and the District of Columbia that have legalized recreational cannabis to some degree, and 33 states that allow legal cannabis use in medical or other limited circumstances; and

Whereas, Cannabis carries approximately a 10% rate of addiction, or 1 in 6 for users under 18, and that cannabis is the primary substance use disorder in 13% of addiction treatment center admissions nationally; i,ii and

Whereas, The medical concerns of cannabis use during adolescence and young adulthood (CW3) include long-term changes to brain development including (1) tetrahydrocannabinol (THC) exposure producing long-term deficits in associative learning and sensorimotor functioning (MB1) (2) cannabis exposure disrupting synaptic and white matter thus leading to adverse emotional and cognitive outcomes (MB2) (3) changes to hippocampal structure as a result of heavy cannabis use which can persist into adulthood (MB3,MB4); and

Whereas, Children and adolescents in states with more liberal marijuana policies are at increased risk for accidental cannabis ingestion and intoxication and need for urgent medical attention (WP1); and

Whereas, Inhaled cannabis is a known threat to respiratory health as (1) inhalation can lead to lung tissue scarring and small vessels damage (2) cannabis smoke contains many of the same toxins, irritants, and carcinogens as tobacco smoke (3) inhaled cannabis can lead to bronchitis, cough, and phlegm production (4) there is a demonstrated risk of acute lung injury, such as seen in the 2019 nationwide outbreak of hundreds of cases of acute lung injury and respiratory failure linked to THC oil inhalation; and

Whereas, Inhaled cannabis has been associated in a small body of research with chronic toxicity and may lead to cancer or chronic lung injury (CW4); and

Whereas, Cannabis use has been negatively associated with mental health including (1) risk of paranoia, anxiety, and disorientation in high use (2) a risk of temporary psychosis (3) increased risk of schizophrenia and (4) worsening comorbid psychosis by increasing relapse rates and worsening psychotic symptoms (CW5); and

Whereas, Synthetic cannabinoids are created to have a stronger binding affinity than natural THC and can be mixed with other agents, and have been linked to acute toxicity and death, including increased death rates in 2014-2015 and toxicity when contaminated with poison in a 2018 outbreak; and

Resolution: 919 (I-19)

Page 2 of 4

Whereas, Public health concerns from cannabis include but are not limited to driving or operating machinery under the influence of cannabis leading to vehicle accidents and trauma (CW1), accidental ingestions of cannabis by adults or children leading to toxicity (CW2); and

Whereas, According to a 2017 report from The Institute of Medicine, "There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research" (CW6) and

Whereas, Current clinical information available to the medical community about the effects of cannabis is constrained by the limited body of scientific evidence available; and

Whereas, Current reference materials available to the medical community are limited in respect to distinguishing the varieties of cannabis products and drug delivery devices and routes, and the corresponding dosage of cannabinoids in the various products; and

Whereas, Although there is an urgent need for counseling and treatment of cannabis use or overuse, there are few current resources for counseling patients or developing treatment plans; and

Whereas, The word "cannabis" refers to plants within the genus Cannabis, including *Cannabis* sativa, Cannabis indica, and Cannabis ruderalis, but hundreds of alternative and vernacular names such as "marijuana" exist, potentially leading to confusion or misinformation among medical professionals and the public; and

Whereas, The natural cannabinoid chemical derivatives of cannabis, such as THC oil, are also referred to by an extensive and evolving list of names and acronyms, some of which overlap with nomenclature for synthetic cannabinoids, thus leading to confusion or misinformation; therefore be it

RESOLVED, That our American Medical Association coordinate with other health organizations to develop medical resources on the known and anticipated impact of cannabis on human health and on methods for counseling and educating patients who use cannabis and cannabinoids (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for stronger public health messaging on the negative effects of cannabis and cannabinoid inhalation and ingestion (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for urgent regulatory changes necessary to fund and perform research related to cannabis and cannabinoids (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for minimum purchasing age for cannabis products of at least 21 years old (Directive to Take Action); and be it further

 RESOLVED, That our AMA continue to use the term "cannabis" in our policies when referencing cannabis plants, and "cannabis derivatives" or "cannabinoids" when referencing their natural chemical derivatives, but will include the term "marijuana" in physician and public education messaging and materials to improve health literacy (Directive to Take Action); and be it further

Resolution: 919 (I-19) Page 3 of 4

RESOLVED, That our AMA amend policy H-95.924, "Cannabis Legalization for Recreational Use." by addition and deletion to read as follows:

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Cannabis Legalization for Recreational Use H-95.924

Our AMA: (1) believes warns that cannabis and cannabinoids can be a threat to health when inhaled or ingested; (2) advocates that cannabis and cannabinoids are is a dangerous drug and as such is a serious public health concern; (23) believes that warns against the legalized use and sale of cannabis and cannabinoids for recreational use should not be legalized purposes, due to their negative impact on human health; (34) discourages warns against cannabis and cannabinoid use for recreational purposes, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, children and young adults, pregnant women, and women who are breastfeeding; (45) believes strongly advocates that states that have already legalized cannabis (for medical or recreational use or both) should be required to take steps to regulate the product cannabis and cannabinoids effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (56) strongly encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis and cannabinoid use; and (67) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis or cannabinoids for personal use. (Modify Current HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/04/19

References:

CW1. Boggs, D., Cortes-Briones, J., Surti, T., Luddy, C., Ranganathan, M., Cahill, J., Sewell, A., D'Souza, D., Skosnik, P. (2018). The dose-dependent psychomotor effects of intravenous delta-9-tetrahydrocannabinol (Δ9-THC) in humans Journal of Psychopharmacology 32(12), 1308-1318. https://dx.doi.org/10.1177/0269881118799953

CW2. Wang, G., Lait, M., Deakyne, S., Bronstein, A., Bajaj, L., Roosevelt, G. (2016). Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015 JAMA Pediatrics 170(9), e160971-e160971. https://dx.doi.org/10.1001/jamapediatrics.2016.0971
CW3. Nader, D., Sanchez, Z. (2017). Effects of regular cannabis use on neurocognition, brain structure, and function: a systematic review of findings in adults The American Journal of Drug and Alcohol Abuse https://dx.doi.org/10.1080/00952990.2017.1306746
CW4. Gates, P., Jaffe, A., Copeland, J. (2014). Cannabis smoking and respiratory health: Consideration of the literature Respirology 19(5), 655-662. https://dx.doi.org/10.1111/resp.12298

CW5. Schoeler, T., Monk, A., Sami, M., Klamerus, E., Foglia, E., Brown, R., Camuri, G., Altamura, A., Murray, R., Bhattacharyya, S. (2016). Continued versus discontinued cannabis use in patients with psychosis: a systematic review and meta-analysis The Lancet Psychiatry 3(3), 215-225. https://dx.doi.org/10.1016/s2215-0366(15)00363-6

CW6. Agenda, C., Practice, B., Division, H., Medicine, N. (2017). The Health Effects of Cannabis and Cannabinoidshttps://dx.doi.org/10.17226/24625

WP1. Wang GS, Roosevelt G, Le lait MC, et al. Association of unintentional pediatric exposures with decriminalization of marijuana in the United States. Ann Emerg Med. 2014;63(6):684-9.

MB1: Abela AR, Rahbarnia A, Wood S, Lê AD, Fletcher PJ. Adolescent exposure to Δ9-tetrahydrocannabinol delays acquisition of paired-associates learning in adulthood. Psychopharmacology (Berl). 2019;236(6):1875-1886.

MB2: Dan I. Lubman, Ali Cheetham, Murat Yücel. Cannabis and adolescent brain development. Pharmacology & Therapeutics 2015;148,1-16.

MB3: Burggren AC, Shirazi A, Ginder N, London ED. Cannabis effects on brain structure, function, and cognition: considerations for medical uses of cannabis and its derivatives. Am J Drug Alcohol Abuse 2019;31:1-17.

MB4: Burggren AC, Siddarth P, Mahmood Z, London ED, Harrison TM, Merrill DA, Small GW, Bookheimer SY. Subregional hippocampal thickness abnormalities in older adults with a history of heavy cannabis use. Cannabis Cannabinoid Res. 2018;3:242–51.

Resolution: 919 (I-19)

Page 4 of 4

RELEVANT AMA POLICY

Cannabis Legalization for Recreational Use H-95.924

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for recreational use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or recreational use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (5) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis use; and (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. CSAPH Rep. 05, I-17

Cannabis and Cannabinoid Research H-95.952

- 1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
- 2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
- 3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
- 4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
- 5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

Citation: CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19

ⁱ Centers for Disease Control and Prevention. "Marijuana: How Can It Affect Your Health?" Accessed October 4, 2019. https://www.cdc.gov/marijuana/health-effects.html

ⁱⁱ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2017. Admissions to and Discharges from Publicly-Funded Substance Use Treatment. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.

Resolution: 920

(I-19)

Introduced by: American Association of Public Health Physicians

Subject: Maintaining Public Focus on Leading Causes of Nicotine-Related Death

Referred to: Reference Committee K

Whereas, Our AMA is dedicated to the protection of the public's health; and

Whereas, The protection of the public's health always requires due consideration of quantitative risks, and often requires comparison of competing risks as well; and

Whereas, Direct and indirect exposure to combustible cigarette smoke continues to cause approximately 480,000 deaths each year in the USA, and that number has not decreased significantly for many years¹; and

Whereas, As of early October 2019, the U.S. outbreak of "vaping-associated pulmonary illness" has risen to approximately 1,080 cases and 19 deaths have been attributed to this outbreak so far²; and

Whereas, Americans' rates of combustible cigarette smoking have dropped at an accelerated rate since 2010, since electronic nicotine delivery systems (ENDS) became widely available in the U.S. market^{3,4}; and

Whereas, A 2013 Gallup survey of former smokers in the USA, with no attempt to weight the sample by year of quitting, showed that 3% of former smokers in the USA stated that electronic cigarettes were the primary stop-smoking method associated with their successful quitting of combustible cigarettes⁵, and no updates of these data since 2013 are available; and

Whereas, The only large randomized controlled trial of e-cigarettes as a smoking cessation aid was done in Britain, and it showed that British e-cigarettes (used in context of British stopsmoking counseling and cultural context) had stop-smoking results that were clearly superior to those of pharmaceutical nicotine replacement products^{6,7}; and

Whereas, There is spirited debate on the real-world effects of e-cigarettes on smoking cessation in the USA⁸; and

Whereas, Public Health England's 2019 update notes that 4.1% of quit attempts assisted by the National Health Service involve the use of electronic cigarettes, and notes on page 95 that, "In every region, quit rates involving the use of an EC were higher than any other type of pharmacotherapy used"⁹; and

Whereas, On August 30, 2019, the U.S. Centers for Disease Control and Prevention (CDC) issued public guidance discouraging use of all ENDS products, regardless of prior nicotine dependence or the purpose of the individual's ENDS use¹⁰; and

Resolution: 920 (I-19) Page 2 of 2

Whereas, Our AMA's public statements during September 2019 basically copied CDC guidance that everyone should stop all use of ENDS products, also regardless of prior nicotine dependence or the purpose of the individual's ENDS use^{11,12}; and

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Whereas, In late September 2019, CDC modified their guidance to state that, "Adults who use e-cigarettes because they have quit smoking should not return to smoking combustible cigarettes." 13. However, because this aspect of the CDC recommendation was buried in page three of a five-page report, it seems to have received very little attention in mainstream media or in public consciousness; and

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Whereas, In early October 2019, the Atlantic published an analysis by James Hamblin MD noting that the news value of a small number of VAPI-associated deaths is far higher than the news value of a huge number of smoking-associated deaths, reminding us that those trying to save lives by stopping smoking must stay vigilant that this part of our message is not drowned out by other messages¹⁴: and

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Whereas, In early October 2018, a highly respected tobacco industry analyst (who is compensated for the accuracy of her predictions, not for raising the value of any industry stock), cautiously predicted, "While still too early to call, we believe further negative news and an FDA-mandated removal of non-tobacco e-cigarette flavors from the market could result in improved combustible cigarette volumes as vapers potentially return to the cigarette category." ¹⁵; and

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Whereas, A significant increase in the number of Americans smoking combustible cigarettes, regardless of the cause of this increase, would result in a public health catastrophe; therefore be it

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RESOLVED, That in public statements on nicotine issues, and in discussions with government officials, our AMA seek every reasonable opportunity to remind the American public about: (1) the massive ongoing death toll from combustible cigarettes; (2) the large and solidly demonstrated death toll from environmental tobacco smoke; and (3) the ongoing need for every smoker to find the best possible way to achieve and maintain abstinence from combustible cigarettes. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received:

¹ https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm, accessed September 20, 2019.

https://www.nytimes.com/2019/10/03/health/vaping-illnesses-cdc.html, accessed October 4, 2019.

³ https://www.cnbc.com/2018/11/08/cdc-says-smoking-rates-fall-to-record-low-in-us.html, accessed October 4, 2019.

⁴ http://tobaccoanalysis.blogspot.com/2019/09/e-cigarettes-are-gateway-to-smoking-so.html, accessed September 12, 2019.

⁵ https://news.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx, accessed October 4, 2019.

⁶ https://www.nejm.org/doi/10.1056/NEJMoa1808779, accessed October 4, 2019.

⁷ https://www.health.harvard.edu/blog/can-vaping-help-you-quit-smoking-2019022716086, accessed October 4, 2019.

https://www.cnn.com/2019/07/15/health/e-cigarettes-quit-smoking-study/index.html, accessed October 4, 2019.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/821179/Vaping_in_England_an_evidence_update_February_2019.pdf, accessed October 7, 2019.

¹⁰ https://emergency.cdc.gov/han/han00421.asp?deliveryName=DM8038, accessed October 4, 2019.

¹¹ https://www.ama-assn.org/press-center/ama-statements/ama-urges-public-avoid-e-cigarette-use-amid-lung-illness-outbreak, accessed September 9, 2019.

¹² https://www.npr.org/2019/09/12/760077445/trump-calls-for-ban-on-non-tobacco-flavored-vaping-products, accessed September 16, 2019.

¹³ https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6839e1-h.pdf?deliveryName=USCDC_921-DM9775, accessed September 27, 2019

¹⁴ https://www.theatlantic.com/health/archive/2019/10/how-dangerous-vaping/599209/, accessed October 2, 2019.

¹⁵ https://www.journalnow.com/business/e-cigarette-sales-begin-to-cool-as-public-health-warnings/article_3eb0c42e-2e70-5bbe-84ae-7e2835c7ebea.html, accessed October 3, 2019.

Resolution: 921

(I-19)

Introduced by: Thomas J. Madejski, MD, Delegate

Subject: Vaping in New York State and Nationally

Referred to: Reference Committee K

Whereas, Recent reports of lung illness associated with the use of vaporization devices have killed or injured multiple people in New York and throughout the nation; and

Whereas, The addiction industry, which includes tobacco, alcohol and now marijuana companies, has been allowed to sell products for human consumption without rigorous study on long term positive and negative effects and patient safety by subverting the FDA approval process; and

Whereas, In the context of a crisis of youth vaping and addiction to nicotine and other substances driven by the addiction industry; and

Whereas, Vaporization delivery device manufacturers such as JUUL have significant ownership by tobacco companies and marijuana companies and plan to expand use of addictive products across all segments of the adult and indirectly the adolescent population despite their protestations to the same; and

Whereas, In the interest of patient safety, and with an abundance of caution, acknowledging incomplete data on the etiology of acute and chronic lung injury associated with vaporization devices and the various substances which can be vaporized, therefore be it

RESOLVED, That our American Medical Association cooperate with the Medical Society of the State of New York (MSSNY) to express our gratitude to New York Governor Andrew Cuomo and Commissioner of the Department of Health Howard Zucker, MD for their prompt action to protect patients by banning the sale of flavored e cigarettes (Directive to Take Action); and be it further

RESOLVED, That our AMA cooperate with MSSNY to express our gratitude to Governor Cuomo and Health Commissioner Zucker for their advice to consumers to avoid vaporization of medical marijuana available under the New York State medical marijuana program (Directive to Take Action); and be it further

 RESOLVED, That our AMA cooperate with MSSNY to recommend to Governor Cuomo, Commissioner Zucker, and New York State Legislators, and in conjunction with other State Medical Societies, other State Executives, Health Commissioners and Legislatures to take further action to protect consumers from exposure to vaporized products with a moratorium on dispensing of vaporized products to new certificate holders for medical marijuana until data on the long term safety of vaporized marijuana is available (Directive to Take Action); and be it

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Resolution: 921 (I-19)

Page 2 of 2

1 RESOLVED, That our AMA cooperate with MSSNY to recommend that state and federal

- representatives work to reschedule marijuana and its' component substances to Schedule II
- 2 controlled substance to reduce barriers to further study on the efficacy and harms of various

marijuana products. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/04/19

Resolution: 922

(I-19)

Introduced by: Michigan

Subject: Understanding the Effects of PFAS on Human Health

Referred to: Reference Committee K

Whereas, Perfluoroalkyl and polyfluoroalkyl chemicals (PFAS) are a group of synthetic compounds that have been used in thousands of industrial applications and consumer products worldwide and are recognized by the Centers for Disease Control and Prevention (CDC) as substances toxic to human health; and

Whereas, The Environmental Protection Agency (EPA) has found PFAS in water and soil nationwide, termed PFAS an "emerging contaminant," and set health advisory levels for two specific PFAS chemicals at 70 parts per trillion (ppt); and

Whereas, Michigan declared a state of emergency in July 2018 for Kalamazoo County for PFAS levels over 20 times higher than the EPA safety limit; and

Whereas, As of February 2019, 43 sites in Michigan detected PFAS, including PFAS levels higher than 70 ppt in six schools, and PFAS in the drinking water that serves more than two million Michigan residents; and

Whereas, The CDC Agency for Toxic Substances and Disease Registry (ATSDR) recommended in June 2018 reducing the minimum risk levels of PFAS ten-fold, from 70 ppt to 7 ppt, because of the chemicals' negative health effects; and

Whereas, PFAS bioaccumlate in human tissues and bodily fluids through contaminated foods, drinking water and consumer products, with half-life estimates ranging from 2.3 to 12 years based on the type of chemical; and

Whereas, PFAS cross the placenta barrier, are transmitted through breast milk and are consistently associated with fetal and postnatal growth and immune function in epidemiologic studies; and

Whereas, PFAS serum levels are negatively associated with vaccine antibody concentrations in adolescents, which may be a result of an inhibited initial vaccination response or a greater waning of immunity over time; and

Whereas, Many additional research studies have suggested that PFAS in humans may increase risk of hypertension and pre-eclampsia during pregnancy, increase cholesterol levels, increase risk of thyroid disease, decrease fertility, and increase risk of kidney disease; and

Whereas, While current research has been limited to a few PFAS chemicals, more than 4000 PFAS chemicals have been manufactured by humans; hundreds of these have been detected in environmental samples and there are not currently assays to detect them all; and

Resolution: 922 (I-19)

Page 2 of 3

1 Whereas, The EPA has not lowered the recommended PFAS health advisory levels since the 2 release of the aforementioned June 2018 CDC report: and

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Whereas, Despite CDC and EPA recommendations, only seven states have developed water guideline levels for PFAS, but their advisory levels range from 13 to 1000 ppt for only a few PFAS chemicals; therefore be it

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RESOLVED, That our American Medical Association advocate for continued research on the impact of perfluoroalkyl and polyfluoroalkyl chemicals on human health (Directive to Take Action); and be it further

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- 12 RESOLVED. That our AMA advocate for states to minimally follow guidelines regarding levels of perfluoroalkyl and polyfluoroalkyl chemicals recommended by the Centers for Disease Control 13 14
 - and Prevention and the Environmental Protection Agency. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Sources:

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- Technical Fact Sheet Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA). (2017). United States Environmental Protection Agency (EPA). https://www.epa.gov/sites/production/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf . Accessed February 19, 2019.
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- Liew, Z., Goudarzi, H., & Oulhote, Y. (2018). Developmental Exposures to Perfluoroalkyl Substances (PFASs): An Update of Associated Health Outcomes. Curr Environ Health Rep, 5(1), 1-19. doi:10.1007/s40572-018-0173-4. https://www.ncbi.nlm.nih.gov/pubmed/29556975. Accessed February 19, 2019.
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- Ellison, G. Blocked report drops PFAS safety level into single digits. (2018). MLive.com. https://www.mlive.com/news/index.ssf/2018/06/atsdr_pfas_toxprofiles_study.html. Accessed February 21, 2019.
- 10. Cordner, A., De La Rosa, V. Y., Schaider, L. A., Rudel, R. A., Richter, L., & Brown, P. (2019). Guideline levels for PFOA and PFOS in drinking water: the role of scientific uncertainty, risk assessment decisions, and social factors. J Expo Sci Environ Epidemiol, 29(2), 157-171. doi:10.1038/s41370-018-0099-9. https://www.nature.com/articles/s41370-018-0099-9. Accessed February 21, 2019.

Resolution: 922 (I-19)

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RELEVANT AMA POLICY

Modern Chemicals Policies H-135.942

Our AMA supports: (1) the restructuring of the Toxic Substances Control Act to serve as a vehicle to help federal and state agencies to assess efficiently the human and environmental health hazards of industrial chemicals and reduce the use of those of greatest concern; and (2) the Strategic Approach to International Chemicals (SAICM) process leading to the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that minimize adverse effects on human health and the environment. Citation: Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 5, A-11; Reaffirmation I-16; Reaffirmed in lieu of: Res. 505, A-19;

Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). Citation: Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13; Reaffirmation I-16;

Modern Chemicals Policies D-135.987

Our AMA: (1) will call upon the United States government to implement a national modern, comprehensive chemicals policy that is in line with current scientific knowledge on human and environmental health, and that requires a full evaluation of the health impacts of both newly developed and industrial chemicals now in use; and (2) encourages the training of medical students, physicians, and other health professionals about the human health effects of toxic chemical exposures.

Citation: Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmation I-16;

Safer Chemical Policies D-135.973

Our AMA will review the recommendations of the National Academies of Sciences with respect to chemical policy reform.

Citation: (Res. 415, A-14)

Resolution: 923

(1-19)

Introduced by: Michigan

Subject: Support Availability of Public Transit Systems

Referred to: Reference Committee K

Whereas, Existing American Medical Association policy states that "climate changes will create conditions that affect public health, with disproportionate impacts on vulnerable populations, including children, the elderly, and the poor" (H-135.938), and supports "maximum feasible reduction of all forms of air pollution" (H-135.998); and

Whereas, A shift from personal car use to public transport use can cause a six-fold decrease in greenhouse gas emissions; and

Whereas, The Lancet Commission on Pollution and Health has concluded that pollution can be controlled by switching to an economy that relies on public transport and discourages private car use in cities; and

Whereas, Cities whose citizens utilize their public transit networks, averaging 50 or more transit trips per year, have half the average fatalities from traffic compared to cities with an average of 20 transit trips per year; and

Whereas, A study that modeled the potential health effects of switching 40 percent of private vehicle transport to alternative transport in a 1.1-million-person metropolitan area showed that per year 508 deaths were prevented due to increased physical activity, 21 deaths were prevented by avoiding traffic fatalities, and 13 deaths were prevented due to improved air conditions; and

Whereas, The implementation of a new transit system has been shown to generate new physical activity and decrease body mass indexes among new users; and

Whereas, In addition to improving air quality and reducing negative effects on the environment, public transport can increase health care access for underserved populations and geographical areas; and

Whereas, Rural cancer patients who lack a car are often unable to access their radiation and chemotherapy treatments in neighboring towns and cities; and

Whereas, 78 percent of people with disabilities have challenges accessing transportation for health care services, and public transportation improves the quality of life and independence of young adults with disabilities; and

Whereas, Ride share programs such as Uber are not legally required to adhere to Americans With Disabilities Act guidelines, which eliminates yet another mode of transportation for people with disabilities; and

Resolution: 923 (I-19) Page 2 of 3

Whereas, Use of public transport by the elderly is associated with decreased depressive symptoms, reduced feelings of loneliness, increased contact with friends and children, and increased volunteering; therefore be it

RESOLVED, That our American Medical Association amend current policy H-135.939, "Green Initiatives and the Health Care Community," by addition and deletion as follows:

Our AMA supports: (1) responsible waste management and clean energy production policies that minimize health risks, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are nontoxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) the establishment, expansion, and continued maintenance of affordable, reliable public transportation; and (6) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities (New HOD Policy); and be it further

RESOLVED, That our AMA amend current policy H-425.993, "Health Promotion and Disease Prevention," by addition and deletion as follows:

The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; and (5) advocates that health be considered one of the goals in transportation planning and policy development including but not limited to the establishment, expansion, and continued maintenance of affordable, reliable public transportation; and (6) strongly emphasizes the important opportunity for savings in health care expenditures through prevention. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Sources:

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Resolution: 923 (I-19)

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RELEVANT AMA POLICY

Green Initiatives and the Health Care Community H-135.939

Our AMA supports: (1) responsible waste management and clean energy production policies that minimize health risks, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities.

Citation: CSAPH Rep. 1, I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 402, A-10; Reaffirmed in lieu of: Res. 504, A-16; Modified: Res. 516, A-18;

Health Promotion and Disease Prevention H-425.993

The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; and (5) strongly emphasizes the important opportunity for savings in health care expenditures through prevention.

Citation: Presidential Address, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: BOT Rep. 8, I-06; Reaffirmed: CSAPH Rep. 01, A-16;

See also:

Global Climate Change and Human Health H-135.938

AMA Position on Air Pollution H-135.998

8.11 Health Promotion and Preventive Care

11.1.4 Financial Barriers to Health Care Access

Resolution: 924

(I-19)

Introduced by: Michigan

Subject: Update Scheduled Medication Classification

Referred to: Reference Committee K

Whereas, Many of the reforms adopted through legislation and the development of guidelines have complicated the prescribing of both opioids and non-opioid scheduled medications; and

Whereas, Substances are placed in their respective controlled substance schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused; and

Whereas, Currently, the controlled substance schedules do not differentiate between opioid containing and non-opioid containing controlled substances; and

Whereas, There are options for differentiating opioids from non-opioids such as dividing each schedule into two classes (e.g., 3-O for opioids and 3-N for non-opioids); therefore be it

RESOLVED, That our American Medical Association amend current policy D-120.979, "DEA Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely, and Without Undue Threat of Prosecution," by addition as follows:

Our AMA supports ongoing constructive dialogue between the DEA and clinicians, including physicians, regarding: (1) a proper balance between the needs of patients for treatment and the needs of the government to provide oversight and regulation to minimize risks to public health and safety; and (2) potential changes to the controlled substances schedules to make it easier to differentiate opioid containing controlled substances from non-opioid controlled substances within each schedule. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/03/19

Resolution: 924 (I-19)

Page 2 of 2

RELEVANT AMA POLICY

DEA Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely, and Without Undue Threat of Prosecution D-120.979

Our AMA supports ongoing constructive dialogue between the DEA and clinicians, including physicians, regarding a proper balance between the needs of patients for treatment and the needs of the government to provide oversight and regulation to minimize risks to public health and safety.

Citation: (Res. 836, I-04; Appended: Sub. Res. 502, A-05; Modified: CSAPH Rep. 1, A-15)

Promoting Pain Relief and Preventing Abuse of Controlled Substances D-120.971 Our AMA will:

- (1) urge the Drug Enforcement Administration (DEA) to publicly restate their commitment to balance in promoting pain relief and preventing abuse of pain medications;
- (2) support an ongoing constructive dialogue among the DEA and physician groups to assist in establishing a clinical practice environment that is conducive to pain management and the relief of suffering, while minimizing risks to public health and safety from drug abuse or diversion;
- (3) strongly urge that the DEA's upcoming recitation of the pertinent legal principles relating to the dispensing of controlled substances for the treatment of pain maintain a patient-centered focus, including reaffirmation of its previous interpretation of law to permit practitioners to issue a series of prescriptions marked "do not fill" until a later date; and
- (4) strongly urge that the DEA should promulgate, in consultation with relevant medical specialty societies and patient advocacy groups, a rational and realistic set of FAQs to assist in providing education to health care practitioners and law enforcement and regulatory personnel about appropriate pain management, and measures to be taken to minimize drug abuse and diversion.

Citation: BOT Rep. 3, A-06; Reaffirmation A-13; Reaffirmed: BOT Rep. 19, A-16; Reaffirmation: A-19;

Curtailing Prescription Drug Abuse While Preserving Therapeutic Use - Recommendations for Drug Control Policy H-95.979

Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug abuse, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and abuse through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug abuse.

Citation: (BOT Rep. PP, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-15)

Resolution: 925

(I-19)

Introduced by: California

Subject: Suspending Sales of Vaping Products / Electronic Cigarettes Until FDA

Review

Referred to: Reference Committee K

Whereas, Nationwide, the number of cases of confirmed and probable vaping-associated lung illnesses has risen to 1,080 across 48 states, with 19 reported deaths, according to the Centers for Disease Control and Prevention (CDC) and therefore, the CDC has warned people to avoid vaping altogether; and

Whereas, Vaping and electronic cigarettes are also increasingly being shown to have negative health impacts including harm to cardiovascular function, addiction to nicotine, secondhand exposure to harmful chemicals, progression to use of tobacco products, and more, with adolescent use skyrocketing in recent years, even erasing more than a decade of progress in reducing youth tobacco consumption; and

Whereas, The U.S. Food and Drug Administration (FDA) recently strengthened its warning to consumers to stop using vaping products containing THC amid more than 1,000 reports of lung injuries--including some resulting in deaths--following the use of vaping products; and

Whereas, The mass marketing of vaping products has been shown in some ways to resemble long time tobacco marketing practices, including downplaying risks and targeting young people, despite restrictions on sale to youth; and

Whereas The explosion of the vaping products industry and marketing has somewhat caught health officials and researchers off-guard, with a "catch-up" scenario playing out as regulation and education lag behind the explosion in use; and

Whereas, The FDA did not gain regulatory power over e-cigarettes until 2016, so many popular brands that launched before that date, including market leader Juul, are currently available for sale despite lacking explicit FDA authorization. The agency has given manufacturers until May 2020 to retroactively apply for authorization; if at that point they cannot prove their products are "appropriate for the protection of public health," they could be removed from the market; and

Whereas, The "precautionary principle," an increasingly accepted guideline for public health and environmental policy, states that "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically; In this context the proponent of an activity,

relationships are not fully established scientifically; In this co rather than the public, should bear the burden of proof"; and

Resolution: 925 (I-19)

Page 2 of 3

Whereas, An increasing number of states (Michigan, New York, Massachusetts, Rhode Island) and municipalities (Los Angeles and San Francisco), among others, are filling a regulatory void caused by federal inaction and are banning sales of flavored tobacco and vaping products as research shows these are harmful, to health, addictive, and marketed towards youth; and

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Whereas, Officials in San Francisco and other municipalities have proposed new regulations that would prohibit the sale of any e-cigarette that has not undergone FDA review; any e-cigarette that is required to have, but has not received, FDA pre-market review could not be sold at a store or bought online and shipped to a San Francisco address until the FDA completes its review and allows the products to be sold;" and

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Whereas, This proposal is in line with both the precautionary principle and Hippocratic dictum, and is increasingly supported by research on the impacts and risks of vaping and electronic cigarettes; therefore be it

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- 16 RESOLVED, That our American Medical Association support regulations that would prohibit the
- sale of any e-cigarette or other vaping product that has not undergone U.S. Food and Drug
- 18 Administration (FDA) pre-market review until the FDA completes its review and allows the
- 19 products to be sold. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/11/19

RELEVANT AMA POLICY

Legal Action to Compel FDA to Regulate E-Cigarettes D-495.992

Our AMA will consider joining other medical organizations in an amicus brief supporting the American Academy of Pediatrics legal action to compel the U.S. Food and Drug Administration to take timely action to establish effective regulation of e-cigarettes, cigars and other nicotine tobacco products.

Citation: Res. 432, A-18

Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution Our AMA:

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and ecigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to

Resolution: 925 (I-19)

Page 3 of 3

minors;

- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and
- (9) opposes the sale of tobacco at any facility where health services are provided; and (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18

Electronic Cigarettes, Vaping, and Health H-495.972

- 1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.
- 2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.
- 3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.

Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19; Appended: Res. 428, A-19

Resolution: 927

(I-19)

Introduced by: Washington, Hawaii

Subject: Climate Change

Referred to: Reference Committee K

Whereas, Climate change could have a devastating effect on human and environmental health, including higher rates of respiratory and heat-related illness, increased prevalence of vector-borne and waterborne diseases, food and water insecurity, and malnutrition; and

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Whereas, Persons who are elderly, sick, or poor are especially vulnerable to these potential consequences; and

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Whereas, Addressing climate change could have substantial benefits to human health and avert dire environmental outcomes; and

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Whereas, Our AMA and its physicians can play a role in achieving that goal; therefore be it

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RESOLVED, That our American Medical Association acknowledge that:

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- 1. Climate change is a critical public health issue.
- 2. Potential effects of climate change on human health include higher rates of respiratory and heat-related illness, increased prevalence of vector-borne and waterborne diseases, food and water insecurity, and malnutrition. Persons who are elderly, sick, or poor are especially vulnerable to these potential consequences.
- 3. We support educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
- 4. We recognize the importance of physician involvement in policymaking at the state, national, and global level and support efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and recognize that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
- 5. We encourage physicians to adopt programs for environmental sustainability in their practices, share these concepts with their patients and their communities. and to serve as role models for promoting environmental sustainability.
- 6. We encourage physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently.
- 7. We support epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/16/19

Resolution: 927 (I-19)

Page 2 of 3

RELEVANT AMA POLICY

AMA Advocacy for Environmental Sustainability and Climate H-135.923

Our AMA (1) supports initiatives to promote environmental sustainability and other efforts to halt global climate change; (2) will incorporate principles of environmental sustainability within its business operations; and (3) supports physicians in adopting programs for environmental sustainability in their practices and help physicians to share these concepts with their patients and with their communities.

Citation: Res. 924, I-16

Global Climate Change and Human Health H-135.938 Our AMA:

- 1. Supports the findings of the Intergovernmental Panel on Climate Change's fourth assessment report and concurs with the scientific consensus that the Earth is undergoing adverse global climate change and that anthropogenic contributions are significant. These climate changes will create conditions that affect public health, with disproportionate impacts on vulnerable populations, including children, the elderly, and the poor.
- 2. Supports educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
- 3. (a) Recognizes the importance of physician involvement in policymaking at the state, national, and global level and supports efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and (b) recognizes that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
- 4. Encourages physicians to assist in educating patients and the public on environmentally sustainable practices, and to serve as role models for promoting environmental sustainability.
- 5. Encourages physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently, and that the AMA's Center for Public Health Preparedness and Disaster Response assist in this effort.
- 6. Supports epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment. Citation: CSAPH Rep. 3, I-08; Reaffirmation A-14; Reaffirmed: CSAPH Rep. 04, A-19

AMA to Protect Human Health from the Effects of Climate Change by Ending its Investments in Fossil Fuel Companies D-135.969

Our AMA, AMA Foundation, and any affiliated corporations will work in a timely, incremental, and fiscally responsible manner, to the extent allowed by their legal and fiduciary duties, to end all financial investments or relationships (divestment) with companies that generate the majority of their income from the exploration for, production of, transportation of, or sale of fossil fuels. Citation: BOT Rep. 34, A-18

Resolution: 927 (I-19)

Page 3 of 3

Stewardship of the Environment H-135.973

The AMA: (1) encourages physicians to be spokespersons for environmental stewardship, including the discussion of these issues when appropriate with patients: (2) encourages the medical community to cooperate in reducing or recycling waste; (3) encourages physicians and the rest of the medical community to dispose of its medical waste in a safe and properly prescribed manner; (4) supports enhancing the role of physicians and other scientists in environmental education; (5) endorses legislation such as the National Environmental Education Act to increase public understanding of environmental degradation and its prevention; (6) encourages research efforts at ascertaining the physiological and psychological effects of abrupt as well as chronic environmental changes; (7) encourages international exchange of information relating to environmental degradation and the adverse human health effects resulting from environmental degradation; (8) encourages and helps support physicians who participate actively in international planning and development conventions associated with improving the environment; (9) encourages educational programs for worldwide family planning and control of population growth; (10) encourages research and development programs for safer, more effective, and less expensive means of preventing unwanted pregnancy; (11) encourages programs to prevent or reduce the human and environmental health impact from global climate change and environmental degradation.(12) encourages economic development programs for all nations that will be sustainable and yet nondestructive to the environment; (13) encourages physicians and environmental scientists in the United States to continue to incorporate concerns for human health into current environmental research and public policy initiatives; (14) encourages physician educators in medical schools, residency programs, and continuing medical education sessions to devote more attention to environmental health issues; (15) will strengthen its liaison with appropriate environmental health agencies, including the National Institute of Environmental Health Sciences (NIEHS); (16) encourages expanded funding for environmental research by the federal government; and (17) encourages family planning through national and international support.

Citation: CSA Rep. G, I-89; Amended: CLRPD Rep. D, I-92; Amended: CSA Rep. 8, A-03; Reaffirmed in lieu of Res. 417, A-04; Reaffirmed in lieu of Res. 402, A-10; Reaffirmation I-16

Resolution: 928

(1-19)

Introduced by: American Society of Clinical Oncology

Subject: CBD Oil and Supplement Use in Treatment

Referred to: Reference Committee K

Whereas, Cannabidiol (CBD) oil has been rising in popularity around the country; and

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> Whereas, According to ASCO's 2018 National Cancer Opinion Survey, which tracks the U.S. public's views on cancer research and care, nearly four in ten Americans believe cancer can be cured through alternative therapies1; and

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Whereas, This news comes despite evidence that patients who use alternative therapies instead of standard cancer treatments have much higher mortality rates; and

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Whereas, The studies around CBD oil and other supplements relieving cancer symptoms or cancer treatment side effects have been mixed and unstandardized³; and

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Whereas, To date the Food and Drug Administration has not approved any CBD products to treat cancer or symptoms and side effects associated with care; and

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Whereas, The FDA has issued a warning letter to at least one company for illegally selling unapproved products containing CBD with unsubstantiated claims that the products treat cancer and other diseases or conditions4; and

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Whereas, More research is needed to evaluate not only the effectiveness of CBD oil and other supplements for cancer patients, but also the side effects and interactions with other, prescribed medications^{5,6}; and

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Whereas, According to a survey by the Arthritis Foundation, 79% of respondents are currently using CBD, have used it in the past, or are considering using it, with 87% of those who are currently using it saying it's to manage their arthritis symptoms²; and

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Whereas, The Arthritis Foundation has issued recommendations warning users of the potential risks associated with CBD and advising them to consult with their physician⁷; therefore be it

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31 RESOLVED, That our American Medical Association actively support and promote private and 32 publicly funded research to support future evidence-based policymaking on Cannabidiol (CBD) 33 products. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/17/19

Page 2 of 2

- 1 American Society of Clinical Oncology (ASCO). National Cancer Opinion Survey. 2018. https://www.asco.org/sites/new-www.asco.org/files/content-files/research-and-progress/documents/2018-NCOS-Results.pdf (Accessed September 24, 2019). 2 Arthritis Foundation. Patients Tell Us About CBD Use. 2019. http://blog.arthritis.org/news/patients-tell-us-cbd-use/ (Accessed October 8, 2019).
- 3 The University of Texas MD Anderson Cancer Center. CBD oil and cancer: 9 things to know. 2019. https://www.mdanderson.org/publications/cancerwise/cbd-oil-and-cancer--9-things-to-know.h00-159306201.html (Accessed September 24, 2019).
- 4 The Food and Drug Administration. FDA warns company marketing unapproved cannabidiol products with unsubstantiated claims to treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety. 2019. https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer?utm_campaign=072319_PR_FDA%20warns%20firm%20selling%20cannabidiol%20products%20with%20unproven%20clai

ms&utm_medium=email&utm_source=Eloqua (Accessed September 24, 2019)

- 5 Stout, S. M., & Cimino, N. M. (2014). Exogenous cannabinoids as substrates, inhibitors, and inducers of human drug metabolizing enzymes: a systematic review. Drug metabolism reviews, 46(1), 86-95.
- 6 Qian, Y., Gurley, B. J., & Markowitz, J. S. (2019). The Potential for Pharmacokinetic Interactions Between Cannabis Products and Conventional Medications. Journal of clinical psychopharmacology, 39(5), 462-471.
- 7 Arthritis Foundation. Arthritis Foundation CBD Guidance for Adults with Arthritis. 2019. https://www.arthritis.org/living-with-arthritis/pain-management/chronic-pain/arthritis-foundation-cbd-guidance-for-adults.php (Accessed October 8, 2019).

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 929

(I-19)

Introduced by: American Association of Public Health Physicians

Subject: Regulating Marketing and Distribution of Tobacco Products and Vaping-

Related Products

Referred to: Reference Committee K

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Whereas, The 2019 outbreak of "E-cigarette and Vapor Associated Pulmonary Illness" (EVAPI) has so far been almost entirely associated with the use of illicit, illegal, and/or user-modified 2 "electronic cigarette" products, especially those containing THC; and 4 Whereas, Nicotine is highly addictive; and 7

Whereas, It is important to decrease the rates of nicotine use and dependence in all age groups, especially youth; and

Whereas, It is important to decrease the morbidity and mortality from nicotine products by all appropriate means; and

Whereas, It is unclear whether prohibition of legal e-cigarette and "vaping" products would increase or decrease the use of illicit, illegal, and/or user-modified products; and

Whereas, The net effect of e-cigarette flavoring bans on adult smokers is unclear; and

Whereas, There is an urgent need to decrease the addictiveness of electronic nicotine delivery systems (ENDS); therefore be it

Resolution: 929 (I-19) Page 2 of 3

RESOLVED, That our American Medical Association support strict marketing standards to prevent all nicotine-related products from being marketed to, or attractive to, children, adolescents, and young adults, including but not limited to the following measures:

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- Banning print advertising except in adult-only publications or media (adults are >85% of audience).
- Banning advertising and/or sponsorship at stadiums, concerts, sporting or other public events that are not primarily targeted to adults.
- Banning offers of any school or college scholarships by any company selling tobacco products.
- Banning television advertising of any tobacco products, including any vapor products.
- Banning advertising, marketing and sale of tobacco products that:
 - Uses the terms "candy" or "candies" or variants in spelling, such as "kandy" or "kandeez," "bubble gum," "cotton candy," and "gummi bear", and "milkshake."
 - Uses the terms "cake" or "cakes" or variants such as "cupcake."
 - Uses packaging, trade dress or trademarks that imitate those of food or other products primarily targeted to minors such as candy, cookies, juice boxes or soft drinks.
 - Uses packaging that contains images of food products primarily targeted to minors such as juice boxes, soft drinks, soda pop, cereal, candy, or desserts.
 - Imitates a consumer product designed or intended primarily for minors
 - Uses cartoons or cartoon characters.
 - Uses images or references to superheroes.
 - Uses any likeness to images, characters, or phrases that are known to appeal primarily to minors, such as "unicorn".
 - Uses a video game, movie, video, or animated television show known to appeal primarily to minors.
- Banning advertising and marketing of tobacco products, including vapor products, that:
 - Does not accurately represent the ingredients contained in the products.
 - Uses contracted spokespeople or individuals that do not appear to be at least 25 years of age.
- Banning advertising on outdoor billboards near schools and playgrounds.
- Requiring labels to include warnings protecting youth such as "Sales to Minors Prohibited" or "Underage Sales Prohibited" and/or "Keep Out of Reach of Children".
- Requiring all advertising to be accurate and not misleading (New HOD Policy); and be it further

RESOLVED, That our AMA support the use of the most up-to-date and effective technology for verifying the age of would-be purchasers of tobacco products and vaping-related products, both online and in bricks-and-mortar retail outlets (New HOD Policy); and be it further

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RESOLVED, That our AMA oppose sales of tobacco products or vaping-related products on any third-party marketplace such as Alibaba, Amazon, eBay, et al, where the third-party marketplace does not take full responsibility for verifying age; blocking unregulated cannabis and THC products; identifying and prohibiting all counterfeit products; and forbidding packaging and other materials that allow illicit sales of any tobacco product (New HOD Policy); and be it further

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RESOLVED, That our AMA support licensing and frequent inspections of all retail outlets selling any tobacco products or vaping-related products, with loss of license for repeated violations (e.g., three violations in a three year period) (New HOD Policy); and be it further

Resolution: 929 (I-19)

Page 3 of 3

RESOLVED, That our AMA support limitations on the concentration, chemical form, and vehicle chemistry of all nicotine-related products, with special attention to the European product standards which seem to lead to much lower addictiveness than many of the ENDS products sold in the USA (New HOD Policy); and be it further

RESOLVED, That our AMA support a ban on all self-service displays of tobacco products, which would require all tobacco products and vaping-related products to be behind a counter or in a locked display and accessible only to a store employee (New HOD Policy); and be it further

RESOLVED, That our AMA support a ban on sales of all tobacco products and vaping-related products except in stores that display signage indicating that (a) "Unaccompanied Minors Are Not Allowed on Premises" or (b) "Products are Not for Sale to Minors" or (c) "Underage Sale Prohibited", and that enforce these rules consistently (New HOD Policy); and be it further

RESOLVED, That our AMA support a ban on "straw man" sellers, which would make it illegal for any person who is not a licensed tobacco product dealer or vaping-related product dealer to sell, barter for, or exchange any tobacco product or vaping-related products (New HOD Policy); and be it further

 RESOLVED, That our AMA support legislation that would discourage "straw man" distribution by prohibiting the retail sale of quantities likely intended for more than one consumer, such as the retail sale to one customer of (a) more than two electronic-cigarette or vape devices; (b) more than five standard packages of e-liquids; (c) more than 20 packs of cigarettes; or (d) similarly determined quantities of other tobacco products and/or vaping-related products. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 10/17/19

Not for consideration

Resolutions not for consideration

- 008 Improving the Health and Safety of Consensual Sex Workers
- 012* Study of Forced Organ Harvesting by China
- 601 Amending AMA Policy G-630.140, "Lodging, Meeting Venues, and Social Functions"
- 926* School Resource Officer Qualifications and Training

^{*} Contained in Handbook Addendum

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 008

(I-19)

Introduced by: Medical Student Section

Subject: Improving the Health and Safety of Consensual Sex Workers

Referred to: Reference Committee on Amendments to Constitution and Bylaws

1 Whereas, The World Health Organization, UNFPA, UNAIDS, the Global Network of Sex Work

2 Projects, Amnesty International, and Human Rights Watch all recommend decriminalization of

consensual sex work to improve access to health care for high risk populations, with the WHO

specifying that decriminalization would help reduce HIV incidence¹⁻³; and

Whereas, Sex work is currently legal in the United Kingdom, Australia, Belgium, Argentina, Denmark, Israel, the Netherlands, New Zealand, Spain, Switzerland, Singapore, and the US state of Nevada⁴⁻¹¹; and

Whereas, Legalization of sex work bestows official legal status on the practice of prostitution, allowing more regulatory control than mere decriminalization¹²; and

Whereas, Studies in Australia found statistically significant decreases in HIV and STI rates and statistically significant increases in condom use with decriminalization¹³⁻¹⁵; and

Whereas, An Australian study revealed 50% of illegal sex workers were offered more money to have sex without a condom compared to 13% of legal sex workers, and 52% of illegal sex workers had been raped by a client in the past year compared to 9% of legal sex workers¹⁶; and

Whereas, In a study on the mental health of legal and illegal sex workers, illegal sex workers were four times more likely to report mental health issues, possibly due to increased risks that come with illegal sex work such as assault and arrest¹⁶; and

Whereas, In countries where sex work is criminalized, sex workers are less likely to seek treatment if they get infected with an STI and less likely to disclose their profession to a physician leading to decreased education and testing^{17,18}; and

Whereas, Because sex work is illegal in the United States, many sex workers struggle to obtain health insurance, leading to the majority being uninsured and paying out of pocket for healthcare¹⁸; and

Whereas, A systematic review of the literature estimates that 15-20% of men in the United States have paid for sex at least once¹⁹; and

Whereas, Following the brief decriminalization of prostitution in Rhode Island in 2003, gonorrhea rates declined by 39%, not only for sex workers, but for the general population²⁰; and

Page 2 of 5

Whereas, In 2016, 33,309 people, many of whom are parents, were arrested for prostitution and commercial vices in the United States, putting their children at an increased risk for depression, anxiety, antisocial behavior, drug use, and cognitive delays^{21,22}; and

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> Whereas, A recent systematic review found lifetime prevalence of workplace-based violence among sex workers to be 45-75%, and a recent study of sex workers in Chicago who had a pimp found that over half of them had experienced violence as coercion with increasing levels of violence since original recruitment²³; and

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Whereas, A study of sex workers in New York City showed 27% had experienced violence and 17% reported sexual harassment, including rape, from police and interactions with the police are commonplace because sex work is illegal^{24,25}; and

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Whereas, The threat of potential arrest forces sex workers to move their business into sparselypopulated and poorly-patrolled areas such as rural or industrial settings, where pimps and clients can perpetrate violence with impunity26; and

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Whereas, The legalization of prostitution in the state of Nevada shows that legalization of sex work reduces violence against sex workers, violence in the community and rates of sexually transmitted diseases²⁷; and

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Whereas, In a nationwide study 12% of trans women reported earning income through sex work, with higher rates among trans women of color, and 77% of these women reported intimate partner violence, 72% reported sexual assault, and 86% reported police harassment²⁸; and

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Whereas, Legalization of sex work could allow for sex worker union formation, a measure shown to decrease income inequality, improve working conditions, and better the health of union and non-union members, as was the case with the formation of the Exotic Dancers Union in 1993²⁹⁻³¹; and

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Whereas, The 2018 Fight Online Sex Trafficking Act (FOSTA) prohibits solicitation of illegal, consensual sex work online, despite internet-vetted sex work causing lower rates of STIs, less reliance on exploitative pimps, and less violence by dangerous clients^{32,33}; and

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Whereas, A meta-analysis of 134 studies across 13 countries found that repressive policing of sex workers, their clients, and sex work venues deprioritized the safety, health, and rights of sex workers and hinders their access to due process of the law²: therefore be it

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RESOLVED, That our American Medical Association recognize the adverse health outcomes of criminalizing consensual sex work. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Date Received: 10/01/19

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RELEVANT AMA POLICY

Commercial Exploitation and Human Trafficking of Minors H-60.912

Our AMA supports the development of laws and policies that utilize a public health framework to address the commercial sexual exploitation and sex trafficking of minors by promoting care and services for victims instead of arrest and prosecution.

Citation: Res. 009, A-17

Promoting Compassionate Care and Alternatives for Individuals Who Exchange Sex for Money or Goods H-515.958

Our AMA supports efforts to offer opportunities for a safe exit from the exchange of sex for money or goods if individuals choose to do so, and supports access to compassionate care and best practices. Our American Medical Association also supports legislation for programs that provide alternatives and resources for individuals who exchange sex for money or goods, and offer alternatives for those arrested on related charges rather than penalize them through criminal conviction and incarceration.

Citation: Res. 14, A-15; Modified: Res. 003, I-17

HIV/AIDS as a Global Public Health Priority H-20.922

In view of the urgent need to curtail the transmission of HIV infection in every segment of the population, our AMA:

- (1) Strongly urges, as a public health priority, that federal agencies (in cooperation with medical and public health associations and state governments) develop and implement effective programs and strategies for the prevention and control of the HIV/AIDS epidemic;
- (2) Supports adequate public and private funding for all aspects of the HIV/AIDS epidemic, including research, education, and patient care for the full spectrum of the disease. Public and private sector prevention and care efforts should be proportionate to the best available statistics on HIV incidence and prevalence rates;
- (3) Will join national and international campaigns for the prevention of HIV disease and care of persons with this disease;
- (4) Encourages cooperative efforts between state and local health agencies, with involvement of state and local medical societies, in the planning and delivery of state and community efforts directed at HIV testing, counseling, prevention, and care;
- (5) Encourages community-centered HIV/AIDS prevention planning and programs as essential complements to less targeted media communication efforts;
- (6) In coordination with appropriate medical specialty societies, supports addressing the special issues of heterosexual HIV infection, the role of intravenous drugs and HIV infection in women, and initiatives to prevent the spread of HIV infection through the exchange of sex for money or goods:
- (7) Supports working with concerned groups to establish appropriate and uniform policies for neonates, school children, and pregnant adolescents with HIV/AIDS and AIDS-related conditions:
- (8) Supports increased availability of anti-retroviral drugs and drugs to prevent active tuberculosis infection to countries where HIV/AIDS is pandemic; and
- (9) Supports programs raising physician awareness of the benefits of early treatment of HIV and of "treatment as prevention," and the need for linkage of newly HIV-positive persons to clinical care and partner services.

Citation: CSA Rep. 4, A-03; Reaffirmed: Res. 725, I-03; Reaffirmed: Res. 907, I-08; Reaffirmation I-11; Appended: Res. 516, A-13; Reaffirmation I-13; Reaffirmed: Res. 916, I-16; Modified: Res. 003, I-17

Page 5 of 5

Our AMA supports continued funding efforts to address the global AIDS epidemic and disease prevention worldwide, without mandates determining what proportion of funding must be designated to treatment of HIV/AIDS, abstinence or be-faithful funding directives or grantee pledges of opposition to the exchange of sex for money or goods.

Citation: Res. 439; A-08; Modified: Res. 003, I-17;

Physicians Response to Victims of Human Trafficking H-65.966

1. Our AMA encourages its Member Groups and Sections, as well as the Federation of Medicine, to raise awareness about human trafficking and inform physicians about the resources available to aid them in identifying and serving victims of human trafficking. Physicians should be aware of the definition of human trafficking and of resources available to help them identify and address the needs of victims.

The US Department of State defines human trafficking as an activity in which someone obtains or holds a person in compelled service. The term covers forced labor and forced child labor, sex trafficking, including child sex trafficking, debt bondage, and child soldiers, among other forms of enslavement. Although it's difficult to know just how extensive the problem of human trafficking is, it's estimated that hundreds of thousands of individuals may be trafficked every year worldwide, the majority of whom are women and/or children.

The Polaris Project -

In addition to offering services directly to victims of trafficking through offices in Washington, DC and New Jersey and advocating for state and federal policy, the Polaris Project:

- Operates a 24-hour National Human Trafficking Hotline
- Maintains the National Human Trafficking Resource Center, which provides
- a. An assessment tool for health care professionals
- b. Online training in recognizing and responding to human trafficking in a health care context
- c. Speakers and materials for in-person training
- d. Links to local resources across the country

The Rescue & Restore Campaign -

The Department of Health and Human Services is designated under the Trafficking Victims Protection Act to assist victims of trafficking. Administered through the Office of Refugee Settlement, the Department's Rescue & Restore campaign provides tools for law enforcement personnel, social service organizations, and health care professionals.

2. Our AMA will help encourage the education of physicians about human trafficking and how to report cases of suspected human trafficking to appropriate authorities to provide a conduit to resources to address the victim's medical, legal and social needs.

Citation: (BOT Rep. 20, A-13; Appended: Res. 313, A-15)

Human Trafficking / Slavery Awareness D-170.992

Our AMA will study the awareness and effectiveness of physician education regarding the recognition and reporting of human trafficking and slavery.

Citation: Res. 015, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 012

(I-19)

Introduced by: District of Columbia

Subject: Study of Forced Organ Harvesting by China

Referred to: Reference Committee on Amendments to Constitution and Bylaws

Whereas, Our AMA's "Declaration of Professional Responsibility: Medicine's Social Contract With Humanity" (attached) adopted by this House of Delegates in December of 2001, outlines and declares that "we, the members of the world community of physicians, solemnly commit ourselves to:"; and

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Whereas, The Independent Tribunal on Forced Organ Harvesting, after thorough study and review, released its findings and conclusions on June 17th 2019 (https://chinatribunal.com); and

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Whereas, The Tribunal's findings and conclusions clearly indicate beyond reasonable doubt that China has killed and continues to kill prisoners of conscience for their organs--and that elements of genocide against Falun Gong members are clearly established; and

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Whereas, Both the Tribunal and Doctors Against Forced Organ Harvesting (DAFOH) have issued calls (http://t2m.io/ogJX931f) for further investigation and reporting on this matter; and

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Whereas, We have pledged to educate ourselves and the public "about present and future threats to the health of humanity"; therefore be it

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20 21 RESOLVED, That our American Medical Association gather and study all information available and possible on the issue of forced organ harvesting by China and issue a report to our House of Delegates at the 2020 Annual Meeting. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 10/17/19

Attachment

DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE'S SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

- 1. Respect human life and the dignity of every individual.
- 2. Refrain from supporting or committing crimes against humanity and condemn all such acts.
- 3. Treat the sick and injured with competence and compassion and without prejudice.
- 4. Apply our knowledge and skills when needed, though doing so may put us at risk.
- 5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
- 6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
- 7. Educate the public and polity about present and future threats to the health of humanity.
- 8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
- 9. Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Adopted by the House of Delegates of the American Medical Association in San Francisco, California on December 4, 2001

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 601

(I-19)

Introduced by: Medical Student Section

Subject: Amending AMA Policy G-630.140, "Lodging, Meeting Venues, and Social

Functions"

Referred to: Reference Committee F

Whereas, The seven regions of our AMA-MSS are a primary link between the national initiatives of our MSS and student members at the section level; and

Whereas, In the fall of 2018, our AMA started a pilot program hosting individual, geographicallyseparate MSS Region Meetings with the goal of strengthening Region cohesion, fostering interstudent mentorship, and enriching the student experience; and

Whereas, The pilot included geographically-separate MSS Region Meetings hosted in each individual Regions because of feedback received from 2015 to 2018, when all Region meetings were held simultaneously, in conjunction with Advocacy Day in Washington, DC; and

Whereas, During this period of time, MSS leadership and staff received reports that students had difficulty attending Region meetings due to financial constraints on travel to Washington, DC and the inflexibility of holding all Region meetings on one day; and

Whereas, Through the Region Meetings pilot program, six Regions planned and held Region Meetings between January and February 2019; and

Whereas, Region 3 was limited in organizing their Region Meeting due to AMA Policy G-630.140 Lodging, Meeting Venues, and Social Functions, which was amended at A-17 to ensure that future AMA-organized or -sponsored meetings do not take place in towns, cities, counties, or states with discriminatory policies; and

Whereas, G-630.140 with the amendment currently restricts the AMA from organizing or sponsoring meetings in Alabama, Kansas, Kentucky, Mississippi, North Carolina, Oklahoma, South Dakota, Tennessee, and Texas; and

Whereas, Based on the list of restricted states, Region 3 cannot hold Region meetings in four of their six states (Kansas, Mississippi, Oklahoma, Texas), and the two remaining states (Arkansas, Louisiana) are not centrally located; and

Whereas, Region 3 held their Region Meeting in Louisiana, and received multiple reports from students about the difficulty of attending the Region Meeting based on travel distance; and

Whereas, Based on the list of restricted states, Region 1 cannot hold meetings in South Dakota,

Region 4 cannot hold meetings in three of their six states (Alabama, North Carolina,

37 Tennessee), and Region 5 cannot hold meetings in Kentucky; and

Resolution: 601 (I-19) Page 2 of 3

Whereas, The AMA Board of Trustees in conjunction with AMA legal counsel determined that Region Meetings do not qualify for exemption from G-630.140 as a special circumstance; and

Whereas, While G-630.140 should be enforced for national meetings such as Annual and Interim to uphold the AMA's commitment to non-discrimination, enforcement for Region Meetings reduces participation in small gatherings for students who are financially and temporally limited in their ability to travel, especially in disproportionately affected Regions; therefore be it

RESOLVED, That our American Medical Association amend Policy G-630.140, "Lodging, Meeting Venues, and Social Functions," be amended by addition to read as follows:

Lodging, Meeting Venues, and Social Functions, G-630.140

- 1. Our AMA supports choosing hotels for its meetings, conferences, and conventions based on size, service, location, cost, and similar factors.
- 2. Our AMA shall attempt, when allocating meeting space, to locate the Section Assembly Meetings in the House of Delegates Meeting hotel or in a hotel in close proximity.
- 3. All meetings and conferences organized and/or primarily sponsored by our AMA will be held in a town, city, county, or state that has enacted comprehensive legislation requiring smoke-free worksites and public places (including restaurants and bars), unless intended or existing contracts or special circumstances justify an exception to this policy, and our AMA encourages state and local medical societies, national medical specialty societies, and other health organizations to adopt a similar policy.
- 4. It is the policy of our AMA not to hold <u>national</u> meetings organized and/or primarily sponsored by our AMA, in cities, counties, or states, or pay member, officer or employee dues in any club, restaurant, or other institution, that has exclusionary policies, including, but not limited to, policies based on, race, color, religion, national origin, ethnic origin, language, creed, sex, sexual orientation, gender, gender identity and gender expression, disability, or age unless intended or existing contracts or special circumstances justify an exception to this policy.
- 5. Our AMA staff will work with facilities where AMA meetings are held to designate an area for breastfeeding and breast pumping. (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 08/28/19

RELEVANT AMA POLICY

Lodging, Meeting Venues, and Social Functions G-630.140

- 1. Our AMA supports choosing hotels for its meetings, conferences, and conventions based on size, service, location, cost, and similar factors.
- 2. Our AMA shall attempt, when allocating meeting space, to locate the Section Assembly Meetings in the House of Delegates Meeting hotel or in a hotel in close proximity.
- 3. All meetings and conferences organized and/or primarily sponsored by our AMA will be held in a town, city, county, or state that has enacted comprehensive legislation requiring smoke-free worksites and public places (including restaurants and bars), unless intended or existing contracts or special circumstances justify an exception to this policy, and our AMA encourages state and local medical societies, national medical specialty societies, and other health organizations to adopt a similar policy.

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4. It is the policy of our AMA not to hold meetings organized and/or primarily sponsored by our AMA, in cities, counties, or states, or pay member, officer or employee dues in any club, restaurant, or other institution, that has exclusionary policies, including, but not limited to, policies based on, race, color, religion, national origin, ethnic origin, language, creed, sex, sexual orientation, gender, gender identity and gender expression, disability, or age unless intended or existing contracts or special circumstances justify an exception to this policy.

5. Our AMA staff will work with facilities where AMA meetings are held to designate an area for breastfeeding and breast pumping.

Citation: Res. 2, I-87 Reaffirmed: Sunset Report, I-97 Res. 512, I-98 Consolidated: CLRPD Rep. 3, I-01 Reaffirmation A-04 Modified: CCB/CLRPD Rep. 3, A-12 Modified: CCB/CLPRD Rep. 2, A-13 Modified: BOT Rep. 17, A-17

Meeting Calendar and Locations G-600.130

AMA policy on the meeting calendar for the House includes the following: (1) Our AMA should make reasonable efforts to avoid scheduling future Annual Meetings that conflict with Father's Day weekend; (2) The Interim Meeting of the House of Delegates will be held in the second or third week in November; and (3) Our AMA supports scheduling more meetings in Washington, DC, specifically including Interim Meetings of the House on a rotating schedule as frequently as practicable. Our AMA believes, however, that it would not be financially prudent to hold all Interim Meetings in Washington, DC, nor would such a decision be equitable for other regions of the country.

Citation: BOT Rep. I, I-90 BOT Rep. 36, A-94 BOT Report 1, I-98 Modified: Speakers Advisory Committee Rep., A-99 Reaffirmed: Sunset Report, I-00 Resolution 609, A-01 Consolidated: CLRPD Rep. 3, I-01 Appended: Res. 610, A-02 Appended: Res. 609, A-04 Reaffirmed in lieu of Res. 609, A-06 CC&B Rep. 3, I-08 CCB/CLRPD Rep. 3, A-12 Modified: Res. 606, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 926

(I-19)

Introduced by: Women Physicians Section

Subject: School Resource Officer Qualifications and Training

Referred to: Reference Committee K

Whereas, There has been a rash of shootings and violence in Colorado, Connecticut, Texas,
 Florida and other less well publicized school settings; and

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Whereas, Many schools throughout this country have hired school resource officers (SROs) who are paid employees; and

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Whereas, Some schools have chosen to arm these individuals without adequate training in child psychology, restorative justice, and conflict de-escalation and resolution, for example; therefore be it

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RESOLVED, That our American Medical Association encourage an evaluation of existing national standards (and legislation, if necessary) to have qualifications by virtue of training and certification that includes child psychology and development, restorative justice, conflict resolution, crime awareness, implicit/explicit biases, diversity inclusion, cultural humility, and individual and institutional safety and others deemed necessary for school resource officers (Directive to Take Action); and be it further

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RESOLVED, That our AMA encourage the development of policies that foster the best environment for learning through protecting the health and safety of those in school, including students, teachers, staff and visitors (New HOD Policy); and be it further

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RESOLVED, That our AMA encourage mandatory reporting of de-escalation procedures by school resource officers and tracking of student demographics of those reprimanded to identify areas of implicit bias. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 10/08/19

Reference:

¹ "Training Courses." National Association of School Resource Officers. Available at https://nasro.org/. Accessed September 2019.

Resolution: 926 (I-19)

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RELEVANT AMA POLICY

Providing Medical Services through School-Based Health Programs H-60.991

(1) The AMA supports further objective research into the potential benefits and problems associated with school-based health services by credible organizations in the public and private sectors. (2) Where school-based services exist, the AMA recommends that they meet the following minimum standards: (a) Health services in schools must be supervised by a physician. preferably one who is experienced in the care of children and adolescents. Additionally, a physician should be accessible to administer care on a regular basis. (b) On-site services should be provided by a professionally prepared school nurse or similarly qualified health professional. Expertise in child and adolescent development, psychosocial and behavioral problems, and emergency care is desirable. Responsibilities of this professional would include coordinating the health care of students with the student, the parents, the school and the student's personal physician and assisting with the development and presentation of health education programs in the classroom. (c) There should be a written policy to govern provision of health services in the school. Such a policy should be developed by a school health council consisting of school and community-based physicians, nurses, school faculty and administrators, parents, and (as appropriate) students, community leaders and others. Health services and curricula should be carefully designed to reflect community standards and values, while emphasizing positive health practices in the school environment. (d) Before patient services begin, policies on confidentiality should be established with the advice of expert legal advisors and the school health council. (e) Policies for ongoing monitoring, quality assurance and evaluation should be established with the advice of expert legal advisors and the school health council. (f) Health care services should be available during school hours. During other hours, an appropriate referral system should be instituted. (g) School-based health programs should draw on outside resources for care, such as private practitioners, public health and mental health clinics, and mental health and neighborhood health programs. (h) Services should be coordinated to ensure comprehensive care. Parents should be encouraged to be intimately involved in the health supervision and education of their children.

Citation: (CSA Rep. D, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: Res. 412, A-05; Reaffirmed in lieu of Res. 908, I-12)

Informational Reports

BOT Report(s)

- 04 Involvement of Women in AMA Leadership, Recognition and Research Opportunities
- 05 Restrictive Covenants of Large Health Care Systems
- 07 2019 AMA Advocacy Efforts
- 11 Re-establishment of National Guideline Clearinghouse
- 12 Distracted Driver Education and Advocacy
- 13 Hospital Closures and Physician Credentialing
- 14 Redefining AMA's Position on ACA and Healthcare Reform

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^{*} Contained in Handbook Addendum

REPORT OF THE BOARD OF TRUSTEES

B of T Report 4-I-19

Subject: Involvement of Women in AMA Leadership, Recognition and Research

Opportunities

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

PURPOSE

American Medical Association (AMA) Policy D-65.989(3), "Advancing Gender Equity in Medicine," directs our AMA to "to collect and analyze comprehensive demographic data and produce a study on the inclusion of women members including, but not limited to, membership, representation in the House of Delegates (HOD), reference committee makeup, and leadership positions within our AMA, including the Board of Trustees, councils and section governance, plenary speaker invitations, recognition awards, and grant funding. These findings will be used to provide regular reports to the HOD and make recommendations to support gender equity." This informational report responds to this directive.

BACKGROUND

 In the United States, the number of women entering medicine is steadily increasing. Women represent more than one third (35.2%) of the active physician workforce, nearly half (45.6%) of all physicians-in-training and more than half (50.7%) of all entering medical students in MD-granting medical schools. Despite the growing number of women in medicine, professional advancement among women physicians in the overall medical community continues to lag.

Professional advancement is associated with acknowledgment of one's work and contributions. Experiences, such as speaking engagements and participation in research teams, allow for recognition of achievements and contribute to professional growth. Various studies have indicated that female physicians generally do not receive major awards or recognitions at the same rate as their male counterparts and may even be excluded from certain professional opportunities (e.g., grand rounds). A 2017 study by Silver et al found that female physicians are underrepresented among recognition award recipients by various medical societies. Such differences in awareness and recognition of accomplishments may contribute to gender-based disparities in pay and promotion.

Accordingly, organizations that provide professional opportunities have a responsibility to ensure equitable participation. The AMA provides numerous opportunities for professional growth and leadership development for its members through committees, award programs and research opportunities. This informational report provides an overview of female AMA member involvement in enterprise-wide leadership, recognition and research opportunities.

METHODOLOGY

A qualitative analysis on the engagement of female AMA members in various leadership opportunities was conducted. In February 2019, the staff of the AMA sections, councils and

advisory committee was invited to participate in an electronic survey to ascertain the number of women members who held leadership positions in the AMA as of year-end 2018. In addition, this survey included questions on plenary speaker invitations, recognition awards, and grant funding. Staff representing other units of the AMA were invited to participate in the survey so that additional information on speaker invitations, recognition awards, and grants could be collected. Of note, data on reference committee composition was extrapolated from the 2018 proceedings for the Annual and Interim Meetings of the AMA HOD.

 In addition, a review of the Council on Long Range Planning and Development (CLRPD) Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership," was conducted. Delegate and alternate delegate lists, which are maintained by the AMA Office of HOD Affairs and based on year-end 2018 delegation rosters provided by medical societies represented in the HOD, served as a primary data source for CLRPD Report 1. Another data source included rosters for the AMA councils as well as the governing councils of the AMA sections and advisory committee. Data on AMA members were taken from the year-end 2018 AMA Physician Masterfile after it was considered final.

RESULTS

According to CLRPD Report 1-A-19, AMA membership was 35.7 percent female as of year-end 2018. Thirty percent of the AMA Board of Trustees members were female. The HOD was comprised of 26.4 percent female Delegates and 33.2 percent female Alternate Delegates, respectively.

In 2018, more than half (51.97%) of the leadership for the AMA sections, councils and advisory committee was female. Of note, the 2018 AMA Staff Survey on Inclusion of Female Members included the chair, vice-chair, delegate, alternate delegate, and speaker positions under leadership roles. For the AMA reference committees, the average percentage of female participants for the Annual and Interim meetings was 41.5 percent and 33 percent, respectively.

Women received 79.1 percent (n = 53) of the AMA recognition awards in 2018. These awards included the Principal Investigator Leadership Award (55%), Excellence in Medicine Awards (40%), and Inspirational Physicians Recognition Program (now known as the Inspiration Award) (88.7%). As the Inspiration Award was created by the AMA Women Physicians Section (AMA-WPS) to recognize physicians who support the professional advancement of women in medicine, the overall percentages of female awardees are skewed.

The AMA Foundation offers financial support to medical students through various scholarship programs. In 2018, the AMA Foundation awarded \$230,000 in scholarships, with 50 percent of the recipients being female.

Through programs such as the Accelerating Change in Medical Education Innovation Grant
Program and the Joan F. Giambalvo Fund for the Advancement of Women, the AMA awarded 30
grants totaling \$290,000 in 2018. Seventy percent of these grant recipients were female. In
addition, more than seventy percent (73.7%) of the principal investigators were female. It is
important to note that AMA-WPS, along with the AMA Foundation, established the Joan F.
Giambalvo Fund for the Advancement of Women to promote the progress of women in the medical
profession, and to strengthen the ability to identify and address the needs of women physicians and

49 medical students.

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The overall number of plenary speaker invitations for meetings in 2018 was not captured precisely. However, survey responses indicated that 42 speaker invitations were extended to women, with 97.6 percent (n = 41) of those invitations being accepted.

Additional results from the 2018 AMA Staff Survey on Inclusion of Female Members can be found in Appendix A of this report.

CONCLUSION

The rate of participation in AMA leadership and involvement opportunities by female members is comparable to the percentage for AMA membership, with considerable representation among the leadership of the AMA sections, councils and advisory committee. Although the AMA has made great strides in increasing the number of women leaders, there is still work to be done. For example, the current percentage of female AMA delegates is only 26.4 percent whereas AMA membership is 35.7 percent female.

Also, females are well represented among scholarship and grant recipients. These study findings demonstrate that female AMA members are actively involved in AMA professional activities. Of note, AMA membership is not a requirement for the recipients of the Joan F. Giambalvo Award for the Advancement of Women, AMA Foundation scholarships and the Inspiration Award.

As part of the AMA's commitment to advancing gender equity in medicine, trends pertaining to the involvement of women in the AMA will be monitored on a routine basis. In accordance with AMA Policy G-600.035, "The Demographics of the House of Delegates," successful initiatives and best practices to promote diversity within state and specialty society delegations, along with statistical data, will be shared through regular reports to the AMA House of Delegates. The most current update on these initiatives can be found in the "Promoting Diversity Among Delegations" section of CLRPD Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership." This portion of the CLRPD report provides a regular overview of efforts to promote diversity that have been implemented by various state and specialty societies. Examples include details on initiatives such as task forces, efforts to recruit women and minorities, and minority

32 mentorship programs.

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APPENDIX A: RESPONSES FROM 2018 AMA STAFF SURVEY ON INCLUSION OF FEMALE MEMBERS

Table 1: 2018 AMA Sections, Councils and Advisory Committee

Table 1: 2018 AMA Sections, Councils and Advisory Committee						
Committee Name	Number of	Percentage	Percentage of			
	Committee	of Female	Female Members			
	Members	Committee	Holding Committee			
		Members	Leadership			
			Positions ¹			
Academic Physicians Section	9	33%	11%			
Advisory Committee on LGBTQ Issues	7	28.6%	0%			
Integrated Physician Practice Section	8	25%	12.5%			
International Medical Graduates Section	8	25%	12.5%			
Medical Student Section	8	75%	75%			
Minority Affairs Section	9	66.7%	33%			
Organized Medical Staff Section	7	14.3%	14.3%			
Resident and Fellow Section	8	37.5%	37.5%			
Senior Physicians Section	7	28.6%	28.6%			
Women Physicians Section	8	100%	50%			
Young Physicians Section	7	85.7%	42.9%			
Council on Constitution and Bylaws	10	70%	40%			
Council on Ethical and Judicial Affairs	9	33%	11%			
Council on Legislation	12	50%	16.7%			
Council on Long Range Planning and Development	10	20%	20%			
Council on Medical Education	12	58.3%	33%			
Council on Medical Service	12	58.3%	41.7%			
Council on Science and Public Health	12	41.7%	8.3%			
OVERALL	279	51.97%	22.58%			

Table 2: AMA Reference Committees

2018 Annual Meeting Reference Committees	Female Members
Reference Committee on Amendments to Constitution and Bylaws	16.6%
Reference Committee A (Medical Service)	57.1%
Reference Committee B (Legislation)	14.3%
Reference Committee C (Medical Education)	57.1%
Reference Committee D (Public Health)	66.7%
Reference Committee E (Science and Technology)	33.3%
Reference Committee F (AMA Governance and Finance)	57.1%
Reference Committee G (Medical Practice)	28.6%

2018 Interim Meeting Reference Committees	Female Members
Reference Committee on Amendments to Constitution and Bylaws	28.6%
Reference Committee B (Legislation)	14.3%
Reference Committee C (Medical Education)	42.9%
Reference Committee F (AMA Governance and Finance)	57.1%
Reference Committee J (Advocacy related to medical service, medical	28.6%
practice, insurance and related topics)	
Reference Committee K (Advocacy related to science and public health)	28.6%

¹ For the purposes of this report, leadership positions within the AMA Sections, Councils and Advisory Committee are defined as Chair, Vice-Chair/Chair-elect, Delegate, Alternate Delegate, and Speaker.

Table 3: 2018 Recognition Awards

Award Name	Awards	Female Awardees
	Granted	
Principal Investigator Leadership Award	11	55%
Excellence in Medicine	5	40%
Inspiration Award	51	88.7%
Total	67	79.1%

Table 4: 2018 Scholarship Funding

Scholarship Name	Number of	Percentage of	Monetary
	Grants	Female	Value
	Awarded	Recipients	
AMA Alliance Grassroots (Physicians of Tomorrow	3	100%	\$30,000
Scholarship Program)			
Cady/ New York Medical Society (Physicians of	2	100%	\$20,000
Tomorrow Scholarship Program)			
Chicago (Physicians of Tomorrow Scholarship	4	25%	\$10,000
Program)			
Dr. Richard Allen Williams and Genita Evangelista	1	0%	\$0
Johnson/Association of Black Cardiologists			
Herman E. Diskin Memorial Scholarship (Physicians	1	0%	\$0
of Tomorrow Scholarship Program)			
Ohio (Physicians of Tomorrow Scholarship Program)	2	100%	\$20,000
Underrepresented in Medicine Scholarship Program	15	40%	\$150,000
Total	28	50%	\$230,000

Table 5: 2018 Grant Funding

Grant Name	Number of	Female	Monetary
	Grants	Principal	Value
	Awarded	Investigators	
Accelerating Change in Medical Education Innovation	13	61.5%	\$270,000
Grant Program			
Joan F. Giambalvo Fund for the Advancement of	2	100%	\$20,000
Women			
Total	15	73.7%	\$290,000

APPENDIX B: Excerpt from CLRPD Report 1-A-19, Demographic Characteristics of the House of Delegates and AMA Leadership

Table 1. Basic Demographic Characteristics of AMA Leadership

		Councils and				
	Delegates	Alternate		Leadership	AMA	All Physicians and
	8	Delegates		of Sections	Members	Medical Students
		Delegates	1145000	and Special	11101110015	Tyredrear Stadents
				Groups		
				~		
Count	594	401	20	170	250,253	1,341,682
Mean Age (Years)	56.4	51.1	57.0	50.4	46.0	51.0
Age distribution						
Under Age 40	14.1%	22.7%	10.0%	32.9%↑	51.5%↑	29.7%
40-49 Years	10.4%	18.7%↑	15.0%	11.2%	9.7%	18.5%
50-59 Years	22.2%	23.9%	15.0%	15.3%	9.9%	17.4%
60-69 Years	34.5%	26.2%	55.0%	24.7%↓	10.8%	16.9%
70 or More	18.7%	8.5%	5.0%	15.9%	18.1%	17.5%
Gender						
Male	73.6%	66.8%↓	70.0%	53.5%↓	64.3%	64.8%
Female	26.4%	33.2%↑	30.0%	46.5%↑	35.7%	34.7%
Unknown	0.0%	0.0%	0.0%	0.0%	0.1%	0.5%
Race/ethnicity						
White, Non-Hispanic	70.2%↓	66.6%	70.0%	59.4%	52.7%↓	51.0%
Black, Non-Hispanic	5.1%	4.0%	15.0%	7.1%	4.6%	4.2%
Hispanic	2.9%	4.7%	0.0%	6.5%	5.5%	5.5%
Asian/Asian	9.1%	13.5%	5.0%	15.3%	14.6%	15.3%
Native American	0.2%	0.0%	0.0%	0.0%	0.3%	0.3%
Other	1.5%	1.0%	0.0%	1.2%	1.4%	1.4%
Unknown	11.1%	10.2%	10.0%	10.6%	20.8%↑	22.3%
Education						
US or Canada	93.3%	90.8%	95.0%	90.0%	82.6%	77.1%
IMG	6.7%	9.2%	5.0%	10.0%	17.4%	22.9%

APPENDIX C: RELEVANT AMA POLICY

Advancing Gender Equity in Medicine D-65.989

1. Our AMA will: (a) advocate for institutional, departmental and practice policies that promote transparency in defining the criteria for initial and subsequent physician compensation; (b) advocate for pay structures based on objective, gender-neutral criteria; (c) encourage a specified approach, sufficient to identify gender disparity, to oversight of compensation models, metrics, and actual total compensation for all employed physicians; and (d) advocate for training to identify and mitigate implicit bias in compensation determination for those in positions to determine salary and bonuses, with a focus on how subtle differences in the further evaluation of physicians of different genders may impede compensation and career advancement. 2. Our AMA will recommend as immediate actions to reduce gender bias: (a) elimination of the question of prior salary information from job applications for physician recruitment in academic and private practice; (b) create an awareness campaign to inform physicians about their rights under the Lilly Ledbetter Fair Pay Act and Equal Pay Act; (c) establish educational programs to help empower all genders to negotiate equitable compensation; (d) work with relevant stakeholders to host a workshop on the role of medical societies in advancing women in medicine, with co-development and broad dissemination of a report based on workshop findings; and (e) create guidance for medical schools and health care facilities for institutional transparency of compensation, and regular gender-based pay audits. 3. Our AMA will collect and analyze comprehensive demographic data and produce a study on the inclusion of women members including, but not limited to, membership, representation in the House of Delegates, reference committee makeup, and leadership positions within our AMA, including the Board of Trustees, Councils and Section governance, plenary speaker invitations, recognition awards, and grant funding, and disseminate such findings in regular reports to the House of Delegates and making recommendations to support gender equity. 4. Our AMA will commit to pay equity across the organization by asking our Board of Trustees to undertake routine assessments of salaries within and across the organization, while making the necessary adjustments to ensure equal pay for equal work.

The Demographics of the House of Delegates G-600.035

1. A report on the demographics of our AMA House of Delegates will be issued annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty. 2. As one means of encouraging greater awareness and responsiveness to diversity, our AMA will prepare and distribute a state-by-state demographic analysis of the House of Delegates, with comparisons to the physician population and to our AMA physician membership every other year. 3. Future reports on the demographic characteristics of the House of Delegates should, whenever possible, identify and include information on successful initiatives and best practices to promote diversity within state and specialty society delegations.

Women in Organized Medicine H-525.998

Our AMA: (1) reaffirms its policy advocating equal opportunities and opposing sex discrimination in the medical profession; (2) supports the concept of increased tax benefits for working parents; (3) (a) supports the concept of proper child care for families of working parents; (b) reaffirms its position on child care facilities in or near medical centers and hospitals; (c) encourages business and industry to establish employee child care centers on or near their premises when possible; and (d) encourages local medical societies to survey physicians to determine the interest in clearinghouse activities and in child care services during medical society meetings; and (4) reaffirms its policy supporting flexibly scheduled residencies and encourages increased availability of such programs.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 5-I-19

Subject: Restrictive Covenants of Large Health Care Systems

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) adopted Policy D-383.978, "Restrictive Covenants of Large Health Care Systems," introduced by the Organized Medical Staff Section, which asked:

1. Our AMA, through its Organized Medical Staff Section will educate medical students, physicians-in-training, and physicians entering into employment contracts with large health care system employers on the dangers of aggressive restrictive covenants, including but not limited to the impact on patient choice and access to care.

2. Our AMA study the impact that restrictive covenants have across all practice settings, including but not limited to the effect on patient access to health care, the patient-physician relationship, and physician autonomy, with report back at the 2019 Interim Meeting.

Testimony noted that this is a significant issue that is rarely looked at, that physicians often are not given a choice but to sign a covenant, and that students are rarely educated on the practice before entering the workforce. Speakers also testified that the practice has negative ramifications for rural medicine, and that physicians can be limited from even volunteering to practice in retirement due to restrictive covenants.

It should be noted that during the 2019 Annual Meeting, the HOD referred Resolution 010 "Covenants not to Compete" to the AMA Board of Trustees. Resolution 010 asked our AMA to consider as the basis for model legislation the New Mexico statute allowing a requirement that liquidated damages be paid when a physician partner who is a part owner in practice is lured away by a competing hospital system. Resolution 010 also asked our AMA to ask our Council on Ethical and Judicial Affairs to reconsider their blanket opposition to covenants not to compete in the case of a physician partner who is a part owner of a practice, in light of the protection that liquidated damages can confer to independent physician owned partnerships, and because a requirement to pay liquidated damages does not preclude a physician from continuing to practice in his or her community. The AMA Board of Trustees will present the HOD with a report concerning Resolution 010 at the 2020 Annual Meeting.

DISCUSSION

Restrictive covenants, which often are included as part of a physician employment contract, typically prohibit physicians from practicing medicine within a specific geographic area and time after employment. For example, a restrictive covenant may prohibit the physician from practicing

medicine within 10 miles of the location where he or she treated patients for two years after employment has ended. With respect to geographic restrictions, physicians should be mindful that the geographic scope of a restrictive covenant can be greatly expanded if the covenant is tied to multiple locations where the employer furnishes health care services. For example, a restrictive covenant may prohibit the physician from practicing within 10 miles from *any* location where a large health care system provides patient care, regardless of whether the physician actually treated patients at a given location. If a large health care system furnishes health care services in multiple locations, the covenant could force the physician to move out of a city or even a state if he or she wanted to keep practicing medicine, which, in turn, may make the physician inaccessible to former patients.

State law governs covenants, and states can vary widely in how they address them. Some states have statutes that regulate restrictive covenants, and some of those statutes prohibit restrictive covenant enforcement against employed physicians. California, Delaware, Massachusetts, New Hampshire, North Dakota, Oklahoma and Rhode Island, for example, have enacted laws that would prohibit restrictive covenant enforcement against employed physicians. Other states may deal with restrictive covenant issues solely through court cases. Absent a specific statute prohibiting the enforcement of a restrictive covenant, courts in most states will generally allow an employer to enforce a reasonable restrictive covenant against an employed physician, notwithstanding the concerns raised by Policy D-383.978.

Application to all care settings where restrictive covenants are concerned

Policy D-383.978 asks our AMA to "study the impact that restrictive covenants have across all practice settings...." This report primarily addresses restrictive covenant use in the large health care system environment. However, this report's discussion about concerns associated with aggressive restrictive covenant enforcement will be applicable across all care settings, since those concerns may arise whenever an employer utilizes restrictive covenants, regardless of practice setting.

Restrictive covenants to protect legitimate business interests

A court will enforce a reasonable restrictive covenant in a physician employment agreement when it determines that the covenant is necessary to protect an employer's legitimate business interest. With respect to physician employment, the legitimate business interest typically is the investment the employer has made in helping the physician establish his or her practice. A physician employer, e.g., a large health system, may spend thousands of dollars recruiting the physician, covering the physician's relocation costs, training, providing administrative support and marketing the physician. The employer may also give the physician access to community referral sources, patient lists and propriety information. This investment will likely be more significant if the employer is recruiting the physician right out of residency. Given this resource commitment, the employer may think it necessary to protect its investment in the physician through a restrictive covenant that will prevent the physician from leaving and joining a rival health system, or otherwise competing with the former employer. Although aggressive enforcement of restrictive covenants can raise the issues identified in Policy D-383.978, restrictive covenants can benefit employed physicians. For example, a potential employer may be much less willing to make the time and resource commitments that are needed to help physicians succeed in medical practice without a restrictive covenant in place.

Concerns that Policy D-383.978 identifies

As Policy D-383.978 notes, aggressive enforcement of restrictive covenants in physician employment contracts can trigger issues regarding the patient-physician relationship, access to health care, physician autonomy and patient choice. A restrictive covenant's application could, for example, negatively impact patient access to care by severing a long-standing patient-physician relationship, particularly in cases where the physician has been regularly and actively involved in helping the patient manage an ongoing mental or physical condition. If a restrictive covenant requires the physician to leave the area in order to continue practicing medicine, for example, the patient may not as a practical matter be able to continue seeing the physician. The result here would be an end to the patient-physician relationship and further, this could potentially hinder the patient's ability to manage his or her condition. Even assuming a smooth care transition to another physician, a significant amount of time might pass before this new patient-physician relationship enjoys the same level of trust and candor as the first.

Aggressive enforcement of a restrictive covenant could also have negative consequences on patient care outside of a long-term patient-physician relationship. For example, depending on the geographic area, there may be just a few physicians, general practitioners or specialists, available to serve the needs of the patient population. This may be particularly true in rural parts of the country. Even if several physicians practice in the community, requiring a physician to leave the area may reduce the number of available physicians. Although a replacement physician may ultimately be brought to the area, recruitment can be a lengthy process. In fact, it may be quite a while before the replacement physician can start seeing the community's patients. In the meantime, the absence of the physician subject to the restrictive covenant could hinder patient access by increasing patient wait times—assuming the community's remaining physicians have the capacity to take on new patients. The situation could be compounded if the community has only one general practitioner or physician of a needed specialty. In that case, obligating a physician to leave the area could deny the community those medical services until a new physician could commence practice. In the interim, patients may have to decide whether they can travel to other communities to obtain those services, which may not always be practically feasible, or do without for the time being.

 As Policy D-383.978 notes, aggressive enforcement of restrictive covenants may also detrimentally impact a patient's choice of physician. Obviously, application of a restrictive covenant can negatively affect patient choice if the covenant obligates the patient's preferred physician to relocate to an area that is beyond the patient's practical reach. But patient choice could still be affected if his or her preferred physician moves to an area that the patient does not regard as geographically inaccessible, e.g., the patient places such a value on continuing the patient-physician relationship that he or she is willing and able to accept inconveniences that the physician's relocation may have created, such as increased travel distance. However, notwithstanding the patient's willingness, relocation may affect the physician's network status with respect to the patient's health insurance coverage or employee benefits plan. If the physician had been out-of-network previously, continued out-of-network status may have little impact on patient choice. But if the physician had been in-network, the increase in the patient's financial obligation to stay with the physician may compel the patient to select another, in-network, physician.

Policy D-383.978 also identifies physician autonomy as a concern raised by aggressive restrictive covenants. AMA policy recognizes the importance of physician autonomy. For example, Policy H-225.950, "AMA Principles for Physician Employment," states in part that "[e]mployed physicians should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment." Further, according to

H-225.950, employed physicians should not be considered to have violated their employment agreements or suffer retaliation for exercising their personal and professional judgment. Notwithstanding H-225-950, if a physician knows that the culture of his or her employer is one of aggressive restrictive covenant enforcement, that knowledge may dampen the physician's willingness to freely and fully exercise his or her autonomy in patients' best interests. For example, typically a physician employment agreement will contain a "without cause" termination provision. This provision allows an employer to end the employment agreement so long as the employer gives the physician prior notice, e.g., 90 days. The physician need not have violated his or her agreement to be subject to "without cause" termination. If the physician is concerned that his or her employer may end their employment under a "without cause" provision in retaliation for strong patient advocacy, for example, the physician may be reluctant to serve as a strong advocate. This may be especially true if the "without cause" termination also triggers the application of a restrictive covenant that may require the physician to move out of the community if the physician wanted to continue practicing medicine.

Potential difference between restrictive covenants in large health systems and independent physician practices

Although Resolution 26 addresses aggressive restrictive covenant enforcement by large health system employers, independent physician practices also use restrictive covenants. The concerns identified in Resolution 26 can apply equally across the board regardless of employer. There may, however, be cases where concerns about restrictive covenants may be greater when the employer is a large health system vis-à-vis a physician practice. One difference could be the extent to which a potential physician employee may be able to negotiate the scope and duration of a restrictive covenant. A large health system may be less inclined than, say, a small physician practice to negotiate the terms of a restrictive covenant or other conditions of employment, e.g., due to institutional policies. However, a physician should never be reluctant to voice his or her concerns about the impact that restrictive covenant language may have on physician autonomy or simply assume that a large health system will not negotiate restrictive covenant language to address those concerns. A large health system may, in fact, be amenable to negotiations depending on the circumstances, which may be highly fact-specific.

 Further, the culture of restrictive covenant structure and enforcement may differ between a large health system employer and an independent physician practice. Physicians frequently own and control independent practices, and thus decide how restrictive covenants will be drafted and enforced. Since physicians are in control, the structure and enforcement of restrictive covenants may be sensitive to the concerns raised by Policy D-383.978 In contrast, in large health systems, non-physicians may dictate how restrictive covenants are structured and enforced and may not be as cognizant of the issues identified in Policy D-383.978. It must, however, be emphasized that simply because a restrictive covenant is used within the context of a small physician practice does not mean that the scope and enforcement of the covenant does not exceed what is reasonable and does not implicate the concerns raised in Policy D-383.978. Furthermore, use of restrictive covenants by large health system employers may not always negatively impact patient access, choice and/or physician autonomy.

Finally, a large health care system's aggressive enforcement of a restrictive covenant may have adverse consequences on network participation which do not often arise when an independent physician practice is involved. For example, in contrast to most independent physician practices, large health care systems may sponsor clinically integrated networks or accountable care organizations (ACOs). Some have also created affiliated health insurers. The system's aggressive enforcement of a restrictive covenant may trigger issues that Policy D-383.978 identifies if the

covenant would force the physician out of the system's clinically integrated network or ACO, or prohibit the physician from participating in the system's health insurance provider network. In some cases, the prospect of adverse network consequences may, in fact, concern the physician as much as the restrictive covenant itself.

1 2

AMA POLICY

 Our AMA has several policies that address restrictive covenants. For example, CEJA Ethical Opinion 11.2.3.1, entitled "Restrictive Covenants" states that, "[c]ompetition among physicians is ethically justifiable when it is based on such factors as quality of services, skill, experience, conveniences offered to patients, fees, or credit terms." That Opinion also states that covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care, and that physicians should not enter into covenants that: (a) unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and (b) do not make reasonable accommodation for patients' choice of physician. The Opinion further adds that physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program.

In addition to the CEJA Opinion, Policy H-310.929, "Principles for Graduate Medical Education," states that restrictive covenants must not be required of residents or applicants for residency education; Policy H-295.910, "Restrictive Covenants During Training," strongly urges residency and fellowship training programs that utilize restrictive covenants to provide written intent to impose such restrictions in advance of the interview process; Policy H-295.901, "Restrictive Covenants in Residency and Fellowship Training Programs," states that physicians-in-training should not be asked to sign covenants not-to-compete as a condition of their entry into any residency or fellowship program; Policy H-225.950, "AMA Principles for Physician Employment," discourages physicians from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment; and Policy H-383.987, "Restrictive Covenants in Physician Contracts," states that "[o]ur AMA will provide guidance, consultation, and model legislation concerning the application of restrictive covenants to physicians upon request of state medical associations and national medical specialty societies."

SOME KEY POINTS AND AMA RESOURCES ON RESTRICTIVE COVENANTS

As the prior discussion shows, physicians should very carefully scrutinize any restrictive covenant language in employment contract offers they receive. Obtaining the assistance of an attorney who has experience representing physicians in employment matters can be very helpful in determining whether proposed restrictive covenant language is reasonable and appropriate. Physicians should proactively bring any concerns they have about restrictive covenant language to the potential employer and should not be afraid to ask for changes.

The following are some key points that can help physicians evaluate the reasonableness of restrictive covenant language:

- what triggers the restrictive covenant, e.g., the employer's terminating the agreement for *any* reason as opposed to termination because the physician failed to live up to his or her contact obligations:
- the duration of the covenant, e.g., one year versus three years;

- the covenant's geographic scope, e.g., is it greater than what is necessary to protect the employer:
 - o for example, 10 miles might be reasonable in a rural area but may not be in an urban setting;
 - o for example, is geographic scope tied to an appropriate site of service, e.g., where the physician actually treated his or her patients or does the scope extend to *any* location where the employer has facilities;
 - does the covenant apply only to the services that the physician furnished, or does it prohibit the physician from practicing medicine entirely or from providing administrative services; and
 - does the covenant contain a reasonable "buy-out" provision that, if satisfied, would free the employed physician from time and geographic restrictions.

Finally, it ought to be noted that the AMA has many resources that educate medical students, physicians-in-training, and physicians about restrictive covenants. For example:

- The AMA Career Planning Resource webpage has a wealth of information discussing
 physician employment issues, which includes information and tips regarding
 restrictive covenants. The AMA Career Planning Resource webpage may be accessed
 at https://www.ama-assn.org/residents-students/career-planning-resource/understanding-employment-contracts.
- The AMA also has two model employment agreements that discuss restrictive covenants, the Annotated Model Physician-Hospital Employment Agreement, 2011 edition: E-Book, free for AMA members at https://commerce.amaassn.org/store/ui/catalog/productDetail?product_id=prod1240028&sku_id=sku12400 37, and the Annotated Model Physician-Group Practice Employment Agreement: E-Book, free for members at https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod2530052&sku_id=sku25301 04. These agreements contain model restrictive covenant language for potential physician employees to consider, which may prove useful in the employment negotiation process.
 - Finally, staff at the AMA Advocacy Resource Center, the state advocacy unit of the AMA, work extensively on physician employment issues. AMA members are encouraged to contact the Advocacy Resource Center at arc@ama-assn.org, if they would like to obtain more information and resources concerning restrictive covenants.

REFERENCES

- ¹ See Cal Bus & Prof Code § 16600; 6 Del. C. § 2707 (allows liquidated damages); ALM GL Ch. 112, § 12X; RSA 329:31-a; N.D. Cent. Code, § 9-08-06; 15 Okl. St. § 219A (so long as the employee does not solicit the former employer's customers); R.I. Gen. Laws § 5-37-33.
- ² Frequently the agreement will (and should) contain a reciprocal "without cause" provision, meaning that the physician can also terminate the agreement if he or she gives the employer the same prior notice as the employer is obligated to provide the physician.

REPORT 7 OF THE BOARD OF TRUSTEES 2019 AMA Advocacy Efforts

EXECUTIVE SUMMARY

Policy G-640.005, "AMA Advocacy Analysis," calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year's advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on American Medical Association (AMA) advocacy activities for the year. (Note: It was prepared in early August based on approval deadlines and may be updated if warranted based on legislative, regulatory, or judicial developments.)

The AMA continues to be a powerful ally for physicians as it shapes the health of the nation by working to reduce dysfunction in the health care system, achieve health equity, train the next generation of physicians, and improve public health. The AMA produced strong results again in 2019 by advancing key policy objectives on physician payment, drug pricing, ill-conceived health insurer policies, the opioid epidemic, and consolidation in the health sector. The AMA's stellar advocacy work is recognized by industry watchers including APCO Worldwide which ranked the AMA as a "top-rated association" in four of 15 categories in its TradeMarks report (coalition building, industry reputation steward, local impact, and bipartisanship) when compared to 50 other associations representing various industries. The AMA was the top-rated association in 11 of 15 categories when compared only to other health care stakeholders.

Key AMA advocacy wins in 2019 include:

- The Centers for Medicare & Medicaid Services (CMS) is recommending adoption of recommendations from the RUC and CPT regarding coding changes and relative work values for office-based E/M services (further work is needed on the E/M component for global surgical services).
- CMS also approved several new Alternative Payment Models (APMs) and is moving towards a
 new approach for the Merit-based Incentive Payment System (MIPS) based on
 recommendations from an AMA-led Federation work group.
- AMA research and advocacy led a federal judge to conduct a rigorous review of the proposed CVS-Aetna merger—decision pending.
- CMS limited step therapy in Medicare Advantage plans and nine states, such as Colorado and Kentucky, enacted state legislation to limit prior authorization across the board.
- Eleven states and Washington, DC enacted laws or implemented policies to limit prior authorization for medication-assisted treatment (MAT) for substance use disorder (SUD).
- Congress is considering drug pricing legislation and the AMA is actively engaged on this issue with over 1 million physician/patient messages sent to Congress through AMA grassroots efforts since the campaign's inception.
- The House of Representatives has passed a universal firearm background check bill, and the AMA is advocating for similar legislation in the Senate.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 7-I-19

Subject: 2019 AMA Advocacy Efforts

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

BACKGROUND

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7 8 Policy G-640.005, "AMA Advocacy Analysis," calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year's advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on American Medical Association (AMA) advocacy activities for the year. (Note: It was prepared in early August based on approval deadlines and may be updated if warranted based on legislative, regulatory, or judicial developments.)

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The AMA collaborates closely with the Federation of Medicine in its advocacy work and greatly appreciates the invaluable contributions made by the national medical specialty societies, state medical associations, and county medical associations to advance our collective goals.

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While advocacy efforts continue in 2019, the AMA is already preparing for 2020 when the presidential election will bring even greater attention to many health care issues. Health care was the top issue for voters in 2018, and it is at the top of the list for voters heading into the 2020 elections.

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DISCUSSION OF 2019 ADVOCACY EFFORTS

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QPP implementation

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- Physicians need support as they continue the transition to the Medicare Quality Payment Program (QPP). The AMA is working to improve the QPP at both the regulatory and legislative levels. AMA Immediate Past President Barbara L. McAneny, MD, testified on May 8 before the Senate Committee on Finance on the Medicare Access and Chip Reauthorization Act (MACRA) and offered ways for Congress to continue improving the QPP.
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Initial results from CMS show that AMA efforts have had an impact. Merit-based Incentive Payment System (MIPS) participation rates increased from 95 percent in 2017 to 98 percent in 2018, with 98 percent of clinicians earning an incentive payment that will apply to Medicare physician fee schedule payments in 2020. The AMA's strong push for additional flexibilities for small practices resulted in nearly 85 percent receiving a positive payment adjustment, up from 74 percent in 2017. Additionally, the number of eligible clinicians who qualified for a 5 percent APM incentive payment nearly doubled from 2017 to 2018, increasing from 99,076 to 183,306 clinicians. The AMA is encouraged by these results and will continue to work with CMS and the Federation to identify further solutions that will reduce the burden and cost to participate in MIPS and increase opportunities for physicians to move to alternative payment models (APMs).

Further on the APM front, the AMA was pleased to host the Secretary of Health and Human Services Alex Azar, along with Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma, and Director Center for Medicare and Medicaid Innovation (CMMI) Adam Boehler, as they announced two new primary care models. Under the programs, Medicare would reward practices for providing more convenient access to care, and start paying for services such as enhanced chronic disease care management, acute care in-home services and palliative care. CMMI is also implementing an APM covering emergency services and another on treatment for kidney disease. The AMA is supportive of the roll out of more APM options for physicians as they seek to be innovative in providing care to their patients.

Finally, CMS issued its 1700-page proposed 2020 Medicare physician payment rule in late July, with comments due at the end of September. Two notable policy provisions were included:

• The agency agreed to coding changes and revised relative work values for office-based evaluation and management (E/M) services that were initially developed by a Federation workgroup and ultimately approved by CPT and the RUC. These changes would be made in lieu of plans the agency announced last year to collapse office E/M codes and payments. The new proposal reflects the increasing complexity of these services and the resources required to provide them and streamlines reporting requirements. Unfortunately, the agency did not propose making the same adjustments to the E/M component of global surgical services, as recommended by the RUC, which would distort the relativity of the fee schedule. The AMA will continue pressing CMS to make these adjustments.

Another provision of the proposed rule is the framework for a more cohesive Merit-based Incentive Payment System (MIPS) that would give physicians the choice to focus on episodes of care rather than following the current, more fragmented approach. Making MIPS more clinically relevant and less burdensome is a top priority for the AMA, and CMS is taking an important step toward this goal.

Prior authorization

Prior authorization (PA) is one of the most vexing issues for patients and physicians in the health care system today, and the AMA is addressing it in multiple venues. Key findings from the AMA's December 2018 PA physician survey include:

- 28 percent of physicians reported that the PA process required by health insurers for certain drugs, tests and treatments had led to a serious adverse event (e.g., death, hospitalization, disability, or another life-threatening event);
- On average, practices complete 31 PAs per physician, per week; and
- 91 percent of physicians surveyed said that PA processes delay access to necessary care.

The AMA has attempted to work directly with health insurers and other stakeholders by identifying joint principles to reform PA, but demonstrable progress by insurers in reducing PA burdens has been negligible. The AMA is also pressing for legislation at the federal and state levels on PA reform. Federal legislation, H.R. 3107, the "Improving Seniors' Timely Access to Care Act," was recently introduced, and the bill aims to streamline PA processes by Medicare Advantage plans. The AMA is supportive of the bill and assisted with a Federation sign-on letter to highlight the broad support for the bill in the physician community. Also at the federal level, CMS moderated its earlier proposed approach to use step therapy and other utilization management tools within the six protected classes of drugs used to treat complex conditions in final regulations on Medicare Advantage and Part D drug plans. While its earlier proposal would have allowed step therapy and other tools to be applied broadly across all six protected classes, the agency's final policy allows step therapy within five of the six protected classes and limits its use to new starts.

Much of the legislative activity on PA in 2019 occurred at the state level. To date, Colorado, Kentucky, Maine, Maryland, Missouri, New Mexico, Texas, Virginia, and West Virginia have enacted PA laws this year despite the state medical associations in those states facing strong opposition from insurers and their local trade associations. Kentucky S.B 54 is a strong PA reform law based on AMA model legislation that was enacted this year, and it will require insurers to respond to PA requests for urgent care within 24 hours and for non-urgent care within 5 days. Another benefit of the Kentucky law for patients is that their prescriptions for maintenance drugs will be valid for one year or until the last day of coverage, and if there is a change in dosage, PA will not be required during this time period.

 In 2019, the AMA enhanced its grassroots advocacy campaign—FixPriorAuth.org—directed at both physicians and patients to spur further activity on PA reform. Campaign components include a successful online hub, an active social media campaign, and videos featuring both patient and physician stories that illustrate the negative impact of utilization management restrictions on timely patient care. To date, the social media campaign has generated more than 610 patient and physician stories and 90,000 signatures on a petition to Congress.

CVS-Aetna

 The AMA has taken a leading role in challenging the massive CVS-Aetna proposed merger, the largest in the history of U.S. health care. If approved, the merger would hurt competition in five key health care markets: Medicare Part D prescription drug plan (PDP); health insurance; pharmacy benefit management; retail pharmacy; and specialty pharmacy. The AMA opposition is evidence-based, the result of months of analysis by nationally-recognized health economists and legal experts. The AMA's advocacy led to an almost unheard-of development: a federal judge holding hearings to evaluate the settlement between the U.S. Department of Justice (DOJ) and CVS-Aetna that led to the DOJ approving the merger.

The AMA's main concerns about the proposed merger and subsequent agreement were contained in a March 2019 filing before Judge Richard Leon. The AMA contends that the DOJ settlement with Aetna, which requires Aetna to sell its PDP assets for the DOJ to approve the CVS-Aetna merger, would not adequately address the merger's anticompetitive effects. The AMA has three main concerns:

- The divestiture would decrease the number of firms in already concentrated and rapidly consolidating PDP markets;
- New entry will not solve the problem because there are high barriers to entry into PDP markets; and

• The merger and divestiture would eliminate the unique and important role of competition between Aetna and CVS in the PDP market.

The AMA participated in closing arguments before Judge Leon on July 19. Many expected this merger to sail through the approval process, but that is clearly not the case. Judge Leon is giving the proposed merger a very rigorous review, and his ruling is expected later this summer/early fall.

Access to care

The AMA remains committed to protecting coverage for the 20 million Americans who acquired it through the Affordable Care Act (ACA) and expanding coverage for those who did not. The AMA also supports policies that would improve coverage options for many who are underinsured and/or cite costs as a barrier to accessing the care they need. The status quo is unacceptable, and federal policymakers need to build upon the ACA instead of attempting to weaken it.

The AMA filed an *amicus* brief with several Federation groups to defend the ACA in 2018 in *Texas v. United States*—a case challenging the validity of the ACA after the individual mandate tax penalty was repealed by Congress. The district court judge sided with those challenging the ACA, so the AMA has filed another *amicus* in 2019 at the appellate level to overturn the lower court ruling. A ruling on the appeal is expected shortly.

The AMA has also advocated for building on and fixing the ACA rather than scrapping it and adopting a single payer model. The AMA advocated in 2019 to build on the foundation of the current system to reach universal coverage through a pluralistic approach involving a strong competitive private market, employer sponsored coverage, a publicly financed safety net, and consumer protections such as the current prohibition against pre-existing condition coverage exclusions. This will be a major issue as the nation heads into a presidential election year where health care will again be front and center, although no legislative action is anticipated before 2021.

At the state level, the AMA has continued to advocate for Medicaid expansion. To date, 36 states and DC have expanded Medicaid eligibility under the ACA. In 2019, three states (Idaho, Nebraska, and Utah) moved forward with expansion plans that were approved by voters via ballot initiative in 2018. Arkansas and Montana reauthorized existing Medicaid expansion programs, and Georgia enacted a law authorizing a waiver for expanded coverage. Many states, however, are coupling burdensome work requirements with coverage expansions and the AMA continues to work with state medical associations to counter restrictions that will cause coverage losses. With AMA support, New Hampshire enacted a law to halt the state's work requirements if a substantial number of beneficiaries are negatively affected, and Montana passed a "trigger" provision requiring the state to reevaluate the work program if a substantial number of enrollees lose coverage. The AMA has also joined *amicus* briefs in legal challenges to Medicaid work requirements in Arkansas, Kentucky, and New Hampshire.

Regulatory relief

The Administration has made regulatory relief for physicians a priority. The AMA successfully called for a reduction in documentation requirements that were in the final Physician Fee Schedule rule last November. CMS is expected to undertake more regulatory reduction efforts for physicians as they issue various upcoming rules. The AMA has had a number of discussions with CMS on prior authorization and is optimistic that CMS will find ways to reduce this burden for physicians. The AMA is also working on responding to a CMS proposed rule regarding electronic prior

authorization (ePA). CMS is seeking comment about how to mitigate burden to support successful adoption of ePA.

CMS also issued a Request for Information (RFI) seeking feedback on regulatory relief more broadly. The AMA solicited input from the specialty societies, the Council on Medical Service, and the Council on Legislation to help identify additional ideas regarding burden reduction to include in the AMA response to the RFI. A lengthy comment letter with detailed recommendations for easing physician regulatory burdens was submitted on August 9.

 Lastly, the AMA has met with HHS about necessary changes to Stark and Anti-Kickback policies. The AMA is providing extensive comments to the HHS RFI on the topic. At the time of this report, there are two separate proposed rules looking to modernize the Stark and Anti-Kickback regulations that are pending Office of Management and Budget (OMB) review. The AMA anticipates clarification as to the definition of key terms and potential new exceptions/safe harbors around value-based care and cybersecurity. The AMA also recommended in recent comments that the federal ban on physician-owned hospitals be lifted.

Surprise billing

Patients, physicians, and policymakers are deeply concerned about the impact that unanticipated medical bills are having on patient out-of-pocket costs and the patient-physician relationship. The AMA and more than 100 state and specialty organizations submitted a letter to Congress laying out seven principles that the AMA believes must guide any federal legislation on surprise billing to ensure that patients are not burdened by unanticipated out-of-network medical bills: (1) insurer accountability; (2) limits on patient responsibility; (3) transparency; (4) universality; (5) setting benchmark payments; (6) alternative dispute resolution; and (7) keep patients out of the middle. On May 21, AMA Trustee Bobby Mukkamala, MD, testified before the House Ways and Means Committee on surprise billing offering the AMA's proposed solutions in his remarks and written testimony.

On July 17, the House Committee on Energy and Commerce reported out several health care bills including the "REACH Act" which would extend funding for Community Health Centers, the Teaching Health Centers GME program and the National Health Service Corps and also included the "No Surprises Act" to address surprise medical billing. As originally introduced, the "No Surprises Act" would have plans pay out-of-network physicians the median in-network contract amount for the service provided in that particular geographic area. Not only would that bind out-of-network physicians to contracted amounts they did not agree to accept, but it would eliminate much of the incentive for plans to contract with an adequate number of physicians in the first place. Furthermore, as the Congressional Budget Office (CBO) has noted on similar proposals, plans would have an incentive to cancel or cut contracted amounts for any physicians currently above the median rate, reducing payment for both in- and out-of-network physicians. Such a solution would tilt the advantage in negotiating fair contracts even further in the direction of plans. On June 24, the Senate Health, Education, Labor, and Pensions Committee approved similar legislation.

At the urging of Energy and Commerce Committee members Rep. Raul Ruiz, MD (D-CA), Rep. Larry Buschon, MD (R-IN) and others, the committee adopted an amendment to provide for an independent dispute resolution process. Under the proposal, if either party was dissatisfied with the initial payment offer, an appeals process could be triggered that would allow an independent entity to decide between the payment offer of the plan and the physician's billed amount while considering a number of other factors related to the circumstances of the case and the training and experience of the physician. While the proposal still needs improvement, it represents an important

step forward, and an improvement over the Senate bill, by recognizing that the resolution of these disputes requires a solution that is fair and encourages both sides to make reasonable offers to resolve the payment dispute. At the time of this report, the AMA is seeking to make further improvements to these provisions and has activated the AMA's grassroots networks. Two other House committees—Education & Labor and Ways & Means, also plan to produce surprise billing legislation.

At the state level, medical societies continue to push for fair solutions and push back on insurer-supported proposals that undercut fair contracting. So far in 2019, more than 40 bills in 20 states related to surprise billing were introduced and many remain in play. In Washington, Texas, Colorado, New Mexico, and Nevada, comprehensive bills were enacted this year (i.e., bills that established both patient protections and payment processes). While none of these new laws is squarely aligned with Federation principles, the new laws are fairer because of strong physician advocacy. Much of the work in these states now turns toward engagement in the regulatory process and implementation.

Opioid epidemic

The opioid epidemic continues to have a devastating effect on our nation; however, there is continuing progress in physicians' actions to help end it. Last fall, the AMA joined the Pennsylvania Medical Society to help secure a landmark agreement in Pennsylvania between the governor and the Commonwealth's seven largest health plans to remove prior authorization requirements for medication-assisted treatment (MAT) to treat a substance use disorder. Since then, AMA advocacy with state and specialty societies has helped enact/implement similar laws and policies in Arkansas, Colorado, Delaware, the District of Columbia, Iowa, Maine, Missouri, New Jersey, New York, Vermont, Virginia, and Washington. The AMA has also worked closely with Manatt Health on reports in Pennsylvania, Colorado, North Carolina and Mississippi to spotlight their efforts to combat the opioid epidemic and areas for future collaboration to strengthen these efforts. The AMA and Manatt will also roll out a national roadmap on this issue building on this state work in the fall.

The AMA Opioid Task Force issued a report in June 2019 updating some of the progress that is being made:

- From 2013-2018 annual opioid prescriptions dropped by one-third, from 251 million to 168 million. Every state has experienced a decrease in opioid prescriptions over the last five years.
- Use of prescription drug monitoring programs (PDMP) is growing—435 million queries were made in 2018—more than triple the total from 2016.
- Naloxone prescriptions increased from 136,000 in 2016 to nearly 600,000 in 2018.
- More than, 700,000 physicians and other health care professionals completed continuing
 medical education trainings and accessed other Federation resources in 2018; in addition, more
 than one million physicians and other readers of the JAMA Network viewed opioid-related
 research and related material.
- The number of physicians trained/certified to provide buprenorphine in-office continues to rise—more than 66,000 physicians are now certified—an increase of more than 28,000 physicians and other providers since 2016.

The AMA was also pleased that the U.S. Centers for Disease Control and Prevention (CDC) recently clarified its opioid prescribing guidelines as recommended by the AMA, and the Food and Drug Administration also issued revised guidance to help protect patients.

Pharmaceutical cost transparency

In 2019, the AMA continued advocacy to increase drug pricing transparency. This includes successfully advocating for Medicare Advantage and Part D to require plans to provide real-time access to drug price data through at least one electronic health record (EHR) or drug e-prescribing system by 2021.

Immediate Past Chair of the Board Jack Resneck, Jr., MD, testified before the House Energy and Commerce Subcommittee on Health on May 9 to press Congress to take action on this issue. The House of Representatives is expected to consider drug pricing legislation this fall. On the Senate side, the Finance Committee recently marked up drug pricing legislation that attempts to reduce the cost of prescription drugs by among other provisions capping Medicare beneficiaries out-of-pocket costs at \$3100 on prescription drugs and placing a limit on prescription drug price increases in Medicare Part D. At the time this report was drafted, the AMA was reviewing the Senate legislation and will review any upcoming House legislation before activating further the AMA's grassroots networks. The AMA's TruthinRx.org grassroots campaign has created a strong network of over 338,000 advocates who have sent over 1 million messages to Congress already, so the AMA is poised to have further impact as the drug pricing debate continues.

 The AMA is working on drug pricing at the state level and has developed model bills that focus on pharmacy benefit manager (PBM) practices. The AMA is also engaging the National Association of Insurance Commissioners, the National Conference of Insurance Legislators, and state attorneys general to reform PBM practices. Maine and New York made progress on this issue in 2019 with Maine enacting legislation that prohibits PBMs from retaining rebates from manufacturers and New York's new law increases transparency and requires PBMs to work "for the best interests primarily of the covered individual."

Vaccines

With the number of measles cases reaching the highest levels in more than 25 years, vaccine exemptions were a hot topic in states across the country, and the AMA was active on the advocacy front helping states address these bills. Several sought to eliminate all nonmedical exemptions to the childhood immunizations required for parents to enroll children in school—including enactments in Maine and New York. These two states join California, Mississippi and West Virginia to bring the total count of states that prohibit all nonmedical exemptions to five. Washington also strengthened its vaccine laws, barring personal and philosophical objection to the measles, mumps, and rubella vaccine. In addition, no new laws were enacted that would discourage immunization. In particular, the AMA worked closely with the Arizona Medical Association to defeat three high-profile bills that would have loosened vaccination laws. The AMA also wrote to major social media companies calling on them to eliminate false and misleading vaccine information from their platforms.

Gun violence

Gun violence in America has reached epidemic proportions. In 2019, the AMA continued its advocacy to find workable, comprehensive solutions to reduce gun violence. At the federal level, the House of Representatives passed a universal background check bill supported by the AMA. The sponsor of H.R. 8, Rep. Mike Thompson (D-CA), spoke at the AMA's National Advocacy Conference and expressed his thanks for AMA's support. The bill awaits consideration in the Senate.

- 1 At the state-level, several states made progress on the issue in 2019. Four states (Colorado, Hawaii,
- 2 New York and Nevada) passed laws authorizing extreme risk protection orders (sometimes called
- 3 "Red Flag laws"). Connecticut expanded safe storage requirements in the home. California
- 4 approved a first-in-the-nation requirement that anyone purchasing ammunition must undergo a
- 5 background check. Washington, New Mexico and Nevada strengthened background check
- 6 requirements, and several states closed loopholes that enable domestic abusers' access to firearms,
- 7 including North Dakota, New Mexico and Washington. Lastly, while no state currently prohibits
- 8 physicians from counseling patients about firearm safety and risks, the AMA continues to watch
- 9 for such legislation.

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Following the mass shootings in Gilroy, CA, El Paso, TX, and Dayton, OH, the AMA joined with other physician groups in a joint call to action that was published online by the *Annals of Internal Medicine* on August 7. The joint document calls for commonsense reforms such as expanded background checks, more federal support for firearms injury research, and other proposals.

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Detention of children at the southern border

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The AMA is very concerned about the treatment of children at the southern border and has expressed these concerns several times to federal officials. In June, the AMA signed on to a letter of support for H.R. 3239, the "Humanitarian Standards for Individuals in Customs and Border Protection Custody Act," along with 13 other health care organizations. H.R. 3239 takes important steps toward ensuring that appropriate medical and mental health screening and care are provided to all individuals, including immigrant children and pregnant women, in U.S. Customs and Border Protection (CBP) custody. In July, the AMA called on the U.S. Department of Homeland Security (DHS) and CBP to address the condition of their facilities at the southern border, which are inconsistent with evidence-based recommendations for appropriate care and treatment of children and pregnant women. The AMA also issued a letter to the House Committee on Oversight and Reform in advance of the upcoming congressional hearings entitled, "Kids in Cages: Inhumane Treatment at the Border," and "The Trump Administration's Child Separation Policy: Substantiated Allegations of Mistreatment." In the AMA letter, CEO and EVP James L. Madara, MD, stated: "Conditions in CBP facilities, including open toilets, constant light exposure, insufficient food and water, extreme temperatures, and forcing pregnant women and children to sleep on cement floors, are traumatizing. These facilities are simply not appropriate places for children or for pregnant women. We strongly urge the Administration and Congress to work with the medical community to develop policies that ensure the health of children and families is protected throughout the immigration process."

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Protecting the patient-physician relationship

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42 43 The AMA filed two major lawsuits in 2019 that challenged governmental intrusion into the patient-physician relationship. Both cases are working their way through the litigation process. The first was filed in conjunction with the Oregon Medical Association and other plaintiffs in federal court in Oregon and argues that proposed Administration regulatory changes would decimate the successful Title X program. The AMA's main concerns are that:

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- The regulation imposes a "gag rule" on physicians that restricts them from providing complete information to patients about all of their health care options and providing appropriate referrals for care.
- It re-directs funds away from evidence-based contraception methods and to non-medical family planning services such as abstinence and "fertility awareness."

• It withholds funds from qualified Title X providers that offer the full range of family planning services to vulnerable populations.

The AMA also filed a lawsuit to challenge the constitutionality of two North Dakota laws that compel physicians and other members of the care team to provide patients with false, misleading, non-medical information about reproductive health. Filed in federal court in North Dakota, the lawsuit asks the court to block enforcement of North Dakota's compelled speech laws, which the AMA argues would inflict irreparable harm on patients and force physicians to violate their obligation to give honest and informed advice.

Nondiscrimination in health care

The AMA is assessing the full impact of the regulatory proposal issued in 2019 to remove antidiscrimination protections related to sexual orientation, gender identity, and termination of pregnancy across a wide range of health care programs and insurance plans. We strongly believe that discrimination on the basis of sex includes discrimination on the basis of gender identity and sexual orientation. Similarly, the AMA does not condone discrimination based on whether a woman has had an abortion. Respect for the diversity of patients is a fundamental value of the medical profession and reflected in long-standing AMA ethical policy opposing discrimination based on race, gender, sexual orientation, gender identity, pregnancy, or termination thereof. The AMA submitted comments that highlight these concerns on August 13.

Conversion therapy

 The AMA opposes the practice of "conversion therapy" on minors and works with states to ban this practice. Four states (Colorado, Massachusetts, Maine and New York) enacted laws prohibiting the practice in 2019. This practice refers to interventions that attempt to change an individual's sexual orientation, sexual behaviors, gender identity, or gender expression. Eighteen states and Washington, DC now prohibit the harmful practice and one state, North Carolina, bars use of state funding for conversion therapy. The AMA produced an issue brief on this topic to assist states that seek to address it in coming legislative sessions.

Tobacco

Tobacco use particularly among youth remains a public health concern for the AMA. There are state and federal efforts to move to an age 21 threshold for tobacco purchase. This year 10 states (Arkansas, Connecticut, Delaware, Illinois, Maryland, Texas, Utah, Virginia, Vermont, and Washington) raised the minimum age to purchase tobacco products to 21 from 18, bringing the total number of Tobacco 21 states to 17 plus Washington, DC. The AMA is also reviewing federal legislation that would create a federal requirement as well. The AMA also has strong policy on e-cigarettes and is monitoring federal and state legislative and regulatory efforts closely. The AMA will continue to seek opportunities to advocate for AMA policy on this public health concern.

Scope of practice

State legislatures considered over 1000 bills seeking to eliminate team-based care models of health care delivery and/or expand the scope of practice of non-physician health care professionals in 2019. For example, nurse practitioners continued to seek independent practice authority and to chip around the edges of state law. Physician assistants were more emboldened this year to seek independent practice with the adoption of the optimal team practice act by the American Academy of PAs (AAPA) last year, and pharmacists sought prescriptive authority in at least a dozen states.

B of T Rep. 7-I-19 -- page 10 of 10

While these three groups of non-physician health care professionals accounted for the vast majority of scope bills this year, hard fought battles also occurred in a number of states on other scope issues. With tough fights in all cases, most bills that threatened passage were defeated, often with AMA support and a coordinated approach from state medical associations and national medical specialty societies through the AMA-led Scope of Practice Partnership (SOPP). The SOPP has provided close to \$2 million in grants to states and specialties since its inception to help on the scope front.

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CONCLUSION

 The AMA continues to be a powerful advocate for physicians as it attacks the major problems that promote dysfunction in health care including payment issues, egregious health insurance practices, industry consolidation, and drug pricing. At the same time, the AMA is seeking to improve public health by working to solve the gun violence crisis, continue progress being made on the opioid epidemic, and promote health equity across the board. AMA advocacy work will continue through the rest of 2019, and the AMA will be prepared as health care policy will go under the microscope again in the presidential primaries and general election in 2020.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 11-I-19

Subject: Re-establishment of National Guideline Clearinghouse

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

This report is pursuant to American Medical Association (AMA) Policy D-410.991, "Reestablishment of National Guideline Clearinghouse (NGC)", passed by the House of Delegates at the 2019 Annual Meeting. The second paragraph of the policy calls on the AMA to research possible and existing alternatives for the functions of the NGC with a report back to the House of Delegates.

BACKGROUND

The mission of the NGC was to provide physicians and other health care professionals, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use.

The NGC was created in 1997 by the Agency for Healthcare Research and Quality (AHRQ) in partnership with the AMA and the American Association of Health Plans (now America's Health Insurance Plans [AHIP]). In January 1999, the database-driven NGC website was made available to the public, and AHRQ maintained and enhanced the NGC for nearly 20 years. The partnership with AMA and AHIP ended in 2002, but AMA remained committed to the mission of the NGC through passage and reaffirmation of AMA Policy H-410.965, "Clinical Practice Guidelines, Performance Measures, and Outcomes Research Activities."

NATIONAL GUIDELINES CLEARINGHOUSE STATUS

The AMA discussed the NGC with AHRQ staff to understand why the NGC website was closed and services suspended as of July 2018. Per AHRQ staff, it was never the intention of AHRQ to eliminate or shut down the NGC. The AHRQ received funding to develop and maintain the NGC per its mission. This funding ended, and the MITRE Corporation was contracted by AHRQ to determine a path(s) to sustaining and advancing NGC without AHRQ funding. The MITRE Corporation is a not-for-profit company that operates multiple federally-funded research and development centers to provide innovative, practical solutions.

- Prior to commissioning the study, AHRQ staff interviewed NGC stakeholders and customers to get a thorough understanding of what they valued about the NGC to guide MITRE in their charge. While clinical practitioners associated with large medical practices or health systems, and many specialists have access to guidelines and related materials, the NGC was most used by researchers, residents and small practices or solo practitioners. Among the stakeholder comments were a continued interest in a repository of evidence-based clinical practice guidelines meeting certain transparent criteria and continued support for public access to the repository (no fee or registration required). During this transition some organizations stepped in to provide similar if not parallel
- services to the NGC. One such organization, ECRI Institute, an independent, nonprofit patient

B of T Rep. 11-I-19 -- page 2 of 2

1	safety organization, launched the ECRI Guidelines Trust TM , a portal to expertly vetted, evidence-
2	based guideline briefs and scorecards. The healthcare community has free access to the website.
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4	The MITRE Corporation has completed its study and per its recommendations AHRQ will
5	transition the NGC to a private entity to sustain the site and thereby provide a source of evidence-
6	based guidelines for clinical decision making. The Agency will achieve this transition through a
7	mechanism that will ensure alignment with principles that have defined AHRQ's support for the
8	resource, including the requirement that guidelines meet specific criteria and adherence to the IOM
9	trustworthiness standards, public access, and protections of guideline developer copyright. AHRQ
10	will have a role in the NGC, which will be specified as the work continues. No information is
11	publicly available at this time regarding the financial support for the new NGC to be managed by a
12	private entity.
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The timeline for migration to a private entity from AHRQ has not been determined but AHRQ will continue to post updates to it website https://www.ahrq.gov/gam/updates/index.html. The AMA will monitor additional plans as they become available.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 12-I-19

Subject: Distracted Driver Education and Advocacy

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

INTRODUCTION

At the 2019 Annual Meeting, the House of Delegates amended Policy H-15.952 asking that our American Medical Association "make it a priority to create a national education and advocacy campaign on distracted driving in collaboration with the Centers for Disease Control and other interested stakeholders" and be it further "that our AMA explore developing an advertising campaign on distracted driving."

This report discusses the development of actions in response to Policy H-15.952, Paragraph 6.

BACKGROUND

 Texting and driving is one of the most dangerous forms of distracted driving. According to National Highway Traffic Safety Administration (NHTSA) at any given moment across America, approximately 660,000 drivers are using or manipulating electronic devices while driving. A higher percentage of U.S. drivers text or use hand-held cell phones while driving compared to drivers in European countries. The CDC states that in 2016, 3,450 people were killed in crashes involving a distracted driver. The CDC also found that in 2015, 391,000 people were injured in motor vehicle crashes involving a distracted driver and one-fourth of all traffic accidents are associated with cell phone use, a number that has held steady since 2010.

There are many external resources on this topic already – including national campaigns by the National Highway Traffic Safety Administration (NHTSA) and AT&T. The NHTSA has four national campaigns to educate on distracted driving: 1) Evergreen Campaign, 2) One Text Or Call Could Wreck It All, 3) Phone In One Hand - Ticket In The Other, and 4) U Drive. U Text. U Pay. Likewise, AT&T's "It Can Wait" campaign has successfully received over 38 million pledges to drive distraction free.

STATUS OF IMPLEMENTATION

- Enterprise Communications will amplify the efforts of Advocacy, Health and Science, and JAMA through appropriate media channels and will work with Physician Engagement to amplify via AMA owned channels such as social media, AMA Wire, etc. Enterprise Communications will evaluate opportunities to support current and future advertising campaigns on distracted driving to
- 35 highlight the risks to the public.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 13-I-19

Subject: Hospital Closures and Physician Credentialing

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

American Medical Association Policy D-230.984, "Hospital Closures and Physician
Credentialing," instructs our AMA to: (a) continue to monitor the development and implementation
of physician credentialing repository databases that track hospital affiliations, including tracking
hospital closures, as well as how and where these closed hospitals are storing physician
credentialing information; and (b) explore the feasibility of developing a universal clearinghouse
that centralizes the verification of credentialing information, and report back to the House of
Delegates at the 2019 Interim Meeting.

The testimony on the original resolution (Resolution 716-A-18) was largely supportive of the intent to develop a universal clearinghouse that centralizes the verification of credentialing information; however, some members noted that the cost of implementation may be significant and that there were still many unanswered questions about the demand for such a service and how it would work. Others were concerned as to whether the AMA is the organization best positioned to take up the issue.

This informational report provides an update on hospital closure activity, changes and updates to associated legal or regulatory requirements, and the status of various efforts to centralize records for impacted institutions.

DISCUSSION

According to Becker's Hospital CFO Review, at least 12 hospitals have closed between January and June of 2019 with another 12 filing for bankruptcy from January through April. This does not include the 100+ year old Philadelphia-based Hahnemann University Hospital, which is the primary teaching hospital affiliated with Drexel University College of Medicine. This announced bankruptcy and facility closure will displace approximately 40% of the hospital's physician and other clinical staff, some 571 residents, fellows, and medical students currently in training. Additionally, a report issued by Navigant Consulting in Chicago, Illinois found that over twenty percent of rural hospitals across the U.S. are at risk of closure. All indications are that this will continue to be an issue that significantly impacts students, residents, and physicians from multiple angles.

Figure 1: Rural Hospital Financial Risk

THE NUMBER AND PERCENTAGE OF RURAL HOSPITALS AT HIGH RISK OF CLOSING* 21% OF U.S. RURAL HOSPITALS are at a HIGH RISK OF CLOSING unless their financial situations improve



As previously reported, a thorough review of existing law revealed few requirements for the retention of physician credentialing records when a hospital closes. Some states have legislation requiring the hospital to implement policies for the preservation of medical staff credentialing files (e.g., Illinois and New York); however, most states have no specific law or regulations providing for the timely transfer of medical staff credentialing files and proper notification to physicians.

Despite the lack of specific legislation, industry credentialing experts have shared anecdotal examples that indicate that institutions generally recognize the importance of these records and often attempt to make arrangements for their files prior to closure. Reportedly, this usually leads to shipping boxes of paper to another local institution for safekeeping. In the case of bankruptcy, the records may be included as part of the bankruptcy proceedings.

Various industry stakeholders have developed processes and programs to manage and store certain information that would traditionally be verified by a hospital or training program with varying success. The Federation of State Medical Boards (FSMB) offers a graduate medical education (GME) closed program service. Through this program, FSMB offers to permanently store the records of residents who attended the program. FSMB charges a fee to the closing program that fluctuates depending on whether they are providing electronic or paper records. They have also consulted with The Joint Commission, the National Committee for Quality Assurance (NCOA), URAC and state licensing boards to ensure that the information provided through this program meets the primary source verification requirements. FSMB charges an institution verifying the credentials of an impacted physician \$60 per physician per program validation. They currently maintain the records from over 30 closed facilities representing well over one hundred individual training programs. FSMB has been in contact with the previously mentioned Hahnemann University Hospital about their services. This program, however, is limited in its scope. Currently it is specific to the storage and maintenance of training records and does not extend to work history or the evaluation of voluntary or involuntary termination of medical staff membership or the voluntary or involuntary limitation, reduction or loss of clinical privileges.

 In January of 2013, the National Association of Medical Staff Services (NAMSS) launched NAMSS Pass, a secure online database that provides access to primary source affiliation history for clinicians. The information includes affiliation history with verified dates. In some instances, a letter of good standing may be included. NAMSS reports that less than 10% of U.S. hospitals have elected to utilize the program. The most common reasons cited for not participating are that it is extra work that does not improve the credentialing process and that the facility's legal department

prohibits the provision of this information to NAMSS Pass. NAMSS continues to work to garner greater adoption and make necessary changes to secure additional information beyond affiliations in the event of a hospital closure.

As noted in previous reports, various states have also been looking at centralizing credentialing activities which has the potential to address the hospital closure issue. Oregon, one of the more recent efforts, announced their decision to suspend their Common Credentialing program citing complexity and expense.

The AMA has been in contact with these organizations as well as others in an effort to identify ways to address the issue of ensuring accessible data after an institution closure as well as to reduce the burden placed on physicians during the credentialing process. Today, the AMA through its Credentialing Profile service acts as a centralized repository of certain credentialing data, including state licensure and actions, board certification, drug enforcement agency (DEA), medical education and Accreditation Council for Graduate Medical Education (ACGME) accredited training. The AMA continually explores the expansion of this service offering, however, recognizes that certain aspects of the credentialing and privileging information maintained by the medical staff office will be extremely challenging to centralize. For example, these files customarily include peer reviews that institutions are reluctant to store outside their organization.

AMA POLICY

AMA policy supports the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes, and other health care facilities. Policy H-230.956, "Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records" states that, where in accordance with state law and regulations, "...(t)he governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility..." and "make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status." Policy H-230.956 also states that the closing facility "...shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information."

CONCLUSION

When a hospital closes, there are significant impacts to students, residents, and physicians, that impact their personal lives and careers including ensuring their training and/or privileging history can be verified during future credentialing events. While several stakeholders are looking to address this issue, currently a universally accepted solution does not exist. Further, because this is not regulated or legally mandated, any planning or transition is primarily voluntary. Institutions, however, generally have the desire to ensure a responsible transition for these records. This is a complex issue that the AMA continues to monitor. The AMA stands committed to exploring cost effective and scalable solutions that preserve medical staff credentialing files and avoid undue delays in future credentialing events.

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APPENDIX - AMA POLICIES RELATED TO THIS REPORT

H-230.956, "Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records"

- 1. AMA policy regarding the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes and other health care facilities, where in accordance with state law and regulations is as follows:
 - A. Governing Body to Make Arrangements: The governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility.
 - B. Transfer to New or Succeeding Custodian: Such a facility shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information. In the alternative, the facility shall seek to make arrangements with a reputable commercial storage firm. The new or succeeding custodian shall be obligated to treat these records as confidential.
 - C. Documentation of Physician Credentials: The governing body shall make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status.
 - D. Maintenance and Retention: Physician credentialing information and CME information transferred from a closed facility to another hospital, other entity, or commercial storage firm shall be maintained in a secure manner intended to protect the confidentiality of the records.
 - E. Access and Fees: The new custodian of the records shall provide access at a reasonable cost and in a reasonable manner that maintains the confidential status of the records.
- 2. Our AMA advocates for the implementation of this policy with the American Hospital Association.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 14-I-19

Subject: Redefining AMA's Position on ACA and Healthcare Reform

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy D-165.938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our American Medical Association (AMA) to "develop a policy statement clearly outlining this organization's policies" on a number of specific issues related to the Affordable Care Act (ACA) and health care reform. The adopted policy went on to call for our AMA to report back at each meeting of the HOD. BOT Report 6-I-13, "Redefining AMA's Position on ACA and Healthcare Reform," accomplished the original intent of the policy. This report serves as an update on the issues and related developments occurring since the most recent meeting of the HOD.

MACRA IMPROVEMENT

 The AMA has continued work with the Centers for Medicare & Medicaid Services (CMS) to make improvements to the Merit-based Incentive Payment System (MIPS) program. While initial data on 2018 results show that 98 percent of eligible clinicians successfully participated in the program, the program's requirements have proven both costly and burdensome for physicians and will likely be increasingly so in coming years. For the past year, the AMA has worked extensively with the physician community and CMS to develop reforms that would move the program from multiple silos of reporting requirements to a more relevant and less burdensome construct centered around episodes of care, conditions, or other public health priorities.

 We are pleased that the 2020 proposed rule introduces MIPS Value Pathways (MVPs) to begin in 2021. The proposed framework would incorporate a foundation that leverages promoting interoperability measures and a set of administration claims-based quality measures to focus on population health priorities, limiting the number of required specialty or condition specific measures physicians are required to report. While this proposal is an important step forward in making the MIPS program more clinically relevant and less burdensome, there are concerns such as the inclusion of population health administrative claims measures which the AMA fought to eliminate from the initial MIPS program. The AMA will work closely with state and national medical specialty societies to analyze the full impact of these and other related proposals in the 2020 proposed rule and make detailed recommendations to CMS to ensure successful implementation of proposed reforms.

While CMS can make considerable improvements to MACRA through regulations, other improvements will require statutory changes by Congress. As outlined in previous editions of this report, the AMA and state and national medical specialty societies have developed a series of recommended reforms that would build on the current efforts of CMS by providing additional flexibility for participating clinicians in MIPS, better alignment of reporting requirements, and facilitating the adoption of Alternative Payment Models (APMs). While many of these proposals could likely be implemented in a budget neutral manner, there are several which will trigger potentially significant scores.

The most significant (and costly) proposal would be to eliminate the zero percent update included in the original MACRA statute for calendar years 2020-2025. Under the law, updates through the year 2019 were to have been 0.5 percent annually, followed by zero percent for the years 2020-2025. Beginning in 2026, physicians participating in MIPS would see updates of 0.25 percent and those participating in APMs would realize updates of 0.75 percent. Updates for the years 2016-2019, however, did not materialize due to subsequent legislation that significantly reduced expected updates to offset the cost of other priorities. The history of minimal updates (and cuts) for the period following the initial SGR-produced cut in 2002 until MACRA passage in 2015 followed by lower than expected updates in the five years following MACRA adoption, has resulted in Medicare physician payment rates that have increased only 6 percent since 2001. Over the same period, the cost of running a medical practice has increased 32 percent as measured by the Medicare economic index. The AMA believes that it is critical that Medicare payment policies provide an adequate margin so that practices may make the necessary investments required to successfully implement MIPS and APMs. Discussions are underway with Congressional staff to address these shortfalls.

STEPS TO LOWER HEALTH CARE COSTS

For much of this year, Congress has been heavily focused on lowering health care for consumers by reducing the cost of prescription drugs, addressing unanticipated (or "surprise") medical bills, and other proposals to increase transparency and improve public health.

In the U.S. House of Representatives, the committees on Energy and Commerce, Ways and Means, and Judiciary have all reported legislation aimed at increasing transparency and spurring competition in the prescription drug markets, consistent with AMA priorities. In all, more than 100 proposals have been introduced that, among other goals, would increase access to data to evaluate the practices of entities within the prescription drug supply and financing chain as well as eliminate incentives and deter practices that impede market entry of generics.

Significantly, prior to the August recess, the Senate Finance Committee reported bipartisan legislation, the "Prescription Drug Pricing Reduction Act of 2019." This bill includes many AMA supported initiatives such as requiring manufacturers to pay rebates to HHS if a drug price increases faster than the rate of inflation, increased transparency of PBM and manufacturer rebate and discount arrangements, promotion of biosimilar products, and site-of-service payment neutrality for Part B drug administration. There are provisions in the bill, however, that require close scrutiny to determine their impact on physician practices, such as capping ASP add on payments for Part B drugs at \$1,000 and excluding the amount of patient coupons from the calculation of ASP. While the Finance Committee proposal received bipartisan support, there are significant issues that must be addressed prior to consideration by the full Senate, including opposition by multiple members to the provision linking permissible price increases to inflation.

It is also expected that following the August recess House Democratic leadership will put forward legislation to empower the government to negotiate with manufactures for lower prescription drug prices. The bill will focus on drugs on the market without competition and give drugmakers the opportunity to recoup their investments but not maintain long standing monopolies, according to the Speaker's office.

The Administration has also put forth several proposals to address the cost of prescription drugs. Most recently, on July 31, HHS announced the "Safe Importation Action Plan" which will be the subject of an upcoming proposed regulation from the department. The plan would offer two potential pathways predicated on the invocation of Section 804 of the Federal Food, Drug and

Cosmetics Act by the Commissioner of the Food and Drug Administration. Under this provision, the Commissioner may allow for the importation from Canada of drugs if he or she certifies that doing so would not jeopardize the public health and would result in significant cost reductions. Under the proposal, there would be two possible pathways. Under the first, states, wholesalers and pharmacies could submit proposed demonstration projects for HHS review. Under a second pathway, manufacturers themselves could import of FDA approved medications. HHS noted that manufacturers have told them that they would like to offer lower cost versions of their own drugs but are prevented from doing so because they are locked into contracts with other parties in the supply chain. This option would allow them to import of their own drugs produced for the Canadian market for that purpose. Certain drugs, such as controlled substances, drugs subject to REMS, and biologics, including insulin, would not be eligible for this program.

 In February 2019, the Administration proposed to eliminate safe harbor protections for rebates paid by manufacturers to PBMs, Part D plan sponsors, and Medicaid MCOs. That plan was withdrawn in July as it became clear that plan sponsors, faced with a loss of rebate revenue, would likely raise premiums for Medicare beneficiaries.

The issue of unanticipated, or "surprise," medical bills continues to be the focus of intense activity in Congress as it has since last year. All parties agree that patients who are cared for by physicians outside of their insurer's network, either due to the emergent nature of their condition or in cases of hospital-based physicians not generally selected by the patient, should not be penalized due to the fact that their plan did not have a contract with that physician. In these cases, the AMA agrees that patients should only be held liable for the same amounts they would have paid had they been seen by an in-network physician. Most of the leading legislative proposals are consistent with this goal. Significant differences exist, however, in how these proposals determine the appropriate amount that the plan should pay the physician for their services.

The "Lower Health Care Cost Act," S. 1895, was reported by the Senate Committee on Health, Education, Labor, and Pensions on June 26, 2019. While this bill contains numerous other provisions to lower health care costs, the primary source of the bill's savings is Title I, "Ending Surprise Medical Bills." Under the proposal, out-of-network (OON) physicians would be paid at the median in-network rate for physicians contracted by the plan in the same geographic region and would be banned from balance billing patients. The Congressional Budget Office has noted that since physicians who decline to accept contract terms offered by plans would be paid at the median in-network rate regardless of their contract status, average rates could fall by 15-20 percent as the average rates coverage around the median—though the absolute number of physicians who will see increases (those now below the median) and those who will see decreases (those above the median) will be roughly the same. It is noteworthy that 80 percent of the savings is derived from lower innetwork rates. Going forward, CBO expresses a good deal of uncertainty on the long-term impact of these changes, with one possibility being increased provider consolidation results in upward pressure on price growth.

The AMA and impacted specialties continue to strongly advocate in the alternative that Congress adopt an independent dispute resolution (IDR) process, like the successful program in New York, to resolve physician-payer disputes while continuing to hold the patient harmless. Support for this approach has been voiced by several members of the HELP committee, including Sen. Bill Cassidy, MD (R-LA), Sen. Maggie Hassan (D-NH), and Sen. Lisa Murkowski (R-AK). During the committee consideration of the bill, Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) committed to consideration of an IDR process, though no resolution has been reached as of this writing.

Of the other health care cost provisions in S. 1896, many are well intentioned though potentially burdensome or impractical for physicians. One would require that all bills would have to be sent to a patient with 45 days or patients would not have to pay. Another would increase physician responsibility for the accuracy of plan's provider directories. The AMA continues to discuss these and other provisions with the committee.

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On July 17, the House Committee on Energy and Commerce reported H.R. 2328, the "Reauthorizing and Extending America's Community Health Act" or the "REACH Act." Title IV of the bill is the text of the "No Surprises Act" offered by Committee Chairman Frank Pallone (D-NJ) and Ranking member Greg Walden (R-OR). The bill follows the general outline of the HELP bill, holding patients harmless from unanticipated bills and paying the OON physician at the in-network median rate. During the committee's consideration of the bill, an amendment by Rep. Raul Ruiz, MD, (D-CA) and Rep. Larry Bucshon, MD, (R-IN) was adopted to include a limited independent dispute resolution process for claims above a \$1,250 threshold. While the provision is not ideal, it represents an important step forward in the efforts of organized medicine to include a fair and independent process to resolve disputes with payers.

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Two additional committees of the House, Ways and Means and Education and Labor, are expected to consider proposals addressing unanticipated medical bills following the August recess. The AMA, state medical associations, and many national medical specialty societies are continuing efforts to ensure the any legislation adopted to address "surprise" bills provides for a fair resolution of payment disputes while holding patients harmless.

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COVERAGE

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Several House committees have reported legislation to strengthen the Affordable Care Act by increasing funding for Navigator programs, expanding the availability of ACA subsidies, providing support for the establishment of state-based marketplaces, increasing outreach and enrollment activities and other actions to preserve and strengthen current coverage options. Despite these actions, it is unlikely that similar legislation will emerge from the Senate in the current environment. Much of the current attention has been focused on single payer plans put forth in both the House and the Senate. The AMA continues to oppose this approach and remains focused on strengthening what works and expanding access to and choice of affordable, quality health insurance. Despite pressure from many members of the Democratic caucus, House leadership remains reluctant to take up single payer proposals. Polling has shown that while the concept of single payer, or "Medicare for All" proposals is popular, support falls off sharply when the implications of doing away with current coverage pathways is more closely examined. The AMA continues to support health insurance coverage for all Americans that is focused on pluralism, freedom of choice, freedom of practice and universal access for patients and will direct our advocacy efforts toward these goals.

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REPEAL OF THE NON-PHYSICIAN PROVIDER NON-DISCRIMINATION PROVISIONS OF THE ACA

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Though the previous Administration determined that no action was necessary to implement the non-physician provider non-discrimination provision of the Affordable Care Act, proponents continue to encourage efforts by the Administration to propose regulations. During the July 17 mark-up of legislation in the House Committee on Energy and Commerce, an amendment was offered and later withdrawn to require the Administration to initiate rulemaking. Though legislation to repeal this provision has not been introduced during the past two Congresses, AMA will continue to seek opportunities to implement HOD policy related to this provision.

CONCLUSION

- Our AMA will remain engaged in efforts to improve the health care system through policies outlined in Policy D-165.938 and other directives of the House of Delegates.
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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 1-I-19

Subject: For-Profit Medical Schools or Colleges

Presented by: Jacqueline A. Bello, MD, Chair

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American Medical Association (AMA) Policy D-305.954, "For-Profit Medical Schools or Colleges," states:

That our American Medical Association study issues related to medical education programs offered at for-profit versus not-for-profit medical schools, to include the: (1) attrition rate of students, (2) financial burden of non-graduates versus graduates, (3) success of graduates in obtaining a residency position, and (4) level of support for graduate medical education, and report back at the 2019 Annual Meeting.

The Council on Medical Education recognized the importance and timeliness of this topic and agreed that appropriate resources and data collection were needed to study this issue and prepare the report. However, meaningful and constructive review of this issue and the data collection required additional time. The Council therefore is presenting this report at the 2019 Interim Meeting.

 For-profit medical schools are a rare phenomenon within the United States, and the numbers of these schools have not increased substantially, with only six for-profit U.S. medical schools. That said, there are a large and growing number of for-profit medical schools located in the Caribbean that are attended by U.S. citizens. This report focuses on for-profit medical schools located in the United States, and provides available attrition rates, general financial information associated with students who attend for-profit vs. not-for-profit medical schools, and data on student transition into residency programs. Very limited data are also included on for-profit medical schools located in the Caribbean, as such data are not publicly available.

BACKGROUND

In the 19th century, the majority of medical schools were the property of the faculty and, therefore, could be considered "for-profit." In 1906, early accreditation standards from the Council on Medical Education required that schools not be conducted for the financial benefit of the faculty. A 1996 ruling against the American Bar Association, related to restraint of trade, opened up the possibility of accreditation of for-profit law schools and set a legal precedent for the establishment of for-profit medical schools. ¹⁻³ Currently, medical school accreditation bodies, including the Liaison Committee on Medical Education (LCME) and American Osteopathic Association Commission on Osteopathic College Accreditation (COCA), are responsible for reviewing the financial status of U.S. medical schools and monitoring graduation rates and student debt.

Four for-profit osteopathic medical schools are in various stages of becoming accredited by COCA. In 2007, provisional accreditation was granted to investor-owned Rocky Vista University College of Osteopathic Medicine in Colorado. The College was founded to address the need for community-based primary care physicians in the Mountain West region. The Burrell College of

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Osteopathic Medicine at New Mexico State University, a privately funded osteopathic medical school founded in 2013, holds pre-accreditation status from COCA, and is expected to be fully accredited when its first class graduates in 2020.⁴ In 2016, the Idaho College of Osteopathic Medicine and the California Health Sciences University College of Osteopathic Medicine were founded to help address regional physician shortages in underserved areas.⁵ Both schools have initiated the accreditation process with COCA.

The LCME, by comparison, has granted accreditation to two for-profit allopathic medical schools. In 2013, the LCME modified its standards to remove mention of "for-profit" in the accreditation of allopathic medical schools. One year later, Ponce Health Sciences University School of Medicine (a 35-year-old not-for profit institution in Puerto Rico reported to be in financial distress) was acquired by Arist Medical Sciences University, a for-profit public benefit corporation, making it the first for-profit allopathic medical school accredited by the LCME. In 2015, California Northstate University College of Medicine, a private, for-profit medical school focused on educating, developing, and training physicians to address the primary care physician shortage in northern California, gained preliminary accreditation from the LCME and enrolled its first class of students.

FOR-PROFIT MEDICAL SCHOOLS IN THE CARIBBEAN

There is a growing number of for-profit medical schools located in the Caribbean, often referred to as "offshore medical schools." Accreditation/approval of these schools is the purview of a variety of bodies, each with varying standards and requirements for quality and duration of education. Currently,75 offshore medical schools are acceptable to the Educational Commission for Foreign Medical Graduates (ECFMG) for graduates to obtain ECFMG certification. Offshore schools typically engage in minimal clinical or scientific research. As a result, offshore proprietary schools have a profitable business model in that their costs are mainly related to the educational program. These schools use their tuition revenue to pay faculty to teach in the basic sciences at U.S. hospitals, and as part of their tuition third- and fourth-year medical students pay to take clinical rotations in the United States.

There are no summary data available on the enrollment of U.S. citizens in offshore medical schools. However, an estimate can be made based on the number of U.S. citizens pursuing certification by the ECFMG. Of the 9,430 ECFMG certificates issued in 2018, 2,398 (25.4 percent) were issued to U.S. citizen graduates of offshore medical schools. The students/graduates registering for certification were from medical schools located in countries in the Caribbean.

ATTRITION RATES

Not-for-profit U.S. Medical Schools

The Association of America Medical Colleges (AAMC) reports that from 1993-1994 through 2012-2013, the total national attrition rate for not-for-profit medical schools remained relatively stable at an average of 3.3 percent (Appendix A, Table 1). The AAMC notes that more medical students left medical school for nonacademic than for academic reasons, and that attrition rates appeared to vary by type of degree program—that is, the attrition rates of students in combined degree programs, such as MD-MPH programs, differ from those for students in MD programs.

- The American Association of Colleges of Osteopathic Medicine (AACOM) calculates attrition rate by dividing the sum of students who withdrew or took a leave of absence by total enrollment.
- Withdrawals and dismissals are types of permanent attrition from the colleges of osteopathic

medicine (COM), while leaves of absence are types of temporary attrition that may become a withdrawal or dismissal after a period of time. 11 Reasons for students' withdrawals/dismissals include academic failure or school policy violation; poor academic standing; transferring to another medical school; medical or personal reasons; changes in career plans; and failure to take or pass COMLEX (per COM policy). Reasons for leaves of absence include poor academic performance/remediation; academic enrichment/research/study for another degree; medical or personal reasons; and failure to take or pass COMLEX (per COM policy). AACOM only reports on those schools with a full four-year enrollment.

Attrition rates for all COMs ranged from a low of 2.63 percent (2009-2010) to a high of 3.59 percent (2012-2013), with an average 3.03 percent attrition rate from 2009-2010 through 2018-2019 (Table 1).¹¹ AACOM reports that first-and third-year students had a higher rate of attrition than their second- and fourth-year counterparts, due largely to the struggles first-year students experience when adjusting to the rigors of medical school and to COMLEX being administered to third-year students.

For-profit Medical Schools

Ponce Health Sciences University School of Medicine reports on its website that its average attrition rate for 2016-2017 was 2.3 percent (Table 1). Although actual attrition rates are not available for California Northstate University College of Medicine, the school's website notes that a total of 60 new students enrolled in fall 2015, one student left the program, and three students fell back a year, with a total attrition of one student (1.7 percent). Rocky Vista University College of Osteopathic Medicine, the only COM that has a full class (four years of students enrolled), reports on its website that 91 percent of Title IV students complete the program within four years. Data on attrition rates for newer U.S. medical and osteopathic schools as well as offshore medical schools are not available.

FINANCIAL BURDEN

Not-for-profit U.S. Medical Schools

In 2018-2019, the median annual tuition and fees at state medical schools were \$38,202; at private medical schools the median cost was \$61,533 (Appendix B, Table 2).¹⁵ In 2019, for students who attended state medical schools, the median debt was \$190,000; for students who attended private medical schools, the median debt was \$210,000.¹⁵ The overall mean osteopathic medical education debt reported by academic year 2017-2018 graduates is \$254,953 (\$222,972 for public schools and \$261,133 for private schools).¹⁶

For-profit Medical Schools

The four-year estimated tuition, fees, and cost of attending a for-profit U.S. medical school can range from \$209,000 to \$342,000 (Table 2). Rocky Vista University College of Osteopathic Medicine reports that four-year estimated tuition, fees, and costs is \$215,748, and its typical graduate leaves with \$294,018 debt.¹⁷ Median student loan debt accrued for attending an offshore medical school ranges from \$191,500 (Ross University School of Medicine) to \$253,072 (American University of the Caribbean School of Medicine).⁷

SUCCESS OF U.S. GRADUATES IN OBTAINING A RESIDENCY POSITION

Not-for-profit U.S. Medical Schools

 The National Resident Matching Program (NRMP) defines a successful match into a residency program as "one that is measured not just by volume, but also by how well it matches the preferences of applicants and program directors." In 2019, U.S. allopathic medical school senior students comprised 18,925 of the active applicants, and the first-year post-graduate (PGY-1) Match rate for U.S. seniors was 93.9 percent.

In 2019, the transition to a single accreditation system resulted in higher participation among students and graduates of U.S. osteopathic medical schools. An all-time high of 6,001 DO candidates submitted NRMP rank and order lists of programs, and the 84.6 percent PGY-1 match rate was the highest in history.¹⁸

 Earlier Match data reflected NRMP and AOA National Matching Service (NMS) systems. Data reported by the COMs show that 98.7 percent of spring 2018 graduates seeking GME successfully placed into GME as of April 12, 2018. This represents 6,224 new physicians beginning their graduate medical education in July 2018. This compares to the 2017 match/placement process, when 5,898 new physicians entered GME (99.3 percent of graduates seeking GME) and 2016, when 5,356 graduates were successfully matched/placed—99.6 percent of graduates seeking to enter GME.

The 2020 Match will be the first single match system administered by the NRMP, to include both allopathic and osteopathic residency programs. This single system will simplify the matching process for osteopathic medical school students. A result of the new process will be a shift in the way the Match rate percentage is reported.

For-profit Medical Schools

The California Northstate University College of Medicine class of 2019 had a 96.3 percent overall Match rate. Rocky Vista University College of Osteopathic Medicine reported that the majority of students (79 percent) found a residency placement through the 2019 NRMP match, while other students matched into their top choices through the AOA Intern/Resident Registration Program (12 percent) or into military-specific residency programs (nine percent).

However, fewer students matched into U.S. residency programs at some of the other for-profit schools. For example, Ponce Health Sciences University School of Medicine reported that its 2016-2017 initial residency Match rate (aside from the Supplemental Offer and Acceptance Program, or SOAP) was 89.4 percent, vs. 84.4 percent in 2017-2018. In 2019, 5,080 U.S. IMGs (primarily graduates of offshore medical schools) participated in the NRMP, and 59 percent (n=2,997) successfully matched.

LEVEL OF SUPPORT FOR GRADUATE MEDICAL EDUCATION

All U.S. allopathic and osteopathic medical schools are required to prepare their students to successfully transition into Accreditation Council for Graduate Medical Education (ACGME)-accredited GME programs. Two new for-profit osteopathic medical schools are in the process of developing their GME programs. Burrell College of Osteopathic Medicine at New Mexico State University has facilitated the ongoing development of new residency programs in family medicine, internal medicine, orthopaedic surgery, and osteopathic neuromusculoskeletal medicine, and

additional new GME programs are under development.²² The leadership at the Idaho College of Osteopathic Medicine body is also focused on being able to provide its students with a high-quality academic and clinical clerkship experience and facilitating their placement into ACGME-accredited residency programs.²³

1 2

Concern has been raised about the paucity of academic teaching hospitals associated with some for-profit medical schools. For example, students who attend Rocky Vista University College of Osteopathic Medicine complete clinical rotations at various hospitals throughout the state of Colorado and the mountain west region.²⁴ Third- and fourth-year medical students in their clerkships could be sent for rotations to nonacademic community hospitals without a strong background in education and research.²⁴ Although the college was established on the premise that physicians practice in locations close to their residency or fellowship programs, many of the graduates have had to leave the state to complete residency training requirements.²⁴

Offshore for-profit medical schools, including those in the Caribbean, continue to provide a large number of medical school graduates who return to the United States for GME.²⁴ However, the accreditation standards these schools are held to, if any, vary widely and may not require that the schools provide career counseling or support for the transition of their students into ACGME-accredited programs.²⁵

RELEVANT AMA POLICY

The AMA has extensive policy related to the cost and financing of medical education.

Policy H-305.925 (20f), "Principles of and Actions to Address Medical Education Costs and Student Debt," states that the costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue related to the Public Service Loan Forgiveness (PSLF) Program, the AMA will advocate that the profit status of a trainee's institution not be a factor for PSLF eligibility.

Policy H-200.949 (3), "Principles of and Actions to Address Primary Care Workforce," directs the AMA, through its work with stakeholders, to encourage development and dissemination of innovative models to recruit medical students interested in primary care, train primary care physicians, and enhance both the perception and the reality of primary care practice, to encompass the following components: a) Changes to medical school admissions and recruitment of medical students to primary care specialties, including counseling of medical students as they develop their career plans; b) Curriculum changes throughout the medical education continuum; c) Expanded financial aid and debt relief options; d) Financial and logistical support for primary care practice, including adequate reimbursement, and enhancements to the practice environment to ensure professional satisfaction and practice sustainability; and e) Support for research and advocacy related to primary care.

Policy D-295.309, "Promoting and Reaffirming Domestic Medical School Clerkship Education," directs the AMA to support agreements for clerkship rotations, where permissible, for U.S. citizen international medical students between foreign medical schools and teaching hospitals in regions that are medically underserved and/or that lack medical schools and clinical sites for training medical students, to maximize the cumulative clerkship experience for all students and to expose these students to the possibility of medical practice in these areas.

Additional related policies are provided in Appendix C.

SUMMARY

Stigma and reputational challenges associated with for-profit medical schools can be traced back to the 1910 Flexner Report on Medical Education in the United States and Canada, which called for quality education that linked medical schools with universities and teaching hospitals.³ The report criticized for-profit schools, and the subsequent linkage between accreditation and licensure requirements led to the collapse of many proprietary medical schools. However, for-profit medical education has reemerged in the United States and has expanded in the Caribbean and elsewhere around the world.^{7, 24} The Ponce Health Sciences University School of Medicine was recently incorporated to facilitate the retention of public benefit.¹

For-profit schools are based on a tuition-dependent business model. For example, at Rocky Vista University College of Medicine approximately 80 percent of revenue, as with the other private osteopathic medical schools, comes from tuition and fees. In contrast, tuition and fees constitute only 14 percent of public osteopathic medical schools' revenues.²⁴

As with any medical school, for-profit medical schools may have a positive impact on the physician workforce. For example, the mission of California Northstate University College of Medicine is to train primary care physicians to serve the needs in underserved areas in northern California. As with other medical schools, however, the graduates of U.S. for-profit medical schools are subject to competition for residency placements. Graduates from for-profit medical schools in the Caribbean need to complete the requirements for ECFMG certification before they can apply for residency training in the United States.

Through its Council on Medical Education, the AMA will continue to monitor the development of for-profit medical schools, both allopathic and osteopathic, and report back to the House of Delegates as needed.

APPENDIX A TABLE 1. ATTRITION RATE OF STUDENTS ATTENDING U.S. MEDICAL SCHOOLS

Not-for-profit	Attrition Rate:
U.S. allopathic medical schools	From 1993-1994 through 2012-2013, the total national attrition rate remained relatively stable at an average of 3.3% ¹
U.S. osteopathic medical schools	From a low of 2.63% (2009-10) to a high of 3.59% (2012-13), with an average of 3.03% attrition rate from 2009-10 through 2018-19. ²
For-profit*	Attrition Rate:
Ponce Health Sciences University School of Medicine	Average attrition rate is 2.3%; retention rate is 97.7% (2016-2017) ³
California Northstate University College of Medicine**	Total of 60 new students enrolled in the Fall of 2015: one student left the program and three students fell back a year; the total attrition of 1 student (1.7%).
Rocky Vista University College of Osteopathic Medicine**	91% of Title IV students complete the program within 4 years with an attrition rate of 9%. ⁵
Burrell College of Osteopathic Medicine at New Mexico State University**	Matriculated 162 students in 2018; retained 154 (95.06%) with an attrition rate of 4.94%. ⁶
Idaho College of Osteopathic Medicine***	Matriculated its inaugural class in August 2018. This class of 2022 is composed of graduates from 97 U.S. colleges and universities, with above average composite medical board (MCAT) scores and highly competitive undergraduate grade point averages. ⁷
California Health Sciences University College of Osteopathic Medicine***	Campus construction underway with targeted completion date of Spring 2020.

- * Similar quality data are not available from offshore medical schools
- ** Attrition rate is extrapolated from the retention rate posted on the medical school's website.
- ***Data on attrition rates for newer U.S. medical schools are not yet available.
- AAMC Data Snapshot. Association of American Medical Colleges. Available at: https://www.aamc.org/download/492842/data/graduationratesandattritionratesofu.s.medicalstudents.pdf (Accessed April 9, 2019).
- 2. 2019-2020 Student Guide to Osteopathic Medical Colleges. American Association of Colleges of Osteopathic Medicine. 2019. Available at: https://www.aacom.org/docs/default-source/presentations/student-guide-for-web-5-28-19.pdf?sfvrsn=4aab3d97_2 (Accessed July 2, 2019).
- Consumer Information and Student Achievement Guide 2017-2018. Ponce Health Sciences University. Available at: https://www.psm.edu/wp-content/uploads/2016/09/Ponce-Health-Sciences-University-Consumer-Information-and-Student-Achievement-Guide.pdf (Accessed July 2, 2019).
- California Northstate University Fact Book, 2017-2018. California Northstate University. Available at: https://www.cnsu.edu/shareddocs/Fact-Book-2017-2018.pdf (Accessed July 2, 2019).
- 5. RVU At A Glance. Rocky Vista University. Available at: http://www.rvu.edu/about/rvu-at-a-glance/ (Accessed July 2, 2019).
- 6. Burrell College of Osteopathic Medicine Institutional Snapshot. Burrell College of Osteopathic Medicine. Available at: https://bcommm.org/wp-content/uploads/2019/05/Institutional-Snapshot.pdf (Accessed July 2, 2019).
- 7. Idaho College of Osteopathic Medicine. About ICOM. Available at: https://www.idahocom.org/ (Accessed July 2, 2019).

APPENDIX B TABLE 2. FINANCIAL BURDEN OF NON-GRADUATES VERSUS GRADUATES OF U.S. MEDICAL SCHOOLS

Not-for-profit	Financial Burden
U.S. allopathic medical schools	In 2018-2019, the median annual tuition and fees at
	state medical schools were \$38,202; at private
	medical schools the median cost was \$61,533.6
	In 2019, for students who attended state medical
	schools the median debt was \$190,000; for students
	who attended private medical schools the median
	debt was \$210,000.1
U.S. osteopathic medical schools	The overall mean osteopathic medical education debt
	reported for academic year 2017-2018 graduates is
	\$254,953 (\$222,972 for public schools and \$261,133
	for private schools). ²
For-profit*	Financial Burden
Ponce Health Sciences University	4-year estimated tuition, fees and costs range from
School of Medicine	\$233,456 to \$342,069. ³
School of Medicine California Northstate University College	4-year estimated tuition, fees, and costs range from
California Northstate University College	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748;
California Northstate University College of Medicine	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000.4
California Northstate University College of Medicine Rocky Vista University College of	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748;
California Northstate University College of Medicine Rocky Vista University College of Osteopathic Medicine	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748; typical graduate leaves with \$294,018 in debt. ⁵
California Northstate University College of Medicine Rocky Vista University College of Osteopathic Medicine Burrell College of Osteopathic Medicine at New Mexico State University** Idaho College of Osteopathic	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748; typical graduate leaves with \$294,018 in debt. ⁵
California Northstate University College of Medicine Rocky Vista University College of Osteopathic Medicine Burrell College of Osteopathic Medicine at New Mexico State University**	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748; typical graduate leaves with \$294,018 in debt. ⁵ 2018-2019 annual cost of attendance is \$80,165. ⁶ 2018-2019 academic year annual tuition is \$49,750 plus \$2,500 in fees. ⁷
California Northstate University College of Medicine Rocky Vista University College of Osteopathic Medicine Burrell College of Osteopathic Medicine at New Mexico State University** Idaho College of Osteopathic	4-year estimated tuition, fees, and costs range from \$240,000 to \$255,000. ⁴ 4-year estimated tuition, fees, and cost are \$215,748; typical graduate leaves with \$294,018 in debt. ⁵ 2018-2019 annual cost of attendance is \$80,165. ⁶ 2018-2019 academic year annual tuition is \$49,750

^{*}Data not available from offshore medical schools

- Medical Student Education: Debt, Costs, and Loan Repayment Fact Card. Association of American Medical Colleges. Available at: https://store.aamc.org/downloadable/download/sample/sample-id/240/ (Accessed July 2, 2019).
- 2017-2018 Academic Year Survey of Graduating Seniors Summary. American Association of Colleges of Osteopathic Medicine. Available at: https://www.aacom.org/docs/default-source/data-and-trends/aacom-2017-2018-academic-year-graduating-seniors-survey-summary-report.pdf?sfvrsn=e14d2197 (Accessed July 2, 2019).
- Ponce Health Sciences University Educational Budget Academic Year 2019-2020 Doctor in Medicine Program (4 years). Ponce Health Sciences University. Available at: https://www.psm.edu/coa/EDUC% 20BUDGETS% 20MD% 204% 20YRS.pdf (Accessed July 23, 2019).
- 4. Cost of Attendance and Tuition and Fees. California Northstate University College of Medicine. Available at: https://www.cnsu.edu/shareddocs/StudentFA/TuitionandFeesCOM2.pdf (Accessed July 23, 2019).
- 5. Rocky Vista University. Available at: http://www.rvu.edu/gedt/gedt.html (Accessed July 16, 2019).
- BCOM Estimated Cost of Attendance (COA). Burrell College of Osteopathic Medicine. Available at: https://bcommm.org/budgeting-your-education/ (Accessed July 23, 2019).
- Idaho College of Osteopathic Medicine. Tuition, Fees & Financial Aid. Available at: https://choosedo.org/idaho-college-of-osteopathic-medicine-icom/ (Accessed July 23, 2019).
- 8. California Health Sciences University College of Osteopathic Medicine. Tuition, Fees & Financial Aid. Available at: https://choosedo.org/california-health-sciences-university-college-of-osteopathic-medicine-chsu-com/ (Accessed July 23, 2019).

^{**}Data on student debt for newer U.S. medical schools are not yet available

APPENDIX C AMA POLICY

D-305.954, "For-Profit Medical Schools or Colleges"

Our AMA will study issues related to medical education programs offered at for-profit versus not-for-profit medical schools, to include the: (a) attrition rate of students; (b) financial burden of non-graduates versus graduates; (c) success of graduates in obtaining a residency position; and (d) level of support for graduate medical education; and report back at the 2019 Annual Meeting. (Res. 302, A-18)

H-305.988, "Cost and Financing of Medical Education and Availability of First-Year Residency Positions"

Our AMA:

- 1. believes that medical schools should further develop an information system based on common definitions to display the costs associated with undergraduate medical education;
- 2. in studying the financing of medical schools, supports identification of those elements that have implications for the supply of physicians in the future;
- 3. believes that the primary goal of medical school is to educate students to become physicians and that despite the economies necessary to survive in an era of decreased funding, teaching functions must be maintained even if other commitments need to be reduced:
- 4. believes that a decrease in student enrollment in medical schools may not result in proportionate reduction of expenditures by the school if quality of education is to be maintained;
- 5. supports continued improvement of the AMA information system on expenditures of medical students to determine which items are included, and what the ranges of costs are;
- 6. supports continued study of the relationship between medical student indebtedness and career choice;
- 7. believes medical schools should avoid counterbalancing reductions in revenues from other sources through tuition and student fee increases that compromise their ability to attract students from diverse backgrounds;
- 8. supports expansion of the number of affiliations with appropriate hospitals by institutions with accredited residency programs;
- 9. encourages for profit-hospitals to participate in medical education and training;
- 10. supports AMA monitoring of trends that may lead to a reduction in compensation and benefits provided to resident physicians;
- 11. encourages all sponsoring institutions to make financial information available to help residents manage their educational indebtedness; and
- 12. will advocate that resident and fellow trainees should not be financially responsible for their training. (CME Rep. A, I-83 Reaffirmed: CLRPD Rep. 1, I-93 Res. 313, I-95 Reaffirmed by CME Rep. 13, A-97 Modified: CME Rep. 7, A-05 Modified: CME Rep. 13, A-06 Appended: Res. 321, A-15 Reaffirmed: CME Rep. 05, A-16 Modified: CME Rep. 04, A-16)

H-305.925, "Principles of and Actions to Address Medical Education Costs and Student Debt"

The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue, our American Medical Association (AMA) will:

- 1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through publicand private-sector advocacy.
- 2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector to promote practice in underserved areas, the military, and academic medicine or clinical research.
- 3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.
- 4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.

- 5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
- 6. Work to reinstate the economic hardship deferment qualification criterion known as the 20/220 pathway, and support alternate mechanisms that better address the financial needs of trainees with educational debt.
- 7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pretax dollars to be used to pay for student loans.
- 8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.
- 9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).
- 10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.
- 11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.
- 12. Encourage medical schools to (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education; (b) Engage in fundraising activities to increase the availability of scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, lowinterest loan programs; (c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students; (d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students; (e) Counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation; (f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen; (g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees; (h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; (i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.
- 13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.
- 14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals: (a) Eliminating the single holder rule; (b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training; (c) Retaining the option of loan forbearance for residents ineligible for loan deferment; (d) Including, explicitly, dependent care expenses in the definition of the cost of attendance; (e) Including room and board expenses in the definition of tax-exempt scholarship income; (f) Continuing the federal Direct Loan Consolidation program, including the ability to lock in a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs; (g) Adding the ability to refinance Federal Consolidation Loans; (h) Eliminating the cap on the student loan interest deduction; (i) Increasing the income limits for taking the interest deduction; (j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001; (k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating; (l) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.

- 15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.
- 16. Continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.
- 17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.
- 18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.
- 19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.
- 20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will: (a) Advocate that all resident/fellow physicians have access to PSLF during their training years; (b) Advocate against a monetary cap on PSLF and other federal loan forgiveness programs; (c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed; (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note: (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer; (f) Advocate that the profit status of a physician s training institution not be a factor for PSLF eligibility; (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed; (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas; (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.
- 21. Advocate for continued funding of programs including Income-Driven Repayment plans for the benefit of reducing medical student load burden.

(CME Report 05, I-18 Appended: Res. 953, I-18 Reaffirmation: A-19)

H-200.949, "Principles of and Actions to Address Primary Care Workforce"

- 1. Our patients require a sufficient, well-trained supply of primary care physicians--family physicians, general internists, general pediatricians, and obstetricians/gynecologists--to meet the nation's current and projected demand for health care services.
- 2. To help accomplish this critical goal, our American Medical Association (AMA) will work with a variety of key stakeholders, to include federal and state legislators and regulatory bodies; national and state specialty societies and medical associations, including those representing primary care fields; and accreditation, certification, licensing, and regulatory bodies from across the continuum of medical education (undergraduate, graduate, and continuing medical education).
- 3. Through its work with these stakeholders, our AMA will encourage development and dissemination of innovative models to recruit medical students interested in primary care, train primary care physicians, and enhance both the perception and the reality of primary care practice, to encompass the following components: a) Changes to medical school admissions and recruitment of medical students to primary care specialties, including counseling of medical students as they develop their career plans; b) Curriculum changes throughout the medical education continuum; c) Expanded financial aid and debt relief options; d) Financial and logistical support for primary care practice, including adequate reimbursement, and

enhancements to the practice environment to ensure professional satisfaction and practice sustainability; and e) Support for research and advocacy related to primary care.

- 4. Admissions and recruitment: The medical school admissions process should reflect the specific institution s mission. Those schools with missions that include primary care should consider those predictor variables among applicants that are associated with choice of these specialties.
- 5. Medical schools, through continued and expanded recruitment and outreach activities into secondary schools, colleges, and universities, should develop and increase the pool of applicants likely to practice primary care by seeking out those students whose profiles indicate a likelihood of practicing in primary care and underserved areas, while establishing strict guidelines to preclude discrimination.
- 6. Career counseling and exposure to primary care: Medical schools should provide to students career counseling related to the choice of a primary care specialty, and ensure that primary care physicians are well-represented as teachers, mentors, and role models to future physicians.
- 7. Financial assistance programs should be created to provide students with primary care experiences in ambulatory settings, especially in underserved areas. These could include funded preceptorships or summer work/study opportunities.
- 8. Curriculum: Voluntary efforts to develop and expand both undergraduate and graduate medical education programs to educate primary care physicians in increasing numbers should be continued. The establishment of appropriate administrative units for all primary care specialties should be encouraged.
- 9. Medical schools with an explicit commitment to primary care should structure the curriculum to support this objective. At the same time, all medical schools should be encouraged to continue to change their curriculum to put more emphasis on primary care.
- 10. All four years of the curriculum in every medical school should provide primary care experiences for all students, to feature increasing levels of student responsibility and use of ambulatory and community-based settings.
- 11. Federal funding, without coercive terms, should be available to institutions needing financial support to expand resources for both undergraduate and graduate medical education programs designed to increase the number of primary care physicians. Our AMA will advocate for public (federal and state) and private payers to a) develop enhanced funding and related incentives from all sources to provide education for medical students and resident/fellow physicians, respectively, in progressive, community-based models of integrated care focused on quality and outcomes (such as the patient-centered medical home and the chronic care model) to enhance primary care as a career choice; b) fund and foster innovative pilot programs that change the current approaches to primary care in undergraduate and graduate medical education, especially in urban and rural underserved areas; and c) evaluate these efforts for their effectiveness in increasing the number of students choosing primary care careers and helping facilitate the elimination of geographic, racial, and other health care disparities.
- 12. Medical schools and teaching hospitals in underserved areas should promote medical student and resident/fellow physician rotations through local family health clinics for the underserved, with financial assistance to the clinics to compensate their teaching efforts.
- 13. The curriculum in primary care residency programs and training sites should be consistent with the objective of training generalist physicians. Our AMA will encourage the Accreditation Council for Graduate Medical Education to (a) support primary care residency programs, including community hospital-based programs, and (b) develop an accreditation environment and novel pathways that promote innovations in graduate medical education, using progressive, community-based models of integrated care focused on quality and outcomes (such as the patient-centered medical home and the chronic care model).
- 14. The visibility of primary care faculty members should be enhanced within the medical school, and positive attitudes toward primary care among all faculty members should be encouraged.
- 15. Support for practicing primary care physicians: Administrative support mechanisms should be developed to assist primary care physicians in the logistics of their practices, along with enhanced efforts to reduce administrative activities unrelated to patient care, to help ensure professional satisfaction and practice sustainability.
- 16. There should be increased financial incentives for physicians practicing primary care, especially those in rural and urban underserved areas, to include scholarship or loan repayment programs, relief of professional liability burdens, and Medicaid case management programs, among others. Our AMA will advocate to state and federal legislative and regulatory bodies, among others, for development of public and/or private incentive programs, and expansion and increased funding for existing programs, to further encourage practice

in underserved areas and decrease the debt load of primary care physicians. The imposition of specific outcome targets should be resisted, especially in the absence of additional support to the schools.

17. Our AMA will continue to advocate, in collaboration with relevant specialty societies, for the recommendations from the AMA/Specialty Society RVS Update Committee (RUC) related to reimbursement for E&M services and coverage of services related to care coordination, including patient education, counseling, team meetings and other functions; and work to ensure that private payers fully recognize the value of E&M services, incorporating the RUC-recommended increases adopted for the most current Medicare RBRVS.

- 18. Our AMA will advocate for public (federal and state) and private payers to develop physician reimbursement systems to promote primary care and specialty practices in progressive, community-based models of integrated care focused on quality and outcomes such as the patient-centered medical home and the chronic care model consistent with current AMA Policies H-160.918 and H-160.919.
- 19. There should be educational support systems for primary care physicians, especially those practicing in underserved areas.
- 20. Our AMA will urge urban hospitals, medical centers, state medical associations, and specialty societies to consider the expanded use of mobile health care capabilities.
- 21. Our AMA will encourage the Centers for Medicare & Medicaid Services to explore the use of telemedicine to improve access to and support for urban primary care practices in underserved settings.
- 22. Accredited continuing medical education providers should promote and establish continuing medical education courses in performing, prescribing, interpreting and reinforcing primary care services.
- 23. Practicing physicians in other specialties--particularly those practicing in underserved urban or rural areas--should be provided the opportunity to gain specific primary care competencies through short-term preceptorships or postgraduate fellowships offered by departments of family medicine, internal medicine, pediatrics, etc., at medical schools or teaching hospitals. In addition, part-time training should be encouraged, to allow physicians in these programs to practice concurrently, and further research into these concepts should be encouraged.
- 24. Our AMA supports continued funding of Public Health Service Act, Title VII, Section 747, and encourages advocacy in this regard by AMA members and the public.
- 25. Research: Analysis of state and federal financial assistance programs should be undertaken, to determine if these programs are having the desired workforce effects, particularly for students from disadvantaged groups and those that are underrepresented in medicine, and to gauge the impact of these programs on elimination of geographic, racial, and other health care disparities. Additional research should identify the factors that deter students and physicians from choosing and remaining in primary care disciplines. Further, our AMA should continue to monitor trends in the choice of a primary care specialty and the availability of primary care graduate medical education positions. The results of these and related research endeavors should support and further refine AMA policy to enhance primary care as a career choice. (CME Rep. 04, I-18)

D-295.309, "Promoting and Reaffirming Domestic Medical School Clerkship Education"

- 1. Our American Medical Association:
- A. Will work with the Association of American Medical Colleges, American Association of Colleges of Osteopathic Medicine, and other interested stakeholders to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support: (1) infrastructure and faculty development and capacity for medical school expansion; and (2) delivery of clinical clerkships and other educational experiences.
- B. Encourages clinical clerkship sites for medical education (to include medical schools and teaching hospitals) to collaborate with local, state, and regional partners to create additional clinical education sites and resources for students.
- C. Advocates for federal and state legislation/regulations to: (1) Oppose any extraordinary compensation granted to clinical clerkship sites that would displace or otherwise limit the education/training opportunities for medical students in clinical rotations enrolled in medical school programs accredited by the Liaison Committee on Medical Education (LCME) or Commission on Osteopathic College Accreditation (COCA); (2) Ensure that priority for clinical clerkship slots be given first to students of LCME- or COCA-accredited medical school programs; and (3) Require that any institution that accepts students for clinical placements ensure that all such students are trained in programs that meet requirements for educational quality,

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curriculum, clinical experiences and attending supervision that are equivalent to those of programs accredited by the LCME and COCA.

- D. Encourages relevant stakeholders to study whether the public service community benefit commitment and corporate purposes of not for profit, tax exempt hospitals impose any legal and/or ethical obligations for granting priority access for teaching purposes to medical students from medical schools in their service area communities and, if so, advocate for the development of appropriate regulations at the state level.
- E. Will work with interested state and specialty medical associations to pursue legislation that ensures the quality and availability of medical student clerkship positions for U.S. medical students.
- 2. Our AMA supports the practice of U.S. teaching hospitals and foreign medical schools entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of medical students in teaching hospitals and other clinical sites that lack appropriate educational resources and experience for supervised teaching of clinical medicine, especially when the presence of visiting students would disadvantage the institution s own students educationally and/or financially and negatively affect the quality of the educational program and/or safety of patients receiving care at these sites.
- 3. Our AMA supports agreements for clerkship rotations, where permissible, for U.S. citizen international medical students between foreign medical schools and teaching hospitals in regions that are medically underserved and/or that lack medical schools and clinical sites for training medical students, to maximize the cumulative clerkship experience for all students and to expose these students to the possibility of medical practice in these areas.
- 4. AMA policy is that U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various U.S. medical licensing jurisdictions, prerequisites for entry into graduate medical education programs, and other relevant factors that should be considered before deciding to undertake the study of medicine in schools not accredited by the LCME or COCA.
- 5. AMA policy is that existing requirements for foreign medical schools seeking Title IV Funding should be applied to those schools that are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding. (CME Rep. 01, I-17)

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 5-I-19

Subject: The Transition from Undergraduate Medical Education to Graduate Medical

Education

Presented by: Jacqueline A. Bello, MD, Chair

INTRODUCTION

A critical step in the development of a physician is the transition from undergraduate medical education (UME), or medical school, to graduate medical education (GME), or residency training. Ensuring a seamless transition supports learners' well-being and their readiness to take on and master the many challenges in their chosen field of medicine. In addition, patient safety in our nation's teaching hospitals is paramount in the public eye, as evidenced by coverage of the "July Effect" in the media. This underscores the need for preparedness among first-year resident physicians as well as the need for a highly effective, efficient, and supportive educational environment.

 The American Medical Association (AMA) has taken a lead role to address these issues and call for medical education to "mind the gap" between the various stages of medical education—in particular, the UME to GME transition—in part through its Accelerating Change in Medical Education initiative and Reimagining Residency initiative, as described in this report. The AMA is working to help smooth the transition from UME to GME as part of its effort to encourage innovation in the development of medical students, trainees, and physicians throughout their career. This report also provides relevant AMA policy on this topic (see the Appendix).

MEDICAL SCHOOL PREPARATION OF GRADUATES FOR RESIDENCY

One body of data that measures medical student preparedness for entry into residency is the Association of American Medical Colleges' (AAMC) Graduation Questionnaire (GQ), a national questionnaire administered to graduates of U.S. MD-granting medical schools accredited by the Liaison Committee on Medical Education (LCME). The GQ is an important tool for medical schools to use in program evaluation and to improve the medical student experience.

The AAMC's <u>All Schools Summary Report for 2018</u>² includes GQ data for the five-year period 2014 to 2018. Eighty-three percent (16,223) of medical school graduates in academic year 2017-2018 (19,537) participated in the 2018 GQ.

Question 12 of the questionnaire asks respondents, "Indicate whether you agree or disagree with the following statements about your preparedness for beginning a residency program." Averaging the data for the five-year period (2014 to 2018) produces the following numbers. In the right-hand column, the percentages from the "Agree" and "Strongly agree" fields are combined; the table is sorted based on this variable, which ranges from a high of 98.3 percent ("I have the communication skills necessary to interact with patients and health professionals") to 90.2 percent ("I am confident that I have acquired the clinical skills required to begin a residency program").

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Percentage of Respondents Selecting Each Rating							
Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Total: Agree and Strongly agree		
I have the communication skills necessary to interact with patients and health professionals.							
0.2	0.2	1.4	26.2	72.1	98.3		
I understand the ethical and professional values that are expected of the profession.							
0.2	0.2	1.5	29.9	68.2	98.1		
I believe I am adequately prepared to care for patients from different backgrounds.							
0.3	0.6	3.4	35.9	59.9	95.8		
I have basic skills in clinical decision making and the application of evidence based information to medical practice.							
0.3	0.7	4.7	46.2	48.2	94.4		
I have a fundamental understanding of the issues in social sciences of medicine (e.g., ethics, humanism, professionalism, organization and structure of the health care system).							
0.3	1.0	4.9	40.9	52.8	93.7		
I have the fundamental understanding of common conditions and their management encountered in the major clinical disciplines.							
0.3	1.0	5.2	52.0	41.5	93.5		
I am confident that I have acquired the clinical skills required to begin a residency program.							
0.5	1.9	7.4	47.9	42.3	90.2		

Another assessment of medical schools' efforts in preparing medical students for residency is the LCME's Annual Medical School Questionnaire Part II.

Particularly relevant to this report are data from the question, "Indicate where in the curriculum the following topics to specifically prepare students for entry to residency training are covered" (question 19 for the 2018-2019 questionnaire). Aggregate data for 151 medical schools are shown, sorted by the sum of the numbers for the five places in the curriculum where the specific topic is taught, as shown in the right-hand column.

	Required 4th Year Transition to Residency Course		Required	Required	Inter- session	
Торіс	Specialty- specific	One course for all students	Sub- internship	3rd Year Clinical Clerkship	or 1th	Total
Training in clinical procedures	55	57	105	135	51	403
Disease management (general or specialty-specific)	44	53	124	140	30	391
Working in teams	32	76	105	124	53	390
Working with the EHR/health records	22	43	110	135	48	358
Hand-off procedures	35	68	100	93	28	324

Patient safety/reporting medical errors	16	77	70	104	51	318
Advanced communication skills	26	68	84	85	44	307
Stress, wellness, and burnout in residency training	19	81	21	63	58	242
Health system content (e.g., team care, health care financing)	12	72	38	73	47	242
On-call emergencies	39	50	84	73	18	264
Experiencing the life of a resident (e.g., night call/float)	24	35	85	75	6	225
Medical regulatory content (e.g., licensure, discipline, DEA)	8	55	10	23	32	128
ACLS/ATLS training and certification	9	47	9	25	35	125

THE AMA'S ACCELERATING CHANGE IN MEDICAL EDUCATION AND REIMAGING RESIDENCY INITIATIVES

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1 2

Phase one of the AMA's Accelerating Change in Medical Education initiative, launched in 2013, was intended to:

[F]oster... a culture of medical education advancement, leading to the development and scaling of innovations at the undergraduate medical education level across the country. After awarding initial grants to 11 U.S. medical schools, the AMA convened these schools to form the Accelerating Change in Medical Education Consortium—an unprecedented collective that facilitated the development and communication of groundbreaking ideas and projects. The AMA awarded grants to an additional 21 schools in 2016. Today, almost one-fifth of all U.S. allopathic and osteopathic medical schools are represented in the 32-member consortium [expanded to 37 schools in 2019], which is delivering revolutionary educational experiences to approximately 19,000 medical students—students who one day will provide care to a potential 33 million patients annually.³

Building upon that impetus, in early 2019 the AMA established the Reimagining Residency initiative—a five-year, \$15 million grant program to address challenges associated with the transition from UME to GME and the maintenance of progressive development through residency and across the continuum of physician training. Grants are intended to promote systemic change in GME and support bold, creative innovations that establish new curricular content and experiences to enhance readiness for practice, support well-being in training, and (of particular relevance to this report) provide a meaningful and safe transition from UME to GME. Learn more at: ama-assn.org/education/improve-gme/ama-reimagining-residency-initiative.

 Included in the Accelerating Change in Medical Education and Reimagining Residency initiatives are grantees that are focusing on the UME/GME transition. For example, at Florida International University (FIU) Herbert Wertheim College of Medicine, readiness for residency is monitored by way of competency-based assessments using the Entrustable Professional Activities (EPAs).

As an awardee for both the UME and GME phases of the AMA's grants, New York University Langone School of Medicine is using its latest grant to further its coaching experience through the "NYU Transition to Residency Advantage." The goal of this work is to "enhance the transition from UME to GME through robust coaching, individualized pathways, and enhanced assessment

tools to enable GME programs to shift away from one-size-fits-all education." Similarly, the University of North Carolina School of Medicine received funding from the Reimagining Residency initiative for Fully Integrated Readiness for Service Training (FIRST): Enhancing the Continuum from Medical School to Residency to Practice. Its goals include "implementing a generalizable health systems science curriculum for GME and competency-based assessment tools that span the educational continuum." In addition, the Association of Professors of Gynecology and Obstetrics received a planning grant for its "Right Resident, Right Program, Ready Day One" project, intended to transform the UME to GME transition for residents entering obstetrics and gynecology programs.

CHALLENGES TO CHANGE

As noted in the introduction, certain innovations that improve the transition from UME to GME may challenge existing processes/systems managed by organizations responsible for medical education accreditation, certification, licensing, and residency matching. For example, one of the innovations being studied in the AMA-led consortium is competency-based medical education, in which learners are advanced to the next level of training upon satisfactory demonstration of the requisite knowledge and skills, versus a strictly time-based system that treats all learners alike. Despite the considerable value of this new paradigm from the learner perspective, it may present hurdles to the system of medical education accreditation, funding, and certification and further inhibit (at least in the short run) the development of a smoother UME/GME transition.

Another concern, which relates to the match into residency, is the growing number of residency program applications being submitted by applicants. This is due, in part, to a growing number of medical school graduates in the U.S. and concerns among residency applicants about limited availability of residency program slots. This issue is particularly pointed in competitive specialties. The increased number of applications is expensive and inefficient for applicants and burdensome for residency program directors and personnel, who must review and prioritize these applications. The rising volume of applications leads programs to employ applicants' scores on the United States Medical Licensing Examination (USMLE) for screening purposes, eliminating applications below a certain arbitrary line.

 This process for applicant screening, while understandable given the circumstances, runs counter to AMA policy, which reflects the principle that "selection of residents should be based on a broad variety of evaluative criteria," and asks that ACGME requirements "state clearly that residency program directors must not use NBME or USMLE ranked passing scores as a screening criterion for residency selection." It also lessens the opportunity for holistic review of candidates, through which more intangible attributes and life experience are given equal (if not greater) weight than school grades and examination scores. Indeed, as noted by the authors of a recent perspective in *JAMA*, "the current USMLE 3-digit scores may be distracting the medical education system from the goal of building an innovative, diverse, and resilient physician workforce."

Invitational Conference on USMLE Scoring (InCUS)

The AMA and other leading organizations in medical education convened an invitational conference in March 2019, the Invitational Conference on USMLE Scoring (InCUS), to explore issues around unintended uses of USMLE scores. As noted in a summary report and preliminary recommendations from the meeting, the general consensus among participants is that "[t]he current UME-GME transition system is flawed and not meeting the needs of various stakeholders. Over time, various stakeholder groups have tried to optimize the system for their own purposes, but this has left some, including applicants, with an undue burden and at worst negatively impacted

diversity." One of the recommendations arising from the conference, also noted in the report, is to "[c] onvene a cross-organizational panel to create solutions for the assessment and transition challenges from UME to GME, targeting an approved proposal, including scope/timelines by end of calendar year 2019." As further noted in the report, these challenges would include "[r]educing the number of applications perceived by residency applicants as necessary to obtain a position," "[i]mproving Residency Program Directors' ability to more holistically evaluate candidates," and "[i]mproving the trust of school-based assessments for residency screening and selection."

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During the ensuing public comment period, the Council on Medical Education developed and submitted comments on the InCUS recommendations; key points included the following:

 The overemphasis on USMLE performance in the residency application process is unacceptable; a single three-digit score detracts from learning and engaging fully in the medical student experience, and may inhibit schools' implementation of curricular innovation. A holistic approach to assessing applicants, in contrast, with attention given to life experience and emotional intelligence, among other qualities, allows for individual talents to emerge and minimizes the impact of any one point, and may help increase the number of successful applicants from racial/ethnic minority populations.

 • Any changes made to the residency application process need to consider the alternative tools for evaluation that remain. Preclinical grades, clinical rotation evaluations, and school-based assessments such as the MSPE/Dean's letter all have considerable shortcomings. Equally problematic is reliance on the reputation of the medical school, which is often determined by research dollars, not the quality of the teaching. Removing the numerical score may discriminate against medical students from new and lesser known U.S. medical schools and U.S. students attending international schools.

• All stakeholders in the process will need to "give" something as part of this transition. For example, students will need to be limited on the number of applications they submit, accrediting bodies (e.g., ACGME, LCME) will need to prohibit the use of USMLE as a program-level metric, and we need to reexamine the Match to see if it is really meeting the current needs. For program directors, a move to pass/fail scores may increase the burden they face in evaluating an ever-growing number of candidates.

The overarching goal of this work needs to be broadened beyond "to decrease reliance on the USMLE Step 1 score for residency screening" and more toward "to improve and enhance the holistic evaluation of resident applicants."

The dialogue leading to the Council's response encompassed a rich and robust exchange of viewpoints among Council members—reflecting the complexity of these issues and the multiple levers, processes, and people affected by "the system" (including, and most importantly, our patients). Through the Council on Medical Education and senior staff, the AMA will continue to monitor, provide feedback on, and report back to the HOD on the status of outcomes from InCUS.

Additional issues in the UME/GME transition were limned in a forum hosted by the Council on Medical Education during the AMA's 2019 Annual Meeting. These include:

- 48 For students:
 - The need for honest self-reflection and assessment of strengths and weaknesses.
 - The need for honest and effective coaching and mentoring.
- 51 For medical schools:

- The need for transparency, accuracy, and honesty in assessments of students.
 The need to balance the responsibility to students (to help them successfully responsibility).
 - The need to balance the responsibility to students (to help them successfully match) with the responsibility to residency programs (to be honest about students' strengths and weaknesses).
 - The fear of unsuccessful matches reflecting poorly on the institution.
 - "Failure to fail" (that is, the failure to fail those students who should not be advanced).

For residency program directors:

- The need to provide feedback to schools about interns' performance.
- The growing popularity of the "residency boot camp" model (e.g., the Resident Prep Curriculum, a weeklong boot camp to help ease the transition into surgical residency⁹).
 - The need for a more holistic review of applications and less reliance on USMLE scores.

13 Overa

- Inadequacy of the medical student performance evaluation (MSPE) to distinguish among applicants to residency (in other words, the "Lake Wobegon" effect).
- The need to move beyond the UME, GME, and CME silos to the lifelong learning model.
- Consider high-frequency, low-stakes assessment models, to look at a learner's real-time, cumulative trajectory of growth in knowledge, clinical skills, and professionalism.
- Multiple "scouts" evaluating performance in many types of venues/situations (not just clinical), to average out multiple direct observations.
- The need for free flow of information (in particular, the "right" information—i.e., that which is insightful, without being overwhelming, such that the signal to noise ratio becomes weak).
- Lack of trust among all parties and "gaming" the system; the match process, by its very nature, encourages masking faults and flaws. "Warm handoffs" may help increase trust in the system.

ENTRUSTABLE PROFESSIONAL ACTIVITIES

 One framework that may provide a more useful assessment of learners to improve the UME/GME transition are the Core Entrustable Professional Activities (EPAs) for Entering Residency of the AAMC. The EPAs "provide expectations for both learners and teachers that include 13 activities that all medical students should be able to perform upon entering residency, regardless of their future career specialty. The guidelines are based on emerging literature documenting a performance gap at the transition point between medical school and residency training." ¹⁰

SUMMARY

 The AMA has taken a lead role in improving and easing the transition from UME to GME for learners, program directors, and patients alike. The process has a wide array of variables and stakeholders. Chief pain points are students submitting an inordinate and increasing number of applications in an attempt to match into programs in their chosen fields, and the (mis)use of USMLE Step 1 scores as a primary screening criterion for interviews. The complexity of the issue demands a wide-ranging solution. Through InCUS and related work, such as the Reimagining Residency initiative, the AMA is working to encourage a transition of the residency application/matching system towards a more holistic evaluation of applicants' full range of competencies and traits that would provide a broader assessment of a student's capabilities and "fit" with a program. In addition, through its Council on Medical Education and its ability to convene key stakeholders involved in medical education, the AMA will continue working to ensure that new residents are ready to undertake the rigors of residency from day one and learn (under supervision) how to serve their patients, from both an individual and a population perspective.

APPENDIX: RELEVANT AMA POLICY

H-295.895, "Progress in Medical Education: Structuring the Fourth Year of Medical School"

It is the policy of the AMA that: (1) Trends toward increasing structure in the fourth year of medical school should be balanced by the need to preserve opportunities for students to engage in elective clinical and other educationally appropriate experiences.

- (2) The third and fourth years as a continuum should provide students with a broad clinical education that prepares them for entry into residency training.
- (3) There should be a comprehensive assessment of clinical skills administered at a time when the results can be used to plan each student's fourth-year program, so as to remedy deficiencies and broaden clinical knowledge.
- (4) Medical schools should develop policies and procedures to ensure that medical students receive counseling to assist them in their choice of electives.
- (5) Adequate and timely career counseling should be available at all medical schools.
- (6) The ability of medical students to choose electives based on interest or perceived academic need should not be compromised by the residency selection process. The American Medical Association should work with the Association of American Medical Colleges, medical schools, and residency program directors groups to discourage the practice of excessive audition electives.
- (7) Our AMA should continue to work with relevant groups to study the transition from the third and fourth years of medical school to residency training, with the goal of ensuring that a continuum exists in the acquisition of clinical knowledge and skills.

(CME Rep. 1, I-98 Reaffirmed: CME Rep. 9, A-07 Reaffirmed: CME Rep. 01, A-17)

H-295.862, "Alignment of Accreditation Across the Medical Education Continuum"

- 1. Our AMA supports the concept that accreditation standards for undergraduate and graduate medical education should adopt a common competency framework that is based in the Accreditation Council for Graduate Medical Education (ACGME) competency domains.
- 2. Our AMA recommends that the relevant associations, including the AMA, Association of American Medical Colleges (AAMC), American Osteopathic Association (AOA), and American Association of Colleges of Osteopathic Medicine (AACOM), along with the relevant accreditation bodies for undergraduate medical education (Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation) and graduate medical education (ACGME, AOA) develop strategies to:
- a. Identify guidelines for the expected general levels of learners' competencies as they leave medical school and enter residency training.
- b. Create a standardized method for feedback from medical school to premedical institutions and from the residency training system to medical schools about their graduates' preparedness for entry.
- c. Identify areas where accreditation standards overlap between undergraduate and graduate medical education (e.g., standards related to the clinical learning environment) so as to facilitate coordination of data gathering and decision-making related to compliance.

All of these activities should be codified in the standards or processes of accrediting bodies.

3. Our AMA encourages development and implementation of accreditation standards or processes that support utilization of tools (e.g., longitudinal learner portfolios) to track learners' progress in achieving the defined competencies across the continuum.

- 4. Our AMA supports the concept that evaluation of physicians as they progress along the medical education continuum should include the following: (a) assessments of each of the six competency domains of patient care, medical knowledge, interpersonal and communication skills, professionalism, practice-based learning and improvement, and systems-based practice; and (b) use of assessment instruments and tools that are valid and reliable and appropriate for each competency domain and stage of the medical education continuum.
- 5. Our AMA encourages study of competency-based progression within and between medical school and residency.
- a. Through its Accelerating Change in Medical Education initiative, our AMA should study models of competency-based progression within the medical school.
- b. Our AMA should work with the Accreditation Council for Graduate Medical Education (ACGME) to study how the Milestones of the Next Accreditation System support competency-based progression in residency.
- 6. Our AMA encourages research on innovative methods of assessment related to the six competency domains of the ACGME/American Board of Medical Specialties that would allow monitoring of performance across the stages of the educational continuum.
- 7. Our AMA encourages ongoing research to identify best practices for workplace-based assessment that allow performance data related to each of the six competency domains to be aggregated and to serve as feedback to physicians in training and in practice. (CME Rep. 4, A-14 Appended: CME Rep. 10, A-15)
- D-295.317, "Competency Based Medical Education Across the Continuum of Education and Practice"
- 1. Our AMA Council on Medical Education will continue to study and identify challenges and opportunities and critical stakeholders in achieving a competency-based curriculum across the medical education continuum and other health professions that provides significant value to those participating in these curricula and their patients.
- 2. Our AMA Council on Medical Education will work to establish a framework of consistent vocabulary and definitions across the continuum of health sciences education that will facilitate competency-based curriculum, andragogy and assessment implementation.
- 3. Our AMA will continue to explore, with the Accelerating Change in Medical Education initiative and with other stakeholder organizations, the implications of shifting from time-based to competency-based medical education on residents' compensation and lifetime earnings. (CME Rep. 3, A-14 Appended: CME Rep. 04, A-16)
- H-275.953, "The Grading Policy for Medical Licensure Examinations"
- 1. Our AMA's representatives to the ACGME are instructed to promote the principle that selection of residents should be based on a broad variety of evaluative criteria, and to propose that the ACGME General Requirements state clearly that residency program directors must not use NBME or USMLE ranked passing scores as a screening criterion for residency selection.
- 2. Our AMA adopts the following policy on NBME or USMLE examination scoring: (a) Students receive "pass/fail" scores as soon as they are available. (If students fail the examinations, they may request their numerical scores immediately.) (b) Numerical scores are reported to the state licensing authorities upon request by the applicant for licensure. At this time, the applicant may

request a copy of his or her numerical scores. (c) Scores are reported in pass/fail format for each student to the medical school. The school also receives a frequency distribution of numerical scores for the aggregate of their students.

- 3. Our AMA will co-convene the appropriate stakeholders to study possible mechanisms for transitioning scoring of the USMLE and COMLEX exams to a Pass/Fail system in order to avoid the inappropriate use of USMLE and COMLEX scores for screening residency applicants while still affording program directors adequate information to meaningfully and efficiently assess medical student applications, and that the recommendations of this study be made available by the 2019 Interim Meeting of the AMA House of Delegates.
- 4. Our AMA will: (a) promote equal acceptance of the USMLE and COMLEX at all United States residency programs; (b) work with appropriate stakeholders including but not limited to the National Board of Medical Examiners, Association of American Medical Colleges, National Board of Osteopathic Medical Examiners, Accreditation Council for Graduate Medical Education and American Osteopathic Association to educate Residency Program Directors on how to interpret and use COMLEX scores; and (c) work with Residency Program Directors to promote higher COMLEX utilization with residency program matches in light of the new single accreditation system. (CME Rep. G, I-90 Reaffirmed by Res. 310, A-98 Reaffirmed: CME Rep. 3, A-04 Reaffirmed: CME Rep. 2, A-14 Appended: Res. 309, A-17 Modified: Res. 318, A-18 Appended: Res. 955, I-18)

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REPORT OF THE SPEAKERS

Speakers' Report 1-I-19

Subject: Speakers' Report: Task Force on Election Reform

Presented by: Bruce A. Scott, MD, and Lisa Bohman Egbert, MD

1 At this past June's meeting the House of Delegates adopted policy calling for the Speaker to 2 appoint a task force that would recommend improvements to our AMA's election processes. The 3 following members were appointed to the task force:

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- Jenni Barlotti-Telesz, MD, American Society of Anesthesiologists
- 6 Richard Evans, MD, Maine
 - James Hay, MD, California
 - Dan Heinemann, MD, American Academy of Family Physicians
- 9 David Henkes, MD, Texas
- Jessica Krant, MD, American Society for Dermatologic Surgery 10
- Josh Lesko, MD, Resident Physician, Virginia 11
- John Poole, MD, New Jersey 12
- Karthik Sarma, immediate past medical student trustee 13
- 14 Stephen Tharp, MD, Indiana
- 15 Jordan Warchol, MD, MPH, Nebraska
 - Bruce Scott, MD, Speaker, Kentucky
 - Lisa Bohman Egbert, MD, Vice Speaker, Ohio

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Interest in the task force was high, with more than 60 requests to serve. Selection was based primarily on experience with AMA elections, either as a candidate or part of a campaign committee, and most members had been involved multiple times and in multiple ways. Consideration was also given to ensuring a broad cross section of the House of Delegates.

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BACKGROUND

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The task force is not yet prepared to propose specific changes to the election rules, but rather is seeking broad input from the HOD. This report describes activities undertaken since the task force was launched and outlines topics that have been discussed among members. Your speakers have arranged for an open forum to be held during the Interim Meeting to solicit thoughts across topics outlined below. A report with recommendations should be expected at the 2020 Annual Meeting.

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- Current election rules are found in both AMA bylaws and policy (see Appendix A) but are also
- 33 dependent on Speaker rulings and discretion (eg, the cap on expenditures for giveaways). Chief among expressed concerns were the expense and time invested in campaigns, but also mentioned 34
- 35 were associated effects such as decisions by otherwise qualified candidates to not seek office and
- the limiting effect of election-related activities on the ability to fully address policy matters. In the 36
- view of the task force, costs are real, measured not only in dollars but in time, distractions and 37
- 38 stress. Moreover, these costs are shared by both candidates and the larger House.

The task force is assessing the entirety of our election process, and while recommendations are forthcoming next June, the task force would note that its primary goal is to ensure that the best candidates are selected as AMA's leaders in free and fair elections and in furtherance of AMA's "Guiding principles for House Elections." For candidates, the task force hopes to make campaigns less expensive and more equitable, while removing obstacles that discourage qualified members from seeking election. At the same time, the task force seeks to ensure that electors constitute an informed electorate. While the task force believes the election process should not be unduly distracting from our policy discussions, we also recognize the importance of our elected leadership and believe it is appropriate for the House to spend time and focus on selecting these individuals.

Additionally, the task force holds that addressing our AMA's election rules should be an evolutionary process, with the task force's eventual recommendations only a step along a path that is sensitive to changes in technology, the needs of the profession, the diversity of AMA membership and the makeup of the House of Delegates. That said, the task force does not mean to suggest that it should be an ongoing entity. Rather changes should henceforth be organic.

For example, in some of the task force discussions questions arose about the value of certain actions or activities that more often than not are part of most candidates' election efforts. The consensus within the task force is that many of these actions add little, if any, value to a candidate's likelihood of election, but candidates or their supporters are hesitant to not continue the activity because "everyone does it." From the perspective of the task force, one would hope that both rules and practice would be modified over time when new norms become the standard.

Task Force Activity

After it was formed, the task force engaged in a series of email exchanges on multiple election-related topics; those have continued even with the approach of the Interim Meeting. Typically, the Speaker, Dr. Scott, proposed a relatively narrow item for discussion, with his initial question directed to all members of the task force and responses shared across the group. As an example, one of the early discussions dealt with the giveaways that are included in the not for official business bag at the opening session of the Annual Meeting. Each discussion thread was conducted independently and allowed to conclude naturally.

The task force also met face to face and will be meeting again during the Interim Meeting. The inperson meetings afford an opportunity for the members to interact and discuss ideas and concerns about more conceptual ideas, not easily handled by email because nuance and slight alterations can affect the ensuing dialog.

ITEMS FOR CONSIDERATION

The task force has discussed and would like input on multiple items, but it should be noted that inclusion on this list does not imply that the task force has concluded its discussion of the matter or that they have adopted a position.

Note in each area of consideration you will find highlighted questions to be discussed at the open forum. These should not be considered as all-inclusive or in any way exclusive of other comments. Open discussion of each topic is welcome.

Additionally, <u>Appendix B</u> includes a list of topics that will be discussed in the open forum.

Interviews

It is common for candidates to be interviewed by literally dozens of caucuses and delegations. This process stretches over several days and has been described as "grueling." Delegations and interview committees spend considerable time listening and evaluating candidates. Some complain that these presentations interrupt their policy discussions and delegates report hearing redundant presentations (others report hearing conflicting comments from some candidates in different venues). While there is no question that this process is time consuming for both the candidates and those interviewing them, others defend this as "the most important way candidates are vetted."

The Office of House of Delegates Affairs currently schedules 10-minute interviews for officer candidates in contested elections. Those interviews are scheduled only with geographic caucuses, because scheduling interviews with every interested group would be prohibitively complex and time consuming. Nonetheless, other groups can and do schedule interviews with officer candidates, and candidates in council elections are scheduled either by the interviewing group or the candidates themselves (or their campaign team). Some delegations employ committees to conduct candidate interviews, with the committee's recommendation then provided to members of that delegation (or caucus). Other groups and caucuses allow candidates to present to the entire delegation. Still other delegations handle officer and council candidates differently.

Open Forum Topic #1

The election task force wants to hear what changes, if any, would improve the interview process. Should there be formalized interview forums (like currently held for president elect candidates) before the entire HOD or large assembly, perhaps just for officers or for all candidates? Would delegations support being grouped together to reduce the number of interviews or do delegations want to continue their individual or small group interviews? What measures should be taken to ensure interviews are equally available to all candidates for a given position? Should council and officer candidates be handled differently? (this same question could be asked about subsequent topics as well)

Campaign expenses

One of the major areas of expressed concern regarding campaigns is the real or anticipated expense. While there is wide variability in the costs of campaigns and some would argue that big budgets don't necessarily lead to election, it has been said that there are individuals that do not seek election because of the anticipated cost. Some delegations have more resources available than others, but most all associations are facing increasing budgetary concerns. In fact, financial concerns have been stated as a reason for some societies to not fill their entire delegation. Budgetary considerations should not be a deciding factor in the election of candidates.

Strict limits on campaign expense or required transparency of expenditures have been recommended to the task force. It is difficult to measure actual expenditures particularly for larger delegations that routinely have receptions, suites, dinners and giveaways. Some delegations are willing and able to spend more on campaigns. Some candidates have more available resources whether financial or otherwise (eg, web design expertise, video studio,) from their family, friends or medical association.

Open Forum Topic #2

Should there be a limit on campaign expense or required reporting? How would actual expenditures be accurately measured and reported? Is there a true correlation between expenditure and election? The possibility of "public funding" of elections has been raised – how would the funds be raised and distributed? Should AMA be expected to

finance the election process? Would delegations be willing to share expense per capita or otherwise?

Campaign receptions

Campaign receptions are likely the largest single expenditure for most campaigns, with estimates ranging upward from \$20,000 and the overall cost dependent on decorations and refreshments, and some costs are shared across a caucus. Providing alcohol is already prohibited by the rules, which serves to some extent to limit the cost. While candidates have been elected without a reception (and others with well attended, elaborate receptions have not been elected) some may be deterred from running because of the perceived need for a reception and the anticipated expense. These continue to be well attended and candidates seem to have no hesitation (and feel welcome) attending other receptions, even that of their opponents, so there seems to be little exclusivity. While there is no question that most, if not all, open receptions have a campaign component, conversations typically include policy discussions and valued social interaction. Some have complained about long receiving lines that delay mingling and constructive discussion.

Open Forum Topic #3

Is there an option that would provide the opportunity for candidates to interact with a broad range of delegates outside the formal interviews and at the same time provide social interaction for others to encourage their attendance? Could individual receptions be replaced by a joint reception or perhaps separate receptions for different categories of candidates (eg, officers versus council candidates)? Some states and regional delegations have parties every year, with or without a candidate (eg, ice cream social, chili, chowder or wine tasting). If a general reception were offered, should separate receptions be allowed? If receptions are continued should receiving lines be

discouraged or should this decision be left to the host?

Campaign memorabilia

Giveaways or gifts: Our current rules allow the Speaker to set an expenditure limit for the giveaways that are distributed via the not for official business bag or at a party. The limit is calculated on a per capita basis given the number of delegates and alternate delegates. This past June the aggregate limit was \$3200. Although not one of the larger campaign expenses, every dollar counts particularly for candidates with limited budgets. Many would say that while they enjoy the treats that this is not a factor in their vote; others argue these allow candidates to display their individuality and draw attention to literature that is often attached.

Open Forum Topic #4

 Should gifts be "discouraged" or even disallowed altogether? What if a state wants to provide a gift that is not "tied to" a candidate? Some states put something in the bag or distribute a gift that they believe represents their state even when they don't have a candidate (eg, Virginia peanuts, New England lobsters).

<u>Pins</u>, <u>buttons</u> and <u>stickers</u>: The rules separate pins, buttons and stickers from campaign giveaways, noting that they do not count against spending limits, but the rules also say they should be simple. Although not a major expenditure, concerns have arisen around their distribution and appropriateness for a professional association. Some individuals feel pressured to wear stickers and object to "forced stickering;" while others say that the stickers are used as a conversation starter and allow one to display their support for a candidate.

Open Forum Topic #5

Should pins / buttons / stickers be disallowed? Several specialty societies and some states have pins or stickers that may not necessarily include a candidate's name but may still be perceived as campaign material. Where do we draw the line?

Campaign literature

Campaign mailings preceding the Annual Meeting are common, and the not for official business bag is generally filled with campaign material. Some of the materials attest to the qualifications of a candidate, while others include little more than a photo and endorsement. Under current rules electronic (email) communications to members of the House "must allow recipients to opt out" of future messages. Considerable effort and funds are spent on creating and distributing this material. Some delegates read the material considering it an important source of information and have commented that it gives them a sense of the candidate's personality and background. Others believe this is a waste of resources, particularly the printed material, and should be banned or at least switched to electronic only.

An AMA election manual has been prepared for the last 33 years and starting in 2016 has appeared exclusively in electronic form on our AMA's <u>website</u>. Candidates are responsible for the content of their submissions, but our AMA does minimal copy editing to ensure a consistent style. The manual is intended in part to reduce the need for other forms of communication as well as provide a level playing field.

Open Forum Topic #6

Does the election manual alone provide sufficient information? If technically feasible, should individuals be allowed to select electronic communications only or opt out of receiving campaign literature altogether? Do materials in the not for official business bag provide meaningful information or are they a waste of resources and should be discouraged or even disallowed?

Election process

Elections are scheduled on <u>Tuesday</u> morning at the Annual Meeting, and the initial round of voting is conducted before the House opens its business session that morning. Runoffs, if they are needed, are held in the House by paper ballot once ballots are prepared. Comments have been heard regarding the timing of the vote, including the day it should occur, along with suggestions to employ electronic voting for runoffs and concerns about the disruptions caused by runoffs and victory and concession speeches. Electronic voting will expedite runoffs (and potentially initial voting as well) and reduce disruption. Victory and concession speeches could be time limited. Any change to the day or time of the elections would likely require other adjustments to our typical schedule.

Open Forum Topic #7

The task force is interested in members' comments about any aspect of the processes associated with the actual voting. Assuming technology can provide secure voting from delegate seats within the House, does the HOD support a move to electronic voting? What are the advantages and disadvantages of moving the day or time of the election? Should post-election speeches be time limited or even not allowed?

Other issues

The task force has received comments regarding "pop up" candidates – previously unannounced candidates that are nominated from the floor when a new opening is created by the election of a sitting council member or trustee to a higher office. These candidates do not receive the scrutiny of

the normal election process yet are elected to a full term. Further concern was expressed that the potential of opening a new seat has become a strategy for election. It has been suggested that sitting council or board members with unexpired terms that are nominated for higher office be required to resign their current position thus opening their seat regardless of the outcome of their new election. This would provide for nominations for the opened seat to follow the normal election process but would truncate the service of experienced leaders and possibly lead to more individuals remaining in their seats for full terms reducing opportunity for new leadership. Others have suggested that the vacated seat remain open until the next annual election. Still others have noted that pop-up candidates choose to "pop-up" because of the opportunity to run for a desired office without the burden of the campaign expense.

Open Forum Topic #8

Do pop-up candidates distort the election process? Should our process of electing individuals for newly opened positions after regular nominations are closed be changed? If so, how?

Concerns have been expressed about suites, dinners and other gatherings that are in effect campaign events occurring at our annual meeting and before "official campaigning" is allowed (National Advocacy Conference, State Legislative Conference and Interim Meeting). These add considerable expense. It is difficult to determine when a gathering in a suite or a dinner is simply a social event for individuals to interact socially, which your task force believes is important, or a campaign event.

Open Forum Topic #9

Would a restriction that dinners be "Dutch treat" if an announced candidate was present be effective? How can we tell delegations they can't entertain their friends or colleagues? Would restrictions on campaign receptions considered above actually drive more resources to these less regulated events?

Final discussion

The election task force believes that while the current election process certainly can and should be improved that the current elected AMA leadership retains our fullest confidence. Your speakers have noted that while there have been general comments about behavior that might be considered a violation of the rules, formal reports of violations have been remarkably few.

Finally, in reviewing the history of our election process the task force wondered how familiar candidates, delegates and alternate delegates are with our current election rules. Many of the expressed concerns including those regarding vote trading, block voting, caucuses attempting to direct individual delegate votes and negative campaigning are contrary to our current "Guiding Principles." Perhaps adherence to the policies and rules previously adopted by the HOD should be given greater emphasis. While one would hope that professionalism alone would demand compliance, the challenge for many of the concerns is surveillance and enforcement. We encourage everyone to review the current rules and principles listed in the appendix of this report.

Open Forum Topic #10

The question arises should election reforms simply discourage undesirable behavior or attempt to prohibit such behavior. The task force welcomes comments regarding monitoring and enforcement of what are often considered the most problematic potential violations which are also those most difficult to track and prevent.

CONCLUSION

The election task force seeks the appropriate balance between an informed electorate who are selecting the best candidates after adequate exposure and proper opportunity for due diligence while eliminating obstacles, particularly those that do not add to the selection of the most qualified candidates. We understand that any recommended changes to our election process must ensure that the best candidates are selected as AMA's leaders in free and fair elections.

This report is meant as informational only. The task force has discussed all the issues detailed here and more. We have planned an open forum at Interim 2019 and look forward to hearing from members of the House. While the agenda of the open forum will include discussion of the topics highlighted above, these are not meant to be totally inclusive and certainly not exclusive. Within discussion of each of these topics we hope to hear what the HOD believes should be retained, modified or eliminated. What do delegates value, what helps you make an informed decision on the best candidates, how to balance distractions from policy discussion with appropriate attention on election of leaders? For candidates what can be done to remove obstacles and create a fair, equitable campaign? We will include time for additional comments on issues not detailed here and

equitable campaign? We will include time for additional comments on issues we continue to welcome written comments from individuals and delegations.

APPENDIX A - AMA Election-related policies

Policy G-610.031, Creation of an AMA Election Reform Committee

Our AMA will create a Speaker-appointed task force for the purpose of recommending improvements to the current AMA House of Delegates election process with a broad purview to evaluate all aspects. The task force shall present an initial status report at the 2019 Interim Meeting.

Policy G-610.020, Rules for AMA Elections

- (1) The Speaker and Vice Speaker of the House of Delegates are responsible for overall administration of our AMA elections, although balloting is conducted under the supervision of the chief teller and the Committee on Rules and Credentials. The Speaker and Vice Speaker will advise candidates on allowable activities and when appropriate will ensure that clarification of these rules is provided to all known candidates. The Speaker, in consultation with the Vice Speaker, is responsible for declaring a violation of the rules:
- (2) Individuals intending to seek election at the next Annual Meeting should make their intentions known to the Speakers, generally by providing the Speaker's office with an electronic announcement "card" that includes any or all of the following elements and no more: the candidate's name, photograph, email address, URL, the office sought and a list of endorsing societies. The Speakers will ensure that the information is posted on our AMA website in a timely fashion, generally on the morning of the last day of a House of Delegates meeting or upon adjournment of the meeting. Announcements that include additional information (e.g., a brief resume) will not be posted to the website. Printed announcements may not be distributed in the venue where the House of Delegates meets. The Speakers may use additional means to make delegates aware of those members intending to seek election;
- (3) Active campaigning for AMA elective office may not begin until the Board of Trustees, after its April meeting, announces the nominees for council seats. Active campaigning includes mass outreach activities directed to all or a significant portion of the members of the House of Delegates and communicated by or on behalf of the candidate. If in the judgment of the Speaker of the House of Delegates circumstances warrant an earlier date by which campaigns may formally begin, the Speaker shall communicate the earlier date to all known candidates;
- (4) An Election Manual containing information on all candidates for election shall continue to be developed annually, with distribution limited to publication on our AMA website, typically on the Web pages associated with the meeting at which elections will occur. The Election Manual provides an equal opportunity for each candidate to present the material he or she considers important to bring before the members of the House of Delegates and should relieve the need for the additional expenditures incurred in making non-scheduled telephone calls and duplicative mailings. The Election Manual serves as a mechanism to reduce the number of telephone calls, mailings and other messages members of the House of Delegates receive from or on behalf of candidates;
- (5) A reduction in the volume of telephone calls from candidates, and literature and letters by or on behalf of candidates is encouraged. The use of electronic messages to contact electors should be minimized, and if used must allow recipients to opt out of receiving future messages;
- (6) At the Interim Meeting, campaign-related expenditures and activities shall be discouraged. Large campaign receptions, luncheons, other formal campaign activities and the distribution of campaign literature and gifts are prohibited at the Interim Meeting. It is permissible at the Interim Meeting for candidates seeking election to engage in individual outreach, such as small group meetings, including informal dinners, meant to familiarize others with a candidate's opinions and positions on issues;
- (7) Our AMA believes that: (a) specialty society candidates for AMA House of Delegates elected offices should be listed in the pre-election materials available to the House as the representative of that society and not by the state in which the candidate resides; (b) elected specialty society members should be identified in that capacity while serving their term of office; and (c) nothing in the above

- recommendations should preclude formal co-endorsement by any state delegation of the national specialty society candidate, if that state delegation should so choose;
- (8) A state, specialty society, caucus, coalition, etc. may contribute to more than one party. However, a candidate may be featured at only one party, which includes: (a) being present in a receiving line, (b) appearing by name or in a picture on a poster or notice in or outside of the party venue, or (c) distributing stickers, buttons, etc. with the candidate's name on them. At these events, alcohol may be served only on a cash or no-host bar basis;
- (9) Displays of campaign posters, signs, and literature in public areas of the hotel in which Annual Meetings are held are prohibited because they detract from the dignity of the position being sought and are unsightly. Campaign posters may be displayed at campaign parties, and campaign literature may be distributed in the non-official business bag for members of the House of Delegates. No campaign literature shall be distributed and no mass outreach electronic messages shall be transmitted after the opening session of the House of Delegates;
- (10) Campaign expenditures and activities should be limited to reasonable levels necessary for adequate candidate exposure to the delegates. Campaign gifts can be distributed only at the Annual Meeting in the non-official business bag and at one campaign party. Campaign gifts should only be distributed during the Annual Meeting and not mailed to delegates and alternate delegates in advance of the meeting. The Speaker of the House of Delegates shall establish a limit on allowable expenditures for campaign-related gifts. In addition to these giveaway gifts, campaign memorabilia are allowed but are limited to a button, pin, or sticker. No other campaign memorabilia shall be distributed at any time;
- (11) The Speaker's Office will coordinate the scheduling of candidate interviews for general officer positions (Trustees, President-Elect, Speaker and Vice Speaker);
- (12) At the Opening Session of the Annual Meeting, officer candidates in a contested election will give a two-minute self-nominating speech, with the order of speeches determined by lot. No speeches for unopposed candidates will be given, except for president-elect. When there is no contest for president-elect, the candidate will ask a delegate to place his or her name in nomination, and the election will then be by acclamation. When there are two or more candidates for the office of president-elect, a two-minute nomination speech will be given by a delegate. In addition, the Speaker of the House of Delegates will schedule a debate in front of the AMA-HOD to be conducted by rules established by the Speaker or, in the event of a conflict, the Vice Speaker;
- (13) Candidates for AMA office should not attend meetings of state medical societies unless officially invited and could accept reimbursement of travel expenses by the state society in accordance with the policies of the society;
- (14) Every state and specialty society delegation is encouraged to participate in a regional caucus, for the purposes of candidate review activities; and
- (15) Our AMA (a) requires completion of conflict of interest forms by all candidates for election to our AMA Board of Trustees and councils prior to their election; and (b) will expand accessibility to completed conflict of interest information by posting such information on the "Members Only" section of our AMA website before election by the House of Delegates, with links to the disclosure statements from relevant electronic documents.

Policy G-610.021, Guiding Principles for House Elections

The following principles provide guidance on how House elections should be conducted and how the selection of AMA leaders should occur:

- (1) AMA delegates should: (a) avail themselves of all available background information about candidates for elected positions in the AMA; (b) determine which candidates are best qualified to help the AMA achieve its mission; and (c) make independent decisions about which candidates to vote for.
- (2) Any electioneering practices that distort the democratic processes of House elections, such as vote trading for the purpose of supporting candidates, are unacceptable.
- (3) Candidates for elected positions should comply with the requirements and the spirit of House of Delegates policy on campaigning and campaign spending.
- (4) Candidates and their sponsoring organizations should exercise restraint in campaign spending. Federation organizations should establish clear and detailed guidelines on the appropriate level of resources that should be allocated to the political campaigns of their members for AMA leadership positions.
- (5) Incumbency should not assure the re-election of an individual to an AMA leadership position.
- (6) Service in any AMA leadership position should not assure ascendancy to another leadership position.

Policy G-610.030, Election Process

AMA guidelines on the election process are as follows: (1) AMA elections will be held on Tuesday at each Annual Meeting; (2) Poll hours will not be extended beyond the times posted. All delegates eligible to vote must be in line to vote at the time appointed for the close of polls; and (3) The final vote count of all secret ballots of the House of Delegates shall be made public and part of the official proceedings of the House.

APPENDIX B - Topics for discussion during open forum.

This listing of topics and questions is not meant to be exhaustive. Rather it is illustrative, and other matters are welcome. An "open discussion" is included as the last topical section. Cutting across all topics, consider whether officer and council candidates should be treated differently.

See the text of the report for fuller discussion of each topic.

Topic 1 – Interviews

Possibility of interview forums

Reducing the number of interviews

Equity of access to interviews across candidates in a race

Topic 2 – Campaign expenses

Should expenses be limited / capped?

Required reporting

Public funding, i.e., AMA contributions and shared expenses among sponsors

Topic 3 – Campaign receptions

Options to allow interaction with candidates

Possibility of joint receptions

Separate receptions for officers and council candidates

Receiving lines

Receptions with and without candidates

Topic 4 – Campaign memorabilia

Giveaways - allowed or disallowed

Gifts unrelated to campaigns

Topic 5 – Pins, buttons and stickers

Allowed or disallowed

Distribution and their role

Topic 6 – Campaign literature

Mailings versus the election manual

Option to choose electronic communications or to opt out of campaign literature

Material in not-for-official-business bag

Topic 7 – Election process

Day and time of election

Secure voting from delegate seats using electronic devices

Thank you and concession speeches

Topic 8 – Pop-up candidates

A distortion of the process?

Filling new vacancies

Topic 9 – Suites, dinners and gatherings

"Dutch treat" dinners if a candidate is present

Would rules changes for receptions lead to more campaign suites and dinners?

Topic 10 – Monitoring and enforcing rules

Appropriate monitoring of rules

Role of professionalism relative to active enforcement of rules

Topic 11 – Open discussion of any topic