# **HOD Handbook Review – Senior Physicians Section**

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
A	Res. 113 (Senior Physicians Section)	Prevention of Hearing Loss- Associated- Cognitive- Impairment through Earlier Recognition and Remediation	RESOLVED, That our American Medical Association promote awareness of hearing impairment as a potential contributor to the development of cognitive impairment in later life, to physicians as well as to the public (Directive to Take Action); and be it further RESOLVED, That our AMA promote, and encourage other stakeholders, including public, private, and professional organizations and relevant governmental agencies, to promote the conduct and acceleration of research into specific patterns and degrees of hearing loss to determine those most linked to cognitive impairment and amenable to correction (Directive to Take Action); and be it further RESOLVED, That our AMA advocate for increased hearing screening, and expanding all avenues for third party coverage for effective hearing loss remediation beginning in mid-life or whenever detected, especially when such loss is shown conclusively to contribute significantly to the development of, or to magnify the functional deficits of cognitive impairment, and/or to limit the capacity of individuals for independent living. (Directive to Take Action) Fiscal Note: Modest - between \$1,000 - \$5,000	
A	Res. 114 (Senior Physicians Section)	Oral Healthcare IS Healthcare	RESOLVED, That our American Medical Association reaffirm that dental and oral health are integral components of basic health care and maintenance regardless of age (Reaffirm HOD Policy); and be it further RESOLVED, That our AMA, through the Center for Health Equity, highlight the substantial contribution of dental and oral healthcare disparities to health inequity as well as to social and economic disparities (Directive to Take Action); and be it further RESOLVED, That our AMA support ongoing research, legislative actions and administrative efforts to promote access to and adequate coverage by public and private payers for preventative and therapeutic dental services as integral parts of overall health maintenance to all populations (New HOD Policy); and be it further RESOLVED, That our AMA work with other organizations to explore avenues to promote efforts to expand Medicare benefits to include	

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
Ref Comm A	Res. 125 (Senior Physicians Section)	Education, Forewarning and Disclosure regarding Consequences of Changing Medicare Plans	preventative and therapeutic dental services, without additional decreases in Medicare Part B Reimbursements. (Directive to Take Action) Fiscal Note: Modest - between \$1,000 - \$5,000 RESOLVED, That our American Medical Association amend policy H-330.870, "Transparency of Costs to Patients for Their Prescription Medications Under Medicare Part D and Medicare Advantage Plans," by addition and deletion to read as follows: Our AMA will: (1) advocate for provision of transparent print and audio/video patient educational resources to patients and families in multiple languages from health care systems and from Medicare - directly accessible - by consumers and families, explaining clearly the different benefits, as well as the varied, programmatic and other out-of-pocket costs for their medications under Medicare, Medicare Supplemental and Medicare Advantage plans on their personal costs for their medications under Medicare Advantage plans—both printed and online video—which health care systems could provide to patients and which consumers could access directly; and	
			(2) advocate for printed and audio/video patient educational resources regarding personal costs, changes in benefits and provider panels that may be incurred when switching (voluntarily or otherwise) between Medicare, Medical Supplemental and Medicare Advantage or other plans, including additional information regarding federal and state health insurance assistance programs that patients and consumers could access directly; and (23) support advocate for increased funding for federal and state health insurance assistance programs and educate physicians, hospitals, and patients about the availability of and access to these such programs. (Modify Current HOD Policy) Fiscal Note: Minimal - less than \$1,000	

# $HOD\ Handbook\ Review-Senior\ Physicians\ Section$

Ref	Resolution/	Title	Recommendation/Resolve	Support/Not
Comm	Report			Support/Monitor/
				Comments
E	Res. 515 (Senior Physicians Section)	Reducing Polypharmacy as a Significant Contributor to Senior Morbidity	RESOLVED, That our American Medical Association work with other organizations e.g., AARP, other medical specialty societies, PhRMA, and pharmacists to educate patients about the significant effects of all medications and most supplements, and to encourage physicians to teach patients to bring all medications and supplements or accurate, updated lists including current dosage to each encounter (Directive to Take Action); and be it further  RESOLVED, That our AMA along with other appropriate organizations encourage physicians and ancillary staff if available to initiate discussions with patients on improving their medical care through the use of only the minimal number of medications (including prescribed or over-the-counter, including vitamins and supplements) needed to optimize their health (Directive to Take Action); and be it further  RESOLVED, That our AMA work with other stakeholders and EHR vendors to address the continuing problem of inaccuracies in medication reconciliation and propagation of such inaccuracies in electronic health records, and to include non-prescription medicines in medication compatibility screens. (Directive to Take Action)  Fiscal Note: Not yet determined	

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
F	Res. 610 (Senior Physicians Section)	Making AMA Meetings Accessible	RESOLVED, That all future American Medical Association meetings be structured to provide accommodations for members who are able to physically attend, but who need assistance in order to meaningfully participate (Directive to Take Action); and be it further RESOLVED, That our AMA investigate ways of allowing meaningful participation in all meetings of the AMA by members who are limited in their ability to physically attend meetings (Directive to Take Action); and be it further RESOLVED, That our AMA revisit our criteria for selection of hotels and other venues for the HOD in order to facilitate maximum participation by members with disabilities (Directive to Take Action); and be it further RESOLVED, That our AMA report back to the HOD by no later than the 2023 Annual Meeting with a plan on how to maximize HOD meeting participation for members with disabilities. (Directive to Take Action) Fiscal Note: Not yet determined	
A	CMS 04	Parameters of Medicare Drug Price Negotiation	The Council on Medical Service recommends that the following be adopted in lieu of the second resolve of Alternate Resolution 113-N-21, as well as the referred amendment proffered during consideration of Alternate Resolution 113-N-21, and that the remainder of the report be filed.  1. That our American Medical Association (AMA) reaffirm Policy D-330.954, which states that 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; 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. (Reaffirm HOD Policy)  2. That our AMA reaffirm Policy H-110.980, which outlines principles to guide AMA support for arbitration as well as the use of international drug	

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
			price averages/indices in determining domestic drug prices. (Reaffirm HOD Policy)  3. That our AMA reaffirm Policy H-110.983, which advocates standards that any revised Medicare Part B Competitive Acquisition Program must meet. (Reaffirm HOD Policy)  4. That our AMA encourage the development of models under the auspices of the CMS Innovation Center (CMMI) to test the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent, and predictable out-of-pocket costs for select prescription drugs. (New HOD Policy)	
A	Res. 106 (New York)	Hospice Recertification for Non-Cancer Diagnosis	RESOLVED, That our American Medical Association request that the Centers for Medicare & Medicaid Services allow automatic reinstatement for hospice if a patient survives for more than 6 months with a non-cancer diagnosis and that prognosis remains terminal. (Directive to Take Action) Fiscal Note: Modest - between \$1,000 - \$5,000	
A	Res. 118 (Medical Student Section, Endocrine Society)	Caps on Insulin Co- Payments for Patients with Insurance	RESOLVED, That our American Medical Association amend Policy H-110.984, "Insulin Affordability," by addition to read as follows: Insulin Affordability H-110.984  Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate; and (2) support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies—; and (3) support state and national efforts to limit the copayments insured patients pay per month for prescribed insulin. (Modify Current HOD Policy) Fiscal Note: Minimal - less than \$1,000	
A	Res. 119 (Medical Student Section)	Medicare Coverage of Dental, Vision, and Hearing Services	RESOLVED, That our American Medical Association support Medicare coverage of preventive dental care, including dental cleanings and x-rays, and restorative services, including fillings, extractions, and dentures (New HOD Policy); and be it further	

Ref	Resolution/	Title	Recommendation/Resolve	Support/Not
Comm	Report			Support/Monitor/ Comments
			RESOLVED, That our AMA support Medicare coverage of routine eye examinations and visual aids, including eyeglasses and contact lenses (New HOD Policy); and be it further RESOLVED, That our American Medical Association amend Policy H- 185.929, "Hearing Aid Coverage," by addition to read as follows: Hearing Aid Coverage H-185.929  1. Our AMA supports public and private health insurance coverage that provides all hearing-impaired infants and children access to appropriate physician-led teams and hearing services and devices, including digital hearing aids.  2. Our AMA supports hearing aid coverage for children that, at minimum, recognizes the need for replacement of hearing aids due to maturation, change in hearing ability and normal wear and tear.  3. Our AMA encourages private health plans to offer optional riders that allow their members to add hearing benefits to existing policies to offset the costs of hearing aid purchases, hearing-related exams and related services.  4. Our AMA supports coverage of hearing tests administered by a physician or physician-led team, aural rehabilitative services, and hearing aids as part of Medicare's Benefit.  5. Our AMA supports policies that increase access to hearing aids and other technologies and services that alleviate hearing loss and its consequences for the elderly.  6. Our AMA encourages increased transparency and access for hearing aid technologies through itemization of audiologic service costs for hearing aids.  7. Our AMA supports the availability of over-the-counter hearing aids for the treatment of mild-to-moderate hearing loss. (Modify Current HOD Policy)  Fiscal Note: Minimal - less than \$1,000	

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
В	Res. 206 (New York)	Medicare Advantage Plan Mandates	RESOLVED, That our American Medical Association advocate for federal legislation to ensure that no person should be mandated to change from traditional Medicare to Medicare Advantage plans. (Directive to Take Action) Fiscal Note: Modest - between \$1,000 - \$5,000	
В	Res. 215 (American College of Cardiology)	Transforming Professional Licensure to the 21st Century	RESOLVED, That our American Medical Association address the issue of state licensure in a comprehensive manner including studying the best mechanisms to ensure interstate licensure for practitioners practicing in multiple states, optimizing state licensure practices to allow for seamless telemedicine practice across state lines, and addressing long delays in practitioners obtaining state licensures which lead to delays in medical care (Directive to Take Action); and be it further RESOLVED, That our AMA research the feasibility of convening a meeting of appropriate stakeholders, including but not limited to state medical boards, medical specialty societies, state medical societies, payers, organizations representing non-physician medical professionals, Centers for Medicare and Medicaid Services-approved accrediting agencies, and patients to develop recommendations to modernize the state medical licensure system including creating mechanisms for multi-state licensure, streamlining the process of obtaining medical licensure, and facilitate practice across state lines (Directive to Take Action); and be it further  RESOLVED, That our AMA report back on these recommendations by the 2022 Interim Meeting. (Directive to Take Action)  Fiscal Note: Modest - between \$1,000 - \$5,000	
E	Res. 502 (New York)	Ensuring Correct Drug Dispensing	RESOLVED, That our American Medical Association request that the United States Food and Drug Administration work with the pharmaceutical and pharmacy industries to facilitate the ability of pharmacies to ensure that a color photo of a prescribed medication and its dosage is attached to the sales receipt to ensure that the drug dispensed is that which has been prescribed. (Directive to Take Action)	

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/ Comments
			Fiscal Note: Minimal - less than \$1,000	
E	Res. 513 (Oklahoma)	Education for Patients on Opiate Replacement Therapy	RESOLVED, That our American Medical Association amend Policy D-95.987, "Prevention of Opioid Overdose," by addition to read as follows:  1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related 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 a drug-related overdose; and (b) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.  3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.  4. Our AMA will advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.	

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Comm	Report			Comments
			5. Our AMA implement an education program for patients on opiate replacement therapy and their family/caregivers to increase understanding of their increased risk of death with concurrent opiate maintenance therapy and the onset of a serious respiratory illness such as SARS-CoV-2. (Modify Current HOD Policy)	
F	Res. 601 (New York)	Development of Resources on End of Life Care	Fiscal Note: Not yet determined  RESOLVED, That our American Medical Association develop educational resources for physicians, allied health professionals and patients on end of life care (Directive to Take Action); and be it further RESOLVED, That our AMA work with all stakeholders to develop proper quality metrics to evaluate and improve palliative and hospice care. (Directive to Take Action)  Fiscal Note: Moderate - between \$5,000 - \$10,000	
F	Res. 608 (Resident and Fellow Section)	Transparency of Resolution Fiscal Notes	RESOLVED, That our American Medical Association amend current policy G-600.061, "Guidelines for Drafting a Resolution or Report," by addition and deletion to read as follows:  (d) A fiscal note setting forth the estimated resource implications (expense increase, expense reduction, or change in revenue) of the any proposed policy, program, study or directive to take action shall be generated and published by AMA staff in consultation with the sponsor prior to its acceptance as business of the AMA House of Delegates.  Estimated changes in expenses will include direct outlays by the AMA as well as the value of the time of AMA's elected leaders and staff. A succinct description of the assumptions used to estimate the resource implications must be included in the AMA House of Delegates Handbook to justify each fiscal note. When the resolution or report is estimated to have a resource implication of \$50,000 or more, the AMA shall publish and distribute a document explaining the major financial components or cost centers (such as travel, consulting fees, meeting costs, or mailing). No resolution or report that proposes policies, programs, studies or actions that require financial support by the AMA shall be considered	

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			without a fiscal note that meets the criteria set forth in this policy. (Modify Current HOD Policy) Fiscal Note: Estimated cost to implement resolution is \$5,810 annually.	
G	Res. 703 (Maryland)	Mandating Reporting of All Antipsychotic Drug Use in Nursing Home Residents	RESOLVED, That American Medical Association Policy D-120.951, "Appropriate Use of Antipsychotic Medications in Nursing Home Patients," be amended by addition and deletion to read as follows: Our AMA will: (1) meet with the Centers for Medicare & Medicaid Services (CMS) for a determination that acknowledges that antipsychotics can be an appropriate treatment for dementia-related psychosis if non-pharmacologic approaches have failed and will ask CMS to cease and desist in issuing citations or financial penalties for medically necessary and appropriate use of antipsychotics for the treatment of dementia-related psychosis; and (2) ask CMS to discontinue the use of antipsychotic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications; and (3) ask CMS to require the reporting of all antipsychotic drugs used and the diagnoses for which they are prescribed. (Modify Current HOD Policy) Fiscal Note: Minimal - less than \$1,000	
G	Res. 720 (Illinois)	Mitigating the Negative Impact of Step Therapy Policies and Nonmedical Switching of Prescription Drugs on Patient Safety	RESOLVED, That our American Medical Association adopt policy supporting the recommendations of the American College of Physicians with respect to insurance step therapy and nonmedical drug switching policies, including:  • All step therapy and medication switching policies should aim to minimize care disruption, harm, side effects and risks to the patient.  • All step therapy and nonmedical drug switching policies should be designed with patients at the center, while accounting for unique needs and preferences.  • All step therapy and nonmedical drug switching protocols should be designed with input from frontline physicians and community	

# $HOD\ Handbook\ Review-Senior\ Physicians\ Section$

Ref Comm	Resolution/ Report	Title	Recommendation/Resolve	Support/Not Support/Monitor/
				Comments
			pharmacists; feature transparent, minimally burdensome processes	
			that consider the expertise of a patient's physician; and include a	
			timely appeals process.	
			• Data concerning the effectiveness and potential adverse consequences	
			of step therapy and nonmedical drug switching programs should be made	
			transparent to the public and studies by policymakers. Alternative	
			strategies to address the rising cost of prescription drugs that do not	
			inhibit patient access to medications should be explored. (New HOD	
			Policy)	
			Fiscal Note: Minimal - less than \$1,000	

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 113 (A-22)

Introduced by: Senior Physicians Section

Subject: Prevention of Hearing Loss-Associated-Cognitive-Impairment through Earlier

Recognition and Remediation

Referred to: Reference Committee A

Whereas, Our AMA holds out as a primary objective "to promote the art and science of medicine and the betterment of public health;" and

2 3 4

Whereas, Our AMA has adopted policy in support of health promotion and preventive care, community preventive services, healthy lifestyles, coverage for preventive care and immunizations, health information and education, training in the principles of population-based medicine, values-based decision-making in the healthcare system, and encouragement of new advances in science and medicine via strong financial and policy support for all aspects of biomedical science and research;<sup>1-8</sup> and

Whereas, Our AMA has prior policy supporting insurance coverage for hearing remediation<sup>9</sup> as well as for dementia treatment;<sup>10</sup> and

Whereas, There is mounting evidence that there is a strong link between hearing impairment in middle and later life and the development of cognitive, as well as social impairments and falls, although its specific causality in relation to later cognitive loss has not yet conclusively been established:<sup>11-31</sup> and

Whereas, The landmark Lancet Commission on Dementia Prevention, Intervention and Care of 2017, amplified by the 2020 follow-up report<sup>13-15</sup> concluded that age-related hearing loss (ARHL) may account for nine percent of all cases of dementia, making this the single largest potentially modifiable risk factor for that condition, beginning in mid-life; and

Whereas, Compared to individuals with normal hearing, those individuals with a mild, moderate, and severe hearing impairment, respectively, have been shown to have a 2-, 3-, and 5-fold increased risk of incident all-cause dementia over 10 years of follow-up in one study;<sup>29</sup> and

Whereas, Based on prior and pilot studies,<sup>30-31</sup> the causative link between hearing impairment in middle age and later life to cognitive impairment is likely to be confirmed by ongoing ACHIEVE<sup>32</sup> and other clinical trials now in progress; and

Whereas, The return on investment for hearing remediation, especially but not exclusively in mid-life, will be substantial and time-sensitive because it may ameliorate (by delay in onset or even prevention of cognitive decline) far more costly care for those with cognitive decline (direct and indirect costs). Delaying the onset of Alzheimer's Disease by even one year has significant fiscal benefits. A 2014 study estimated a one-year delay in the onset of Alzheimer's disease would save the US \$113 Billion by 2030. 33-40 This underscores the urgency of current action to reduce subsequent dementia related healthcare costs (perhaps especially, to Medicare) while simultaneously improving the quality of life of affected individuals; and

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Whereas, A generally held calculation for the yearly cost of caring for those with dementia exceeds \$307 billion as of 2010, and is expected to rise to \$624 billion in 2030 and \$1.5 trillion by 2050. The current yearly market cost of hearing aids in the US is estimated at \$9 billion. This suggests that, with a 9% increase in risk of development of cognitive loss later in life due to unaddressed hearing loss, <sup>13,15</sup> remediating even this <u>single</u> important element linked to cognitive decline would be cost-effective immediately, and will be increasingly so in the future; <sup>39,40</sup> and

Whereas, The issue of hearing impairment is also a matter of health and social equity, with serious immediate and long-term consequences resulting from neglect of remediation. Unaddressed hearing loss reduces earnings potential and increases disability during gainful years, even before factoring in the likelihood of developing cognitive loss later. Sadly, the cost of hearing amplification and other forms of remediation is significant enough (even with over-the-counter products, which while possibly helpful do not come with professional guidance) to deter purchase and implementation by an indigent population;<sup>46</sup> and

Whereas, It is indisputable that promotion of any possibly effective means of delay, prevention, as well as timely treatment of cognitive impairment and dementia is highly desirable for public health, for humane as well as financial reasons; and

Whereas, Congress has shown interest in expanding coverage for hearing remediation in the most recent bill, HR 1118, 'Medicare Hearing Act of 2021,' filed in the current Congressional Session, affording a strategic opportunity for our AMA to more effectively advocate now for expanding coverage to include coverage of preventive strategies in middle age, by promoting this as a way to mitigate future Medicare costs;<sup>41-43</sup> and

Whereas, Some developed countries such as Brazil have launched national efforts to bring hearing remediation to the masses<sup>45</sup> as a means of reducing later cognitive decline, suggesting that early remediating of hearing is felt by other nations to be a cost-effective pursuit; and

Whereas, The issues involved in analyzing all factors impeding adequate distribution of hearing remediation are complex, and require physicians to be current, informed, and involved in the discussion with patients;<sup>44,47-48</sup> and

Whereas, A number of groups have a stake in promoting hearing remediation, including professional and citizen and Federal Agencies, such as the Agency for Health Research and Quality and the National Institute on Deafness and Other Communication Disorders (NIDCD); therefore be it

RESOLVED, That our American Medical Association promote awareness of hearing impairment as a potential contributor to the development of cognitive impairment in later life, to physicians as well as to the public (Directive to Take Action); and be it further

RESOLVED, That our AMA promote, and encourage other stakeholders, including public, private, and professional organizations and relevant governmental agencies, to promote the conduct and acceleration of research into specific patterns and degrees of hearing loss to determine those most linked to cognitive impairment and amenable to correction (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for increased hearing screening, and expanding all avenues for third party coverage for effective hearing loss remediation beginning in mid-life or whenever detected, especially when such loss is shown conclusively to contribute significantly to the development of, or to magnify the functional deficits of cognitive impairment, and/or to limit the capacity of individuals for independent living. (Directive to Take Action)

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

Received: 04/07/22

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- 8. H-450.938 Value-Based Decision-Making in the Health Care System
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# AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 114

(A-22)

Introduced by: Senior Physicians Section

Subject: Oral Healthcare IS Healthcare

Referred to: Reference Committee A

Whereas, Nationwide, around 50% of Americans 65 and older lack any source of dental insurance, and since its inception in 1965, Medicare has only covered dental care under narrowly prescribed circumstances;<sup>1</sup> and

Whereas, Nearly half of Americans 65 and over didn't visit a dentist in the last year, citing expense, (and 12% have not received dental care in five or more years). Nearly one in five have lost all their natural teeth (even higher in black and non-Hispanic populations);<sup>2</sup> and

Whereas, Unaddressed tooth and gum disease dramatically increases the risks of cardiovascular events such as heart attacks and stroke, and such events are leading causes of death and disability in Medicare recipients, and there is a correlation between poor oral health and chronic diseases more common in the elderly, such as diabetes and Alzheimer's, as well as head and neck cancers:<sup>3</sup> and

Whereas, Prevention and treatment of dental diseases is effective in reducing many of these adverse health consequences;<sup>4</sup> and

Whereas, Dental issues are a major source of pain, interfering directly with nutrition and hydration, and painful dental infections are a common cause of emergency department visits, some life threatening, requiring hospitalization and major expense; and

Whereas, In a 2019 AARP poll, 84 percent of Americans supported adding dental, vision and hearing coverage to Medicare, even if their costs would increase;<sup>5</sup> and

Whereas, In all populations, including seniors, dental issues are a major source of both economic as well as healthcare disparity;<sup>6</sup> and

Whereas, Expanded use of medication for Opioid Use Disorder has seen increasing prescription of Suboxone in buccal or sublingual form, which delivery method has been shown to dramatically increase the incidence of severe dental disease, including even loss of all teeth;<sup>7-9</sup> and

Whereas, Congress is poised to consider Medicare expansion under various current and pending proposals; therefore be it

RESOLVED, That our American Medical Association reaffirm that dental and oral health are integral components of basic health care and maintenance regardless of age (Reaffirm HOD Policy); and be it further

Resolution: 114 (A-22)

Page 2 of 2

RESOLVED, That our AMA, through the Center for Health Equity, highlight the substantial contribution of dental and oral healthcare disparities to health inequity as well as to social and economic disparities (Directive to Take Action); and be it further

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RESOLVED, That our AMA support ongoing research, legislative actions and administrative efforts to promote access to and adequate coverage by public and private payers for preventative and therapeutic dental services as integral parts of overall health maintenance to all populations (New HOD Policy); and be it further

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- 10 RESOLVED, That our AMA work with other organizations to explore avenues to promote efforts
- 11 to expand Medicare benefits to include preventative and therapeutic dental services, without
- 12 additional decreases in Medicare Part B Reimbursements. (Directive to Take Action)

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

Received: 04/07/22

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#### **RELEVANT AMA POLICY**

### Medicare Coverage for Dental Services H-330.872

Our AMA supports: (1) continued opportunities to work with the American Dental Association and other interested national organizations to improve access to dental care for Medicare beneficiaries; and (2) initiatives to expand health services research on the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population, the optimal dental benefit plan designs to cost-effectively improve health and prevent disease in the Medicare population, and the impact of expanded dental coverage on health care costs and utilization. Citation: CMS Rep. 03, A-19;

#### .....

## Importance of Oral Health in Patient Care D-160.925

Our AMA: (1) recognizes the importance of (a) managing oral health and (b) access to dental care as a part of optimal patient care; and (2) will explore opportunities for collaboration with the American Dental Association on a comprehensive strategy for improving oral health care and education for clinicians. Citation: Res. 911, I-16; Reaffirmed: CMS Rep. 03, A-19;

# AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 125

(A-22)

Introduced by: Senior Physicians Section

Subject: Education, Forewarning and Disclosure regarding Consequences of

**Changing Medicare Plans** 

Referred to: Reference Committee A

Whereas, 1 in 4 senior physicians with regular Medicare insurance already have a Medicare Supplement Insurance or "Medigap," policy<sup>1</sup>; and

Whereas, Some Seniors who enroll in Medicare Advantage plans are not able to use Medigap insurance for their cost sharing and therefore stop paying their Medigap premiums; and

Whereas, If seniors decide to disenroll from Medicare Advantage and return to regular Medicare, they may: (1) have difficulty getting a Medigap plan and may have to provide medical information to qualify to purchase it; (2) may not be able to get the same Medigap plan they had before; and/or (3) need to pay a higher premium for their new Medigap policy; and

Whereas, Most seniors with Medicare have an overwhelming number of plans from which to choose from when turning 65 years of age: Medicare vs. Medicare Advantage, Medicare supplemental policies, and Medicare Part D policies and without guidance to help them understand the intricacies of transitioning from one plan to another, seniors can find themselves with less robust coverage than they need; and

Whereas, It may not be widely appreciated that Medicare switching costs increase if you take Medicare Advantage and then decide to go back to Medicare; and

Whereas, Under current programs being investigated by CMS' Center for Medicare and Medicaid Innovation, beneficiaries may be funneled involuntarily into accountable care organizations without warning or instructions on how they might opt out; therefore be it

Resolution: 125 (A-22)

Page 2 of 3

1 RESOLVED, That our American Medical Association amend policy H-330.870, "Transparency of Costs to Patients for Their Prescription Medications Under Medicare Part D and Medicare Advantage Plans," by addition and deletion to read as follows:

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5 Our AMA will: (1) advocate for provision of transparent print and audio/video patient educational 6 resources to patients and families in multiple languages from health care systems and from 7 Medicare - directly accessible - by consumers and families, explaining clearly the different 8 benefits, as well as the varied, programmatic and other out-of-pocket costs for their medications 9 under Medicare, Medicare Supplemental and Medicare Advantage plans on their personal costs 10 for their medications under Medicare and Medicare Advantage plans—both printed and online video--which health care systems could provide to patients and which consumers could access 11 12 directly; and

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(2) advocate for printed and audio/video patient educational resources regarding personal costs, changes in benefits and provider panels that may be incurred when switching (voluntarily or otherwise) between Medicare, Medical Supplemental and Medicare Advantage or other plans, including additional information regarding federal and state health insurance assistance programs that patients and consumers could access directly; and

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(23) support advocate for increased funding for federal and state health insurance assistance programs and educate physicians, hospitals, and patients about the availability of and access to these such programs. (Modify Current HOD Policy)

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

Received: 05/03/22

#### REFERENCE

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## **RELEVANT AMA POLICY**

## **Medicare Advantage Policies H-285.913**

Our AMA will:

1. pursue legislation requiring that any Medicare Advantage policy sold to a Medicare patient must include a seven-day waiting period that allows for cancellation without penalty;
2. pursue legislation to require that Medicare Advantage policies carry a separate distinct page, which the patient must sign, including the statement, "THIS COVERAGE IS NOT TRADITIONAL MEDICARE. YOU HAVE CHOSEN TO CANCEL YOUR TRADITIONAL MEDICARE COVERAGE; NOT ALL PHYSICIANS, HOSPITALS AND LABORATORIES ACCEPT THIS NEW MEDICARE ADVANTAGE POLICY AND YOU MAY PERMANENTLY LOSE THE ABILITY TO PURCHASE MEDIGAP SECONDARY INSURANCE" (or equivalent statement) and specifying the time period before they can resume their traditional Medicare coverage; and 3. petition the Centers for Medicare and Medicaid Services to implement the patient's signature page in a Medicare Advantage policy.

Citation: Res. 907, I-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 01, A-18; Reaffirmation: I-18

# Deemed Participation and Misleading Marketing by Medicare Advantage Private Fee for Service Plans D-330.930

Our AMA will continue its efforts to educate physicians and the general public on the implications of participating in programs offered under Medicare Advantage and educate

Resolution: 125 (A-22)

Page 3 of 3

physicians and the public about the lack of secondary coverage (Medigap policies) with Medicare Advantage plans and how this may affect enrollees.

Citation: BOT Action in response to referred for decision Res. 711, I-06; Reaffirmation A-08;

Modified: CMS Rep. 01, A-19

# Legislation for Assuring Equitable Participation of Physicians in Medicare Advantage H-330.916

Our AMA seeks to have the CMS, while contracting with Medicare Advantage organizations for Medicare services, require the following guarantees to assure quality patient care to medical beneficiaries: (1) a Medicare Advantage patient shall have the right to see a duly licensed physician of the appropriate training and specialty; (2) if CMS decertifies a Medicare Advantage plan, enrollees in that plan who are undergoing a course of treatment by a physician at the time of such termination shall continue to receive care from their treating physician until an appropriate transfer is accomplished; and (3) any Medicare Advantage plan deselection of participating physicians may occur only after the physician has been given the opportunity to appeal the deselection decision to an Independent Review Body.

Citation: Res. 707, I-98; Reaffirmed: BOT Rep. 23, A-09; Modified: CMS Rep. 01, A-19

# Transparency of Costs to Patients for Their Prescription Medications Under Medicare Part D and Medicare Advantage Plans H-330.870

Our AMA will: (1) advocate for transparent patient educational resources on their personal costs for their medications under Medicare and Medicare Advantage plans--both printed and online video--which health care systems could provide to patients and which consumers could access directly; and (2) support increased funding for federal and state health insurance assistance programs and educate physicians, hospitals, and patients about the availability of these programs.

Citation: Res. 817, I-19

## Medicare Advantage Opt Out Rules H-330.913

Our AMA: (1) opposes managed care "bait and switch" practices, whereby a plan entices patients to enroll by advertising large physician panels and/or generous patient benefits, then reduces physician reimbursement and/or patient benefits, so that physicians leave the plan, but patients who can't must choose new doctors; (2) supports current proposals to extend the 30 day waiting period that limits when Medicare recipients may opt out of managed care plans, if such proposals can be amended to create an exemption to protect patients whenever a plan alters benefits or whenever a patient's physician leaves the plan; and (3) supports changes in CMS regulations which would require Medicare Advantage plans to immediately notify patients, whenever such a plan alters benefits or whenever a patient's physician leaves the plan, and to give affected patients a reasonable opportunity to switch plans.

Citation: Res. 707, A-99; Reaffirmed: CMS Rep. 5, A-09; Modified: CMS Rep. 01, A-19

# **Support for Seamless Physician Continuity of Care H-390.836**

Our AMA encourages physicians who encounter contractual difficulties with Medicare Advantage (MA) plans to contact their Centers for Medicare & Medicaid Services (CMS) Regional office.

Citation: BOT Action in response to referred for decision Res. 816, I-16

# AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 515 (A-22)

Introduced by: Senior Physicians Section

Subject: Reducing Polypharmacy as a Significant Contributor to Senior Morbidity

Referred to: Reference Committee E

Whereas, Excessive, unnecessary, or incompatible medication use increases the risk of adverse drug effects, including falls, cognitive impairment, adverse drug interactions and drug-disease interactions:<sup>1,4,5</sup> and

Whereas, Older patients often have multiple complex conditions making drug therapy an essential part of medical management; yet multiple medications in complex patients may shift the benefit of drug therapy from positive to negative:<sup>2, 6</sup> and

Whereas, Although some EHRs are automatically screening patient med lists for incompatibilities, they may not include supplements and OTC meds; and fidelity with actual current regimens is compromised when self reporting is relied upon, especially in the setting of cognitive decline; and

Whereas, Consumer patient education on polypharmacy has been raised by such groups as AARP, Consumer Reports, and governmental units such as CDC with questionable penetrance to the affected population; and

Whereas, Physicians are the natural source for patient education and engagement;3 and

Whereas, It is advisable for the AMA to use its resources to educate patients about the dangers of polypharmacy, and to assist physicians to take steps to recognize and reduce it;<sup>7-10</sup> therefore be it

RESOLVED, That our American Medical Association work with other organizations e.g., AARP, other medical specialty societies, PhRMA, and pharmacists to educate patients about the significant effects of all medications and most supplements, and to encourage physicians to teach patients to bring all medications and supplements or accurate, updated lists including current dosage to each encounter (Directive to Take Action); and be it further

RESOLVED, That our AMA along with other appropriate organizations encourage physicians and ancillary staff if available to initiate discussions with patients on improving their medical care through the use of only the minimal number of medications (including prescribed or over-the-counter, including vitamins and supplements) needed to optimize their health (Directive to Take Action); and be it further

 RESOLVED, That our AMA work with other stakeholders and EHR vendors to address the continuing problem of inaccuracies in medication reconciliation and propagation of such inaccuracies in electronic health records, and to include non-prescription medicines in medication compatibility screens. (Directive to Take Action)

Resolution: 515 (A-22)

Page 2 of 4

Fiscal Note: Not yet determined

Received: 05/03/22

#### REFERENCES:

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## **RELEVANT AMA POLICY**

# Improving the Quality of Geriatric Pharmacotherapy H-100.968

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.

Citation: CSA Rep. 5, A-02; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 01, A-20

# Supporting Safe Medical Products as a Priority Public Health Initiative H-120.958

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 on 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 coding system for prescription medicine packaging in an effort to improve patient safety; and (5) seek opportunities to work collaboratively with other stakeholders 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. Citation: Res. 416, A-99; Appended: Res. 504, I-01; Reaffirmation A-10; Modified: CSAPH Rep. 01, A-20

## **Geriatric Medicine H-295.981**

1. Our AMA reaffirms its support for: (a) the incorporation of geriatric medicine into the curricula of medical school departments and its encouragement for further education and research on the problems of aging and health care of the aged at the medical school, graduate and continuing medical education levels; and (b) increased training in geriatric pharmacotherapy at the medical student and residency level for all relevant specialties and encourages the Accreditation Council

Resolution: 515 (A-22)

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for Graduate Medical Education and the appropriate Residency Review Committees to find ways to incorporate geriatric pharmacotherapy into their current programs.

2. Our AMA recognizes the critical need to ensure that all physicians who care for older adults, across all specialties, are competent in geriatric care, and encourages all appropriate specialty societies to identify and implement the most expedient and effective means to ensure adequate education in geriatrics at the medical school, graduate, and continuing medical education levels for all relevant specialties.

Citation: Res. 137, A-85; Reaffirmed by CLRPD Rep. 2, I-95; Appended: CSA Rep. 5, A-02; Appended: Res. 301, A-10; Reaffirmed: BOT Rep. 05, I-16

# National Health Information Technology D-478.995

and safety of these systems.

- 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,
- 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.
- 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:

Resolution: 515 (A-22)

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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; Reaffirmation I-15; Reaffirmed: CMS 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; Reaffirmed: CMS Rep. 3, I-19

# AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 610 (A-22)

Introduced by: Senior Physicians Section

Subject: Making AMA Meetings Accessible

Referred to: Reference Committee F

Whereas, AMA has as a major goal the reduction of health care disparities; and

Whereas, AMA's Code of Ethics Opinion 8.5 states that "physicians should: (h) strive to increase the diversity of the physician workforce as a step toward reducing health care disparities"; and

Whereas, The self-reported incidence of disability in the general US population is over 25%<sup>1</sup>, and this is likely an under-estimate for a variety of reasons; and up to 40% in those over 65<sup>2</sup>, while the self-reported incidence of disability in the US *physician* population is approximately 3.1%<sup>3</sup>, which is undoubtedly an underestimate of the actual incidence, for a variety of historical and social reasons; and

Whereas, Discrimination against various marginalized physician membership populations has occurred in AMA throughout its history, and demographic surveys of AMA physician leadership as required by Policy G-600.035 do not include questions regarding disability, so there is no information in the CLRPD Report<sup>4</sup> on this important demographic variable amongst AMA leaders; and

Whereas, Intentional inclusion of individuals with disabilities in all aspects of AMA leadership will predictably lead to increased integration of persons with disabilities amongst members and leaders, and increased awareness of the lived experience and worldviews of physicians and patients with disabilities; and

Whereas, Provision of accommodations to promote full participation and accessibility by those with disabilities is required by the ADA<sup>5</sup> of all large employers (including AMA) and regulatory agencies and of places of public accommodation, extending even into internet accessibility; and

Whereas, On-site AMA meetings spread out through a variety of physical venues present unique challenges to participants who are mobility impaired or have other disability related impediments to participation; and

Whereas, AMA members who are experiencing temporary illness, injuries, caretaking responsibilities, or travel or mobility limitations may be unable to participate physically in on-site leadership meetings; and

Whereas, Pandemic exigency and non-disability related travel restriction has demonstrated the ability of organization such as our AMA to develop mechanisms for holding virtual meetings; and

Resolution: 610 (A-22) Page 2 of 4

Whereas, Hybrid (meaning on-site AS WELL AS virtual) meetings are being held by many organizations during the transition from pandemic, demonstrating the capability of organizations to make appropriate accommodations for accessibility to all participants; therefore be it

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RESOLVED, That all future American Medical Association meetings be structured to provide accommodations for members who are able to physically attend, but who need assistance in order to meaningfully participate (Directive to Take Action); and be it further

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RESOLVED, That our AMA investigate ways of allowing meaningful participation in all meetings of the AMA by members who are limited in their ability to physically attend meetings (Directive to Take Action); and be it further

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RESOLVED, That our AMA revisit our criteria for selection of hotels and other venues for the HOD in order to facilitate maximum participation by members with disabilities (Directive to Take Action); and be it further

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- RESOLVED, That our AMA report back to the HOD by no later than the 2023 Annual Meeting with a plan on how to maximize HOD meeting participation for members with disabilities.
- 19 (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 05/03/22

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# **RELEVANT AMA POLICY**

# 8.5 Disparities in Health Care

Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to differences in individual patientsclinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.

This represents a significant challenge for physicians, who ethically are called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics. To fulfill this professional obligation in their individual practices physicians should:

- (a) Provide care that meets patient needs and respects patient preferences.
- (b) Avoid stereotyping patients.
- (c) Examine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.
- (d) Work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients.
- (e) Encourage shared decision making.

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(f) Cultivate effective communication and trust by seeking to better understand factors that can influence patients health care decisions, such as cultural traditions, health beliefs and health literacy, language or other barriers to communication and fears or misperceptions about the health care system.

The medical profession has an ethical responsibility to:

- (g) Help increase awareness of health care disparities.
- (h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.
- (i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

# **AMA Principles of Medical Ethics: I.IV.VII.VIII.IX**

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

# 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

# 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.

Citation: CCB/CLRPD Rep. 3, A-12; Appended: Res. 616, A-14; Appended: CLRPD Rep. 1, I-15; Modified: Speakers Rep., I-17; Modified: BOT Rep. 27, A-19

# Advocacy for Physicians and Medical Students with Disabilities D-615.977

Our AMA will: (1) establish an advisory group composed of AMA members who themselves have a disability to ensure additional opportunities for including physicians and medical students with disabilities in all AMA activities; (2) promote and foster educational and training opportunities for AMA members and the medical community at large to better understand the role disabilities can play in the healthcare work environment, including cultivating a rich understanding of so-called invisible disabilities for which accommodations may not be immediately apparent; (3) develop and promote tools for physicians with disabilities to advocate for themselves in their own workplaces, including a deeper understanding of the legal options available to physicians and medical students to manage their own disability-related needs in the workplace; and (4) communicate to employers and medical staff leaders the importance of including within personnel policies and medical staff bylaws

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protections and reasonable accommodations for physicians and medical students with visible and invisible disabilities.

Citation: BOT Rep. 19, I-21

# Strategies for Enhancing Diversity in the Physician Workforce H-200.951

Our AMA: (1) supports increased diversity across all specialties in the physician workforce in the categories of race, ethnicity, disability status, sexual orientation, gender identity, socioeconomic origin, and rurality; (2) commends the Institute of Medicine (now known as the National Academies of Sciences, Engineering, and Medicine) for its report, "In the Nation's Compelling Interest: Ensuring Diversity in the Health Care Workforce," and supports the concept that a racially and ethnically diverse educational experience results in better educational outcomes; (3) encourages the development of evidence-informed programs to build role models among academic leadership and faculty for the mentorship of students, residents, and fellows underrepresented in medicine and in specific specialties; (4) encourages physicians to engage in their communities to guide, support, and mentor high school and undergraduate students with a calling to medicine; (5) encourages medical schools, health care institutions, managed care and other appropriate groups to adopt and utilize activities that bolster efforts to include and support individuals who are underrepresented in medicine by developing policies that articulate the value and importance of diversity as a goal that benefits all participants, cultivating and funding programs that nurture a culture of diversity on campus, and recruiting faculty and staff who share this goal; and (6) continue to study and provide recommendations to improve the future of health equity and racial justice in medical education, the diversity of the health workforce, and the outcomes of marginalized patient populations. Citation: CME Rep. 1, I-06; Reaffirmed: CME Rep. 7, A-08; Reaffirmed: CCB/CLRPD Rep. 4, A-13; Modified: CME Rep. 01, A-16; Reaffirmation A-16; Modified: Res. 009, A-21; Modified: CME Rep. 5, A-21

# Advocacy for Physicians with Disabilities D-90.991

- 1. Our AMA will identify medical, professional and social rehabilitation, education, vocational training and rehabilitation, aid, counseling, placement services and other services which will enable physicians with disabilities to develop their capabilities and skills to the maximum and will hasten the processes of their social and professional integration or reintegration.
- 2. Our AMA supports physicians and physicians-in-training education programs about legal rights related to accommodation and freedom from discrimination for physicians, patients, and employees with disabilities.

Citation: Res. 617, A-19; Reaffirmed: CME Rep. 2, I-21; Modified: BOT Rep. 19, I-21

REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (A-22) Parameters of Medicare Drug Price Negotiation (Alternate Resolution 113-N-21) (Reference Committee A)

## **EXECUTIVE SUMMARY**

At the November 2021 Special Meeting, the House of Delegates referred the second resolve of Alternate Resolution 113, as well as an amendment proffered during consideration of Alternate Resolution 113. The second resolve of Alternate Resolution 113 asked that our American Medical Association (AMA) reaffirm Policy H-110.980, which outlines principles guiding the use of international price indices and averages in determining the price of and payment for drugs, including those covered in Medicare Parts B and D. In contrast, the amendment to Alternate Resolution 113 opposed reaffirmation of Policy H-110.980, and instead asked our AMA to advocate for Medicare drug price negotiation to reduce prices paid by Medicare for medications in Part B and Part D and physician acquisition costs for medications in Part B.

In addition, the amendment proposed to amend Policy H-110.980[2(a)] by addition and deletion to read as follows:

- 2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
- a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
- a. Any international drug price index used to determine Medicare Part D drug prices should be based on a reasonable percentage of the drug's volume weighted net average price in at least six large western industrialized nations;

The Council understands that the introduction of original Resolution 113-N-21, as well as amendments made during consideration of Alternate Resolution 113-N-21, stemmed from strong support in the House of Delegates for the AMA to advocate on the issue of prescription drug pricing more actively and strongly. The AMA has been "at the table," advocating AMA policy on drug pricing with Congress via meetings with legislators and their staff as well as letters and other communications. The AMA also has engaged the Administration through comment letters in response to regulatory activity as well as direct interactions and meetings. Finally, the AMA and members of the Federation have similarly advocated at the state level.

The AMA's advocacy priorities have been to preserve patient access to necessary medications, and limit burdens on and protect physician practices. While recent legislative and regulatory proposals incorporating international drug price averages and/or indices in Medicare drug pricing have not met these and other important thresholds outlined in Policy H-110.980, the Council believes that is not a reason to change AMA policy. AMA policy needs to be able to proactively respond to the more likely path forward on this issue—through regulation, targeting Medicare Part B drug payment—and needs to be consistent across not only all of Medicare, but across all health plans. The Council does, however, see promise in testing the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent. and predictable out-of-pocket costs for select prescription drugs.

## REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-A-22

Subject: Parameters of Medicare Drug Price Negotiation

(Alternate Resolution 113-N-21)

Presented by: Asa C. Lockhart, MD, MBA, Chair

Referred to: Reference Committee A

At the November 2021 Special Meeting, the House of Delegates referred the second resolve of 1 2 Alternate Resolution 113, Supporting Medicare Drug Price Negotiation, as well as an amendment 3 proffered during consideration of Alternate Resolution 113. The second resolve of Alternate 4 Resolution 113 asked that our American Medical Association (AMA) reaffirm Policy H-110.980, 5 Additional Mechanisms to Address High and Escalating Pharmaceutical Prices, which outlines 6 principles guiding the use of international price indices and averages in determining the price of 7 and payment for drugs, including those covered in Medicare Parts B and D. In contrast, the 8 amendment to Alternate Resolution 113 opposed reaffirmation of Policy H-110.980, and instead 9 asked our AMA to advocate for Medicare drug price negotiation to reduce prices paid by Medicare for medications in Part B and Part D and physician acquisition costs for medications in Part B. 10

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In addition, the amendment proposed to amend Policy H-110.980[2(a)] by addition and deletion to read as follows:

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2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:

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a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;

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a. Any international drug price index used to determine Medicare Part D drug prices should be based on a reasonable percentage of the drug's volume weighted net average price in at least six large western industrialized nations;

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This report provides background on the impacts of high and escalating prescription drug prices and costs; outlines proposals to leverage an international price index in Medicare Parts B and D; summarizes significant AMA policy and advocacy on prescription drug pricing; and presents policy recommendations.

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#### **BACKGROUND**

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The Council understands that the intent of the amendments proposed to Policy H-110.980 was to take significant and concrete action to lower Medicare Parts D and B drug prices and associated patient cost-sharing. Some recent legislative proposals that incorporate international price indices and averages in Medicare drug price negotiation, addressed by Policy H-110.980, would not only extend negotiated prices to Medicare and Medicare Advantage, but also to private health insurance unless the insurer opts out. The Council agrees wholeheartedly that unsustainably high and

escalating prescription drug prices and costs constitute a consistent and paramount concern for patients and their physicians, employers, states, and the federal government, underpinning the introduction of legislation, or promulgation of regulations, on both the federal and state levels.

Spending on retail prescription drugs totaled \$348.4 billion in 2020, accounting for eight percent of total health spending.¹ Other estimates suggest that spending on prescription drugs as a percent of total health spending is greater when other factors, including the non-retail drug markets and gross profits of other stakeholders involved in drug distribution, payment, and reimbursement are included. Significantly, spending on specialty drugs now constitutes more than one-half of drug spending (53 percent).² The most recent National Health Expenditure data showed that retail prescription drug spending was estimated to have increased by three percent in 2020. Drivers behind the lower rate of growth in prescription drug spending include a slower overall utilization of prescription drugs and a higher use of coupons, which resulted in a reduction in out-of-pocket expenditures.³

Approximately 6.3 billion prescriptions were dispensed in the United States (US) in 2020, 90 percent of which were dispensed as generics.<sup>4</sup> 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 2020—most of whom are Medicare beneficiaries who would be impacted by the proposed, referred amendments to Policy H-110.980—the average annual retail price of therapy with specialty drugs was \$84,442, dropping to \$6,604 for brand-name drugs, both dwarfing the annual price of therapy for generics.<sup>5</sup>

In Medicare, patients face different cost-sharing for prescription drugs, depending on whether the drugs are covered under Medicare Part B or D. In general, Medicare Part B covers prescription drugs that typically are not self-administered; Part B drugs can be provided in a physician's office as part of their service. In addition, Part B covers limited outpatient prescription drugs, including certain oral cancer drugs. Most other retail prescription drugs for medically accepted indications that are not covered by other parts of Medicare fall under Medicare Part D. Within Medicare Part D, the typical formulary design consists of five tiers: preferred generics, generics, preferred brands, non-preferred drugs, and specialty drugs. Within these tiers, among all stand-alone Medicare Part D prescription drug plans, median standard cost sharing in 2022 is \$0 for preferred generics, \$5 for generics, \$42 for preferred brands, 40 percent coinsurance for non-preferred drugs, and 25 percent coinsurance for specialty drugs. For prescription drugs covered under Medicare Part B, for traditional Medicare beneficiaries without a supplemental plan, cost-sharing for covered Part B drugs equates to 20 percent of the Medicare-approved amount after paying any applicable Part B deductible, with no out-of-pocket limit.

Overall, in the Medicare program, between 2007 and 2019, Part D program spending grew by an average annual rate of 5.5 percent and amounted to \$88.4 billion in 2019. Premiums paid by Part D enrollees for basic benefits (not including low-income subsidy enrollees) amounted to \$13.9 billion in 2019, a decrease of 2.1 percent from 2018, before which premiums paid by enrollees had been growing by an average of 12 percent per year. Under Medicare Part B, total drug spending amounted to \$37 billion in 2019, with the top 50 drugs ranked by total spending accounting for 80 percent of total Medicare Part B drug spending.

Relevant to legislative proposals that extend drug prices achieved by Medicare drug price negotiation to private health insurance, 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. Higher costs of prescription drugs often translate to higher premiums, higher prescription drug costsharing, and additional prescription drug tiers to accommodate the higher costs of specialty and

certain generic drugs. In 2021, 88 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.<sup>10</sup>

Overall, patient out-of-pocket costs for retail prescription drugs reached \$61 billion in 2020, with non-retail out-of-pocket costs amounting to \$16 billion. Across Medicare, Medicaid and commercial health plans, eight 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 17 percent paying more than \$500 out-of-pocket.<sup>11</sup>

The higher costs of prescription drugs impact patient health outcomes and 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.

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, 16 percent of adults have not filled a prescription in the past year due to cost, 22 percent chose to take an over-the-counter medication instead, and 13 percent cut pills in half or skipped doses.<sup>12</sup>

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. Many health plans have a formulary design with fixed copays for brand drugs of less than \$30 for preferred products, with a rate of abandonment of 12 percent or less. For non-preferred brand drugs with a copay of \$75, the rate of abandonment is 26 percent or higher. Fifty-six percent of prescriptions with a final cost of over \$500 are not picked up by patients.<sup>13</sup>

# LEVERAGING AN INTERNATIONAL PRICE INDEX IN MEDICARE PARTS B AND D

Proposals previously put forward by the Trump Administration and members of Congress attempted to lower US drug costs by tying them to international prices, and/or would have used an average of international prices, or an international reference price, to help define whether a price of a drug is excessive. While significant legislation addressing drug pricing has passed in the House of Representatives, negotiations have stalled following House passage. The Biden Administration has also stated that it will not implement a model utilizing an international price index in Medicare Part B without further rulemaking.

Current Status of Prescription Drug Price Negotiation in Medicare Parts D and B

The "noninterference clause" in the Medicare Modernization Act of 2003 (MMA) states that the Secretary of Health and Human Services (HHS) "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Instead, participating Part D plans compete with each other based on plan premiums, cost-sharing and other features, which provides an incentive to contain prescription drug spending. To contain spending, Part D plans not only establish formularies, implement utilization management measures, and encourage beneficiaries to use generic and less-expensive brand-name drugs, but are

required under the MMA to provide plan enrollees access to negotiated drug prices. Similar to how drug prices are determined in other commercial plans available in the employer, individual and small-group markets, these prices are achieved through direct negotiation with pharmaceutical companies to obtain rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

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In efforts to lower drug prices and patient out-of-pocket costs in Medicare Part D, multiple bills have been introduced in Congress to enable and/or require the Secretary of HHS to negotiate covered Part D drug prices on behalf of Medicare beneficiaries. However, historically, the Congressional Budget Office (CBO), as well as Centers for Medicare & Medicaid Services (CMS) actuaries, have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D. 14,15

In fact, CBO has previously acknowledged that, in order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions. In the absence of such authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited." CMS actuaries have concurred, stating "the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation. Manufacturers would have little to gain by offering rebates that are not linked to a preferred position of their products, and we assume that they will be unwilling to do so." 17

The Council underscores that recent legislative and regulatory proposals that aimed to incorporate international drug price indices or averages in Medicare have targeted Part B in addition to Part D; therefore, it is imperative to understand how prices of Part B drugs are determined as well. Under current law, the Secretary of HHS also does not negotiate prices of and payment for Part B drugs. Instead, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high-volume purchases—plus a percentage of the ASP. Accordingly, any proposal to change how Part B drugs are priced—including the incorporation of international drug price indices and/or averages—also could significantly change how and the level at which physicians are paid for Part B drugs.

## Recent Significant Legislative Developments

Legislation preceding Build Back Better, H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, which passed the House of Representatives during the 116th Congress, would have opened the door to the Secretary of HHS to negotiate the prices of certain drugs. Title I of H.R. 3 would require the Secretary of HHS to directly negotiate with 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. Under H.R. 3, the Secretary of HHS would be required to negotiate maximum prices for: (1) insulin products; (2) with respect to 2023, at least 25 single-source, brand-name drugs that do not have generic competition and that are among either the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage (MA); (3) beginning in 2024, at least 50 such single-source, brand-name drugs; and (4) newly approved single-source, brand-name drugs with wholesale acquisition costs equal to or greater than the median household income. The negotiated

prices would be offered under Medicare and Medicare Advantage, as well as under private health insurance unless the insurer opts out. 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.<sup>18</sup>

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Showing the impact of negotiating leverage, the December 10, 2019 CBO cost estimate "Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act" stated that Title I of the legislation would reduce federal direct spending for Medicare by \$448 billion over the 2020-2029 period. 19 In its October 11, 2019 estimate, CBO estimated that the largest savings would be the result of lower prices for existing drugs that are sold internationally, which would be impacted by the application of the "average international market price" outlined in the bill. <sup>20</sup> CBO also estimated that due to the collective provisions of H.R. 3, approximately eight fewer drugs would be introduced to the US market over the 2020-2029 period, with approximately 30 fewer drugs introduced to the US market over the following decade. <sup>21</sup> There would be a reduction of drugs introduced in the US market due to the enactment of H.R. 3 "because the potential global revenues for a new drug over its lifetime would decline as a result of enactment, and in some cases the prospect of lower revenues would make investments in research and development less attractive to pharmaceutical companies....The effects would be larger in the 2030s because of the considerable time needed to develop new drugs and because of the larger effects that would occur when more phases of development are affected."<sup>22</sup> In addition, CBO estimated that "[t]he introduction of new drugs would tend to be delayed in the six reference countries: Australia, Canada, France, Germany, Japan, and the United Kingdom. Prices of new drugs in those countries would rise somewhat."<sup>23</sup>

While H.R. 3 was reintroduced in this Congress, the latest congressional action on drug pricing was a part of H.R. 5376, the Build Back Better Act, which passed the House of Representatives in November 2021. If enacted into law, the House-passed version of Build Back Better would allow the Secretary of HHS to negotiate the prices of a small number of high-cost drugs covered under Medicare Part D (starting in 2025) and Part B (starting in 2027). The negotiation process would apply to no more than 10 single-source brand-name drugs or biologics that lack generic or biosimilar competitors in 2025, ramping up to no more than 20 in 2028 and later years. The drugs selected for negotiation would be required to be among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. All insulin products would also be subject to negotiation.<sup>24</sup>

Certain drugs would be exempt from negotiation, including those that are less than nine years (for small-molecule drugs) or 13 years (for biological products) from their U.S. Food and Drug Administration (FDA)-approval or licensure date. "Small biotech drugs" would also be exempt from negotiation until 2028; these drugs are defined as those which account for 1 percent or less of Part D or Part B spending and account for 80 percent or more of spending under each part on that manufacturer's drugs. In addition, the legislation exempts from negotiation drugs with Medicare spending of less than \$200 million in 2021 (increased by the Consumer Price Index for All Urban Consumers (CPI-U) for subsequent years) and drugs with an orphan designation as their only FDA-approved indication.<sup>25</sup>

Due to lack of congressional support for incorporating international price indices/averages into the
Medicare drug price negotiation process for drugs covered under Medicare Parts D and B, the
Build Back Better Act as passed by the House of Representatives instead establishes an upper limit
for the negotiated price (the "maximum fair price") equal to a percentage of the non-federal
average manufacturer price (AMP)—the average price wholesalers pay manufacturers for drugs
distributed to non-federal purchasers. The "maximum fair price" is defined as 75 percent of the

non-federal AMP for small-molecule drugs more than 9 years but less than 12 years beyond approval; 65 percent for drugs between 12 and 16 years beyond approval or licensure; and 40 percent for drugs more than 16 years beyond approval or licensure. The payment for Part B drugs selected for negotiation would be based on the maximum fair price, versus ASP under current law. 26 The Council underscores that at the time this report was written, there remains insufficient support in the House of Representatives and Senate to incorporate international price indices/averages into the Medicare drug price negotiation process for drugs covered under Medicare Parts D and B.

The significant differences between the drug negotiation provisions of the Build Back Better Act and H.R. 3 cause more limited cost savings and impacts on drug development under the Build Back Better Act. CBO estimated \$78.8 billion in Medicare savings in the 2022-2031 period from the drug negotiation provisions in the Build Back Better Act. In addition, CBO estimated that one fewer drug would come to the US market over the 2022-2031 period, four fewer over the subsequent decade, and approximately five fewer the decade after that.<sup>27</sup>

# Recent Regulatory Activity

The regulatory process is a pathway that cannot be ignored in its potential to change the way and level at which drugs are paid for under Medicare Part B through the incorporation of international drug price indices or averages. Notably, the AMA has been active in its advocacy efforts in response to regulatory proposals to date. In October of 2018, the Trump Administration released an Advance Notice of Proposed Rulemaking (ANPRM) entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but rather outlined the Administration's thinking at the time, and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. The ANPRM outlined a new payment model for physician-administered drugs paid under Medicare Part B that would 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 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 would 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. Instead, providers would continue to be entitled to bill a drug administration fee, and would also be entitled to receive a drug add-on fee. While the ANPRM was somewhat short on detail on exactly how this add-on fee would be calculated, it appears the add-on fee would be a flat fee that is based on six percent of the historical average sales price for the drug in question.<sup>28</sup>

In September 2020, an executive order, "Lowering Drug Prices by Putting America First," was issued, and called for testing of payment models to apply international price benchmarking to Part B and Part D prescription drugs and biological products. For Part B, the executive order instructed

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the Secretary of HHS to implement rulemaking to test a payment model under which "Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." The executive order defined the "most-favored-nation price" as "the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." For Part D, the executive order instructed the Secretary of HHS to develop and implement rulemaking to test a payment model for high-cost Part D drugs, limiting payment to these drugs to the most-favored-nation price, to the extent feasible.<sup>29</sup>

In November of 2020, the Trump Administration issued an interim final rule entitled "Most Favored Nation (MFN) Model" to establish a model through CMMI that would phase in changing Medicare's payment for approximately 50 Part B drugs that make up a high percentage of Part B spending from paying solely based on manufacturers' ASP to the lowest adjusted international price for the drug, defined as the lowest gross domestic product (GDP)-adjusted price paid by an OECD member country with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the US GDP per capita. Addressing physician payment, the add-on payment based on six percent of ASP for the individual drug would be replaced with a flat payment per dose that would be uniform for all included drugs in the MFN Model. As the model was scheduled to become effective January 1, 2021, on December 28, 2020, the US District Court for the Northern District of California issued a nationwide preliminary injunction in *Biotechnology Innovation Organization v. Azar*, which preliminarily enjoined HHS from implementing the Most Favored Nation Rule. Given this preliminary injunction, the MFN Model was not implemented on January 1, 2021. The interim final rule was formally rescinded in December 2021 and will not be implemented without further rulemaking.<sup>30</sup>

# RELEVANT AMA POLICY

 AMA policy on prescription drug pricing is diverse, multifaceted, and allows the AMA to advocate on a breadth of issues to tackle high and escalating drug pricing, not limited to Medicare drug price negotiation or opening the door for the use of international drug price indices and averages in Medicare Parts D and B. This strong foundation of AMA policy addressing prescription drug pricing, coverage and payment has allowed the AMA to actively engage on legislative and regulatory proposals on drug pricing on both the federal and state levels.

Significantly, Policy H-110.987 supports legislation that limits Medicare annual drug price increases to the rate of inflation—a significant provision that has been included in recent legislation addressing prescription drug prices. The policy also supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations, as well as for biologics. 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.

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Policy H-110.980[3] supports 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 list price at the time of market introduction. Policy D-100.983 outlines standards for the importation of prescription drug products. 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.

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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.

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Numerous policies aim to improve generic drug pricing and access. Policy H-110.988 states that our AMA will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the FDA, the U.S. Federal Trade Commission (FTC), and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs. The policy also states that our AMA will work 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. In addition, the policy encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and supports measures that increase price transparency for generic prescription drugs. Policy H-100.950 states that our AMA will advocate with interested parties for legislative or regulatory measures that require prescription drug manufacturers to seek FDA and FTC approval before establishing a restricted distribution system; will support requiring pharmaceutical companies to allow for reasonable access to and purchase of appropriate quantities of approved out-of-patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays; and will advocate with interested parties for legislative or regulatory measures that expedite the FDA approval process for generic drugs, including but not limited to application review deadlines and generic priority review voucher programs. Policy H-110.989 supports: (1) the FTC in its efforts to stop "pay for delay" arrangements by pharmaceutical companies; and (2) federal legislation that makes tactics delaying conversion of medications to generic status, also known as "pay for delay," illegal in the United States.

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AMA policy also addresses other primary stakeholders in the prescription drug pricing arena, including pharmacy benefit managers (PBMs). Policy D-110.987 supports the active regulation of PBMs under state departments of insurance; 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; encourages increased transparency in how DIR fees are determined and calculated; and 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. In addition, the policy outlines provisions to be disclosed as part of improved transparency of PBM operations.

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Addressing the impact of prescription cost-sharing requirements on rates of prescription abandonment by patients, Policy H-125.979 contains significant AMA policy provisions promoting improved prescription drug formulary transparency, which address mid-year formulary changes, utilization management requirements and access to accurate, real-time formulary data at the point of prescribing. Policy D-155.994 advocates for third-party payers and purchasers to make cost data available to physicians in a useable form at the point of service and decision-making, including the cost of each alternate intervention, and the insurance coverage and cost-sharing requirements of the respective patient. Policy H-120.919 supports efforts to publish a Real-Time Prescription Benefit (RTPB) standard that meets the needs of physicians, utilizing any electronic health record, and prescribing on behalf of all patients.

AMA policy also recognizes that benefit design can be leveraged to ensure improved prescription drug cost-sharing affordability to promote improved patient adherence to prescribed medication regimens. Policy H-155.960 encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. The policy stipulates that consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance. Similarly, Policy H-110.990 states that cost-sharing requirements for prescription drugs should be based on considerations such as the unit cost of medication, availability of therapeutic alternatives, medical condition being treated, personal income, and other factors known to affect patient compliance.

Shifting to policies directly applicable to the referrals responded to by this report, Policy D-330.954 states that: (1) our American Medical Association (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; and (3) our AMA will prioritize its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

 Council on Medical Service Report 4-I-19 established a set of safeguards in AMA policy, now Policy H-110.980[2], pertaining to the use of international price indices and averages in determining the price of and payment for drugs. The following principles established in the policy are applicable to the pricing of prescription drugs under any health plan or proposal, and are not solely relevant to drugs covered under Medicare Part D, or even Medicare more broadly:

- a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
- b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
- c. The use of any international drug price index or average should preserve patient access to necessary medications;
- d. The use of any international drug price index or average should limit burdens on physician practices; and
- e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.

Significantly, Policy H-110.980[1] advocates standards guiding the use of arbitration in determining the price of prescription drugs 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;
- c. 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 costeffectiveness analysis addressing the drug in question;
- e. The arbitration process should include the submission of a value-based price 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;
- g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
- h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
- i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.

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. Applicable to any vendor program that would be established in Medicare Part B to implement a pilot or permanent model implementing international price averages or indices, 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.

# AMA ADVOCACY ON PRESCRIPTION DRUG PRICING

The Council understands that the introduction of original Resolution 113-N-21, as well as amendments made during consideration of Alternate Resolution 113-N-21, stemmed from strong support in the House of Delegates for the AMA to more actively and strongly advocate on the issue of prescription drug pricing. The AMA has been "at the table," advocating for the enactment of AMA policy pertaining to drug pricing with Congress via meetings with legislators and their staff as well as through letters and other communications. The AMA also has engaged the Administration through comment letters in response to regulatory activity as well as direct interactions and meetings. Finally, the AMA and members of the Federation have similarly advocated at the state level.

Showing the diversity and comprehensiveness of AMA policy and advocacy on drug pricing, the Council is providing a summary below to the House of Delegates of recent significant comments, letters and testimony addressing the introduction of and discussions surrounding prescription drug pricing legislation, and the promulgation of regulations addressing drug pricing.

• In March 2022, the AMA submitted a comment <u>letter</u> in response to the proposed rule outlining Medicare Advantage and prescription drug benefit policies for contract year 2023, in which the AMA supported the proposal to require the application of all pharmacy price concessions, including DIR fees, to drug prices in Medicare Part D at the point-of-sale.

• In August 2021, the AMA submitted a <u>letter</u> to congressional leadership to provide our perspective on health care issues related to the budget reconciliation proposal (Build Back Better). The letter supported efforts to eliminate prohibitions on the negotiation of prescription drug prices within the Medicare program and outlined AMA policy addressing the parameters of Medicare drug price negotiation, including the use of international drug price averages/indices, arbitration and value-based drug pricing. The letter also supported efforts to increase transparency in all aspects of the drug pricing process, as well as measures to address increases in prescription drug prices that exceed the rate of inflation. In addition, the letter outlined AMA policy on and support for efforts to cap patient out-of-pocket prescription drug expenses; pay-for-delay agreements between brand and generic drug manufacturers; and limit the use of drug utilization management tools by payers.

In December 2020, the AMA submitted a comment <u>letter</u> in response to the MFN Model interim final rule, outlining significant concerns regarding the MFN Model and its impact on patient access to essential treatments, as well as the model's financial impact on physician practices.

• In March 2020, the AMA submitted a comment <u>letter</u> in response to the Importation of Prescription Drugs proposed rule.

 • In February 2020, the AMA submitted a comment <u>letter</u> in response to released draft guidance regarding the importation of certain FDA-approved human prescription drug and biological products.

 In May of 2019, the AMA <u>testified</u> as part of the hearing before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health titled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain," submitting <u>answers</u> to follow-up questions after the hearing in August.

In April 2019, the AMA submitted a comment <u>letter</u> in response to the proposed rule, "Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-Of-Sale Reductions in

- Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.
  - In March 2019, the AMA submitted a letter to the leadership of the House Energy and Commerce Committee in support of its efforts, and pending legislation, to address the escalating prices of prescription medication by removing barriers to market entry for affordable prescription medication and shining a light on anticompetitive practices in the pharmaceutical supply chain that can lead to price escalations.
  - In December 2018, the AMA submitted a comment letter in response to the ANPRM on an International Pricing Index Model (IPI model) for Medicare Part B Drugs, in which the AMA highlighted the need for significant reforms to the Medicare Part B competitive acquisition program (CAP) and the IPI model to ensure that beneficiaries have timely access to necessary treatments. The AMA also raised strong concerns with the proposed add-on formula, stating that "reimbursement models based on an 'add-on' formula are intended to adequately reimburse physicians for the costs of acquisition, proper storage and handling, and other administrative costs associated with providing these treatment options for patients. Many drugs included in this model, such as biological products, are complicated drug products that require special attention to handling and storage to remain stable and viable for administration to patients. Drugs that require specific conditions for shipping, storage, and handling result in significantly higher administrative costs to physician practices than many small molecule-type drugs. Due to the special nature of these products, these costs are fixed, and will not decrease as the price of the drug goes down. Given these fixed administrative costs, we are very concerned that, should drug prices decrease as this model predicts, any add-on payment based on an ASP would ultimately decrease with the price of the drug and would no longer be sufficient to cover the administrative costs to the practice. If add-on reimbursement decreases enough that it is no longer sufficient to cover the expenses associated with providing these treatment options, it is likely that practices will no longer be able to offer these options for patients. We strongly urge CMS to consider the impact on the add-on as the IPI model over time could reduce this amount below actual clinician cost."
  - In July 2018, the AMA submitted a comment letter in response to American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint) Request for Information (RFI). In the letter, the AMA strongly supported a select number of Blueprint provisions to the extent that they would promote the following and recommended prompt regulatory action to: (1) require pharmaceutical supply chain transparency; (2) accelerate and expand regulatory action to increase pharmaceutical market competition and combat anti-competitive practices; (3) ensure 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) ensure federal programs and commercial practices billed as lowering prescription medication prices do so for patients directly. The AMA opposed Blueprint proposals that increased patient costs and erected barriers, including onerous insurer paperwork requirements that impede timely patient access to affordable and medically necessary medications and treatments. Further, the AMA opposed policies that would financially penalize physicians and pharmacists for high-cost prescription medication.

# **DISCUSSION**

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Since 2004, AMA Policy D-330.954 has supported giving the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and in 2017, formally prioritized AMA's support for the CMS to negotiate pharmaceutical pricing for all applicable medications covered by CMS. As previously referenced in the report, the CBO and CMS actuaries have

estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D. In order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, CBO stated that the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions."

Addressing the need for administrative leverage in Medicare drug price negotiations, the Council recognizes that incorporating international drug price indices and averages has become a popular proposal to significantly lower drug prices through said negotiations. However, the Council notes that recent legislative and regulatory proposals have not stopped at incorporating international prescription drug prices in Part D—they have extended to Medicare Part B, as well as to private health plans, unless they opt out. In fact, the proposal closest to being implemented in this arena has been via regulation, and solely addressing payment for prescription drugs in Medicare Part B. Therefore, AMA policy addressing the use of international drug price indices and averages in determining domestic drug prices needs to be consistent across not only all of Medicare, but across all health plans.

Recent legislative and regulatory proposals have not met the criteria established in Policy H-110.980, which guides AMA support for the use of international drug price averages/indices in determining domestic drug prices. Ultimately, the priority for the AMA in its advocacy efforts has been to preserve patient access to necessary medications, and limit burdens on and protect physician practices. While recent legislative and regulatory proposals have not met these and other important thresholds outlined in the policy, the Council believes that is not a reason to change AMA policy. In addition, the Council stresses that on the legislative front, at the time this report was written, there remains insufficient support in the House of Representatives and Senate to incorporate international price indices/averages into the Medicare drug price negotiation process for drugs covered under Medicare Parts D and B. Therefore, AMA policy moving forward needs to be able to respond to the more likely path to incorporate international drug price averages and/or indices in Medicare drug pricing—through regulation, targeting Medicare Part B drug payment.

 The amendments proposed to Policy H-110.980 would have significant, negative, unintended consequences for the pricing of and payment for drugs under Medicare Part B, impacting patient access and physician practices. It also could set a dangerous precedent guiding the future payment of physician services. The Council instead firmly supports using arbitration as a lever in prescription drug price negotiations, including in Medicare, instead of a price ceiling based on international prices that does not meet existing policy principles. As such, the Council recommends the reaffirmation of Policy H-110.980. The Council also recommends the reaffirmation of Policy H-110.983, which advocates standards that any revised Medicare Part B Competitive Acquisition Program must meet, as a vendor program has often been proposed along with a model or new program to incorporate international drug price averages or indices in Medicare Part B.

To make patient cost-sharing obligations in the Medicare program more affordable, the Council believes that there is tremendous promise for models under the auspices of the CMMI to test the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent and predictable out-of-pocket costs for select prescription drugs. The Part D Senior Savings Model,<sup>31</sup> which is testing the impact of offering beneficiaries an increased choice of enhanced alternative Part D plan options that offer lower out-of-pocket costs for insulin, is a needed first step in the right direction.

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On the whole, there is significant potential for other components of the AMA prescription drug 1 2 pricing policy agenda to be implemented through legislation and/or regulations, and your Council 3 believes that the focus of AMA advocacy efforts must continue to be multifaceted, diverse and 4 nimble to achieve results for our patients and the physicians who provide their care. Medicare 5 prescription drug price negotiation is only a piece of the larger drug pricing puzzle, which requires 6 interventions to improve transparency and competition in the pharmaceutical marketplace; 7 strengthen regulation of PBMs; limit drug price increases in Medicare to the rate of inflation; and 8 ensure benefit design improves patient medication adherence.

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## RECOMMENDATIONS

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The Council on Medical Service recommends that the following be adopted in lieu of the second resolve of Alternate Resolution 113-N-21, as well as the referred amendment proffered during consideration of Alternate Resolution 113-N-21, and that the remainder of the report be filed.

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1. That our American Medical Association (AMA) reaffirm Policy D-330.954, which states that 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; 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. (Reaffirm HOD Policy)

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2. That our AMA reaffirm Policy H-110.980, which outlines principles to guide AMA support for arbitration as well as the use of international drug price averages/indices in determining domestic drug prices. (Reaffirm HOD Policy)

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3. That our AMA reaffirm Policy H-110.983, which advocates standards that any revised Medicare Part B Competitive Acquisition Program must meet. (Reaffirm HOD Policy)

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33 34 That our AMA encourage the development of models under the auspices of the CMS Innovation Center (CMMI) to test the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent, and predictable out-ofpocket costs for select prescription drugs. (New HOD Policy)

Fiscal note: Less than \$500

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- <sup>29</sup> The White House. Executive Order on Lowering Drug Prices by Putting America First. September 13, 2020. Available at: <a href="https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/">https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/</a>.
- <sup>30</sup> Centers for Medicare & Medicaid Services. Most Favored Nation Model. Available at: <a href="https://innovation.cms.gov/innovation-models/most-favored-nation-model">https://innovation.cms.gov/innovation-models/most-favored-nation-model</a>.
- <sup>31</sup> Centers for Medicare & Medicaid Services. Part D Senior Savings Model. Available at: https://innovation.cms.gov/innovation-models/part-d-savings-model.

Resolution: 106

(A-22)

Introduced by: New York

Subject: Hospice Recertification for Non-Cancer Diagnosis

Referred to: Reference Committee A

Whereas, The number of Americans ages 65 and older is projected to more than double from 46 million today to over 98 million by 2060; and

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Whereas, The rate of dementia and failure to thrive at the end of life for older Americans is increasing because of these demographic shifts; and

Whereas, The ability to predict the end of life is an art as opposed to a science; and

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Whereas, These patients will need hospice care; therefore be it

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- RESOLVED, That our American Medical Association request that the Centers for Medicare &
- Medicaid Services allow automatic reinstatement for hospice if a patient survives for more than
- 13 6 months with a non-cancer diagnosis and that prognosis remains terminal. (Directive to Take
- 14 Action)

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

Received: 03/22/22

Resolution: 118

(A-22)

Introduced by: Medical Student Section, Endocrine Society

Subject: Caps on Insulin Co-Payments for Patients with Insurance

Referred to: Reference Committee A

Whereas, Diabetes affects approximately 9.4% of the U.S. population and is the seventh leading cause of death nationally<sup>1,2</sup>; and

Whereas, Direct medical costs for diagnosed diabetes were estimated at \$327.2 billion in 2017, with nearly \$102 billion lost due to lower productivity resulting from diabetes<sup>3</sup>; and

Whereas, The annual average medical cost per person with diabetes is \$13,240 with approximately 44% of expenditures stemming from prescription medications, including insulin<sup>4</sup>; and

Whereas, From 2012 to 2016, the average point-of-sale price of insulin nearly doubled from 13 cents per unit to 25 cents per unit, translating to a daily cost increase from \$7.80 to \$15 for a patient with Type 1 diabetes using an average amount of insulin (60 units per day)<sup>5</sup>; and

Whereas, One in four patients reported cost-related insulin underuse, including taking smaller doses and skipping doses, which was independent of the patient's prescription drug coverage plan<sup>6</sup>; and

Whereas, Patients who report cost-related underuse were more likely to have poor glycemic control, which is associated with an increased risk for complications such as hypertension, chronic kidney disease, neuropathy, lower limb amputations, retinopathy, stroke, coronary heart disease, depression, and cancer<sup>6,7</sup>; and

Whereas, Seven states have approved legislation on insulin copayment caps since April 2020, instituting a \$35-\$100 maximum copayment for a 30-day insulin supply<sup>8</sup>; and

Whereas, The Centers for Medicare & Medicaid Services (CMS) plans to limit insulin prescription costs through Medicaid Part D for the 2021 plan year to a maximum \$35 copay for a 30-day supply, and estimate annual out-of-pocket savings per patient to be reduced by 66%; and

Whereas, Individual and family savings resulting from caps on insulin copayments have the potential to alleviate financial burden<sup>10</sup>; and

Whereas, The AMA has policy consistent with the principle of increasing access to prescription medications including insulin for patients<sup>11-16</sup>; and

Resolution: 118 (A-22) Page 2 of 6

1 Whereas, Some private insurance programs have shown the capability to offer a capped 2 copayment on insulin for their customers, without any increased cost to their insurance premium 3 or plan<sup>17</sup>; therefore be it

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RESOLVED, That our American Medical Association amend Policy H-110.984, "Insulin Affordability," by addition to read as follows:

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14 15 Insulin Affordability H-110.984

Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the

Department of Justice to monitor insulin pricing and market competition and take

enforcement actions as appropriate; and (2) support initiatives, including those by

12 national medical specialty societies, that provide physician education regarding the 13

cost-effectiveness of insulin therapies.; and (3) support state and national efforts to

limit the copayments insured patients pay per month for prescribed insulin. (Modify

Current HOD Policy)

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

Date Received: 04/08/22

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- 10. Chua K, Lee JM, Conti RM. Potential Change in Insulin Out-of-Pocket Spending Under Cost-Sharing Caps Among Pediatric Patients With Type 1 Diabetes. JAMA Pediatr. 2020. doi:10.1001/jamapediatrics.2020.1065. Accessed September 20, 2020.
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- 16. American Medical Association. Reducing Prescription Drug Prices D-110.993. https://policysearch.amaassn.org/policyfinder/detail/Reducing Prescription Drug Prices D-110.993?uri=/AMADoc/directives.xml-0-49.xml. Accessed February
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# **RELEVANT AMA POLICY**

# Additional Mechanisms to Address High and Escalating Pharmaceutical Prices H-110.980

- 1. Our AMA will 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;
- c. 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 costeffectiveness analysis addressing the drug in question;
- e. The arbitration process should include the submission of a value-based price 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;
- g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
- h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
- i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
- 2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
- a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
- b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
- c. The use of any international drug price index or average should preserve patient access to necessary medications;
- d. The use of any international drug price index or average should limit burdens on physician practices; and
- e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.
- 3. Our AMA supports 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 list price at the time of market introduction.

CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20

## Insulin Affordability H-110.984

Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate; and (2) support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies. CMS Rep. 07, 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

Page 4 of 6

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 supports legislation that limits Medicare annual drug price increases to the rate of inflation.

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; Appended: Res. 113, I-21

# 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.

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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. Sub. Res. 106, A-15: Reaffirmed: CMS 2, I-15; Reaffirmed in lieu of: Res. 2017, A-17; Reaffirmed: BOT Rep. 14, A-18

# **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;
- (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

# 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.

Page 6 of 6

CMS Rep. 3, I-04; Modified: CMS Rep. 1, A-14; Reaffirmation: A-14; 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; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Reaffirmed: Res. 113, I-21

Resolution: 118

(A-22)

Introduced by: Medical Student Section, Endocrine Society

Subject: Caps on Insulin Co-Payments for Patients with Insurance

Referred to: Reference Committee A

Whereas, Diabetes affects approximately 9.4% of the U.S. population and is the seventh leading cause of death nationally<sup>1,2</sup>; and

Whereas, Direct medical costs for diagnosed diabetes were estimated at \$327.2 billion in 2017, with nearly \$102 billion lost due to lower productivity resulting from diabetes<sup>3</sup>; and

Whereas, The annual average medical cost per person with diabetes is \$13,240 with approximately 44% of expenditures stemming from prescription medications, including insulin<sup>4</sup>; and

Whereas, From 2012 to 2016, the average point-of-sale price of insulin nearly doubled from 13 cents per unit to 25 cents per unit, translating to a daily cost increase from \$7.80 to \$15 for a patient with Type 1 diabetes using an average amount of insulin (60 units per day)<sup>5</sup>; and

Whereas, One in four patients reported cost-related insulin underuse, including taking smaller doses and skipping doses, which was independent of the patient's prescription drug coverage plan<sup>6</sup>; and

Whereas, Patients who report cost-related underuse were more likely to have poor glycemic control, which is associated with an increased risk for complications such as hypertension, chronic kidney disease, neuropathy, lower limb amputations, retinopathy, stroke, coronary heart disease, depression, and cancer<sup>6,7</sup>; and

Whereas, Seven states have approved legislation on insulin copayment caps since April 2020, instituting a \$35-\$100 maximum copayment for a 30-day insulin supply<sup>8</sup>; and

Whereas, The Centers for Medicare & Medicaid Services (CMS) plans to limit insulin prescription costs through Medicaid Part D for the 2021 plan year to a maximum \$35 copay for a 30-day supply, and estimate annual out-of-pocket savings per patient to be reduced by 66%; and

Whereas, Individual and family savings resulting from caps on insulin copayments have the potential to alleviate financial burden<sup>10</sup>; and

Whereas, The AMA has policy consistent with the principle of increasing access to prescription medications including insulin for patients<sup>11-16</sup>; and

Resolution: 118 (A-22) Page 2 of 6

Whereas, Some private insurance programs have shown the capability to offer a capped copayment on insulin for their customers, without any increased cost to their insurance premium or plan<sup>17</sup>; therefore be it

4 5

RESOLVED, That our American Medical Association amend Policy H-110.984, "Insulin Affordability," by addition to read as follows:

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Insulin Affordability H-110.984

- Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the
- 10 Department of Justice to monitor insulin pricing and market competition and take
- enforcement actions as appropriate; and (2) support initiatives, including those by
- 12 national medical specialty societies, that provide physician education regarding the
- 13 cost-effectiveness of insulin therapies.; and (3) support state and national efforts to
- 14 <u>limit the copayments insured patients pay per month for prescribed insulin.</u> (Modify
- 15 Current HOD Policy)

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

Date Received: 04/08/22

#### References:

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- Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States. Atlanta, GA: U.S. Department of Health and Human Services; 2017.
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- assn.org/policyfinder/detail/prescription%20drug%20price?uri=%2FAMADoc%2FHOD.xml-0-101.xml. Accessed February 15, 2020.

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# **RELEVANT AMA POLICY**

# Additional Mechanisms to Address High and Escalating Pharmaceutical Prices H-110.980

- 1. Our AMA will 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;
- c. 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 costeffectiveness analysis addressing the drug in question;
- e. The arbitration process should include the submission of a value-based price 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;
- g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
- h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
- i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
- 2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
- a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
- b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
- c. The use of any international drug price index or average should preserve patient access to necessary medications;
- d. The use of any international drug price index or average should limit burdens on physician practices; and
- e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.
- 3. Our AMA supports 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 list price at the time of market introduction.

CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20

## Insulin Affordability H-110.984

Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate; and (2) support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies. CMS Rep. 07, 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

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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 supports legislation that limits Medicare annual drug price increases to the rate of inflation.

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; Appended: Res. 113, I-21

# 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.

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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. Sub. Res. 106, A-15: Reaffirmed: CMS 2, I-15; Reaffirmed in lieu of: Res. 2017, A-17; Reaffirmed: BOT Rep. 14, A-18

# **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;
- (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

# 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.

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CMS Rep. 3, I-04; Modified: CMS Rep. 1, A-14; Reaffirmation: A-14; 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; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Reaffirmed: Res. 113, I-21

Resolution: 206

(A-22)

Introduced by: New York

Subject: Medicare Advantage Plan Mandates

Referred to: Reference Committee B

Whereas, Some municipalities are requiring their retirees to change from traditional Medicare health insurance coverage to Medicare Advantage plans; and

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Whereas, Medicare Advantage plans may have restrictive networks; and

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Whereas, Medicare Advantage plans further privatize patients' Medicare, without discussion or agreement by the persons concerned, all in the interest of saving money for the employer; and

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Whereas, Forcing use of Medicare Advantage plans does not consider the retiree's personal health concerns, including the ability to find continued care with their own doctors or hospitals with whom they may have long relationships; therefore be it

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13 RESOLVED, That our American Medical Association advocate for federal legislation to ensure

that no person should be mandated to change from traditional Medicare to Medicare Advantage

15 plans. (Directive to Take Action)

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

Received: 03/22/22

# **RELEVANT AMA POLICY**

# **Ending Medicare Advantage Auto-Enrollment H-285.905**

Our AMA will work with the Centers for Medicare and Medicaid Services and/or Congress to end the procedure of "auto-enrollment" of individuals into Medicare Advantage Plans. Citation: Res. 216, I-16

# Deemed Participation and Misleading Marketing by Medicare Advantage Private Fee for Service Plans D-330.930

Our AMA will continue its efforts to educate physicians and the general public on the implications of participating in programs offered under Medicare Advantage and educate physicians and the public about the lack of secondary coverage (Medigap policies) with Medicare Advantage plans and how this may affect enrollees.

Citation: BOT Action in response to referred for decision Res. 711, I-06; Reaffirmation A-08; Modified: CMS Rep. 01, A-19

# Elimination of Subsidies to Medicare Advantage Plans D-390.967

1. Our AMA will seek to have all subsidies to private plans offering alternative coverage to Medicare beneficiaries eliminated, that these private Medicare plans compete with traditional

Resolution: 206 (A-22)

Page 2 of 2

Medicare fee-for-service plans on a financially neutral basis and have accountability to the Centers for Medicare and Medicaid Services.

2. Our AMA will seek to prohibit all private plans offering coverage to Medicare beneficiaries from deeming any physician to be a participating physician without a signed contract specific to that product, and that our AMA work with CMS to prohibit all-products clauses from applying to Medicare Advantage plans and private fee-for-service plans.

Citation: Res. 229, A-07; Modified: CMS Rep. 01, A-17

Resolution: 215 (A-22)

Introduced by: American College of Cardiology, American Society of Echocardiography,

American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular

Computed Tomography

Subject: Transforming Professional Licensure to the 21st Century

Referred to: Reference Committee B

Whereas, The US Supreme Court in 1889 affirmed the power of individual states to regulate medical practice within their borders, in conjunction with the exercise of appropriate professional responsibility by local medical societies and all practicing physicians, to protect the public health and safety; and

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Whereas, The Flexner Report of 1911 transformed the nature and process of medical education in America to a comprehensive national standard, with national medical board examinations, nationally accredited residency programs and national certifications from medical specialty boards; and

Whereas, Individual state medical boards, having verified an applicant's standardized general medical training, professional character and compliance with local state regulations, issue broad general medical licenses which are not specialty specific nor tailored to anticipated need for direct physical interaction or face-to-face contact between the patient and the professional being licensed; and

Whereas, Individual state medical boards also evaluate a licensed physician's ongoing professional conduct, reviewing complaints from patients, malpractice data, information from hospitals and other health care institution and reports from government agencies, imposing discipline as necessary to protect the public; and

Whereas, Congress established the National Practitioner Data Bank in 1986 as a nationwide repository for reports containing information on medical malpractice payments and certain adverse actions related to health care practitioners, providers, and suppliers in order to improve health care quality, protect the public and reduce health care fraud and abuse, preventing practitioners from moving state to state without disclosure or discovery of previous damaging performance; and

Whereas, The Federation of State Medical Boards, the Federation Credential Verification Service, the National Board of Medical Examiners, the Interstate Medical Licensing Compact and other national organizations serve to streamline and facilitate collaboration among the 70 independent state-based medical boards authorized to regulate medical practice within their borders; and

Whereas, Current state licensing procedures, while constantly improving, fail to promote efficient use of modern telecommunication and delivery of a broad range of health care services across state lines, are unnecessarily complex, nonuniform, redundant, expensive, time

Resolution: 215 (A-22) Page 2 of 10

1 consuming, and poorly focused on actual patient care, resulting in the inhibition of free flow of professional expertise and services across state lines; and

Whereas, Telemedicine has developed rapidly over the last decades into an integrated system of healthcare delivery that incorporates many different remote diagnostic and monitoring devices and other technologies that are not dependent on in-person or face-to-face patient encounters: and

Whereas, Incentives to reduce the high cost of medical care have led to shorter hospital stays, increased use of outpatient facilities and home care with less intense in-person physician supervision, and more frequent collaborative care delivered by non-physician professionals; and

Whereas, Telemedicine has been proven effective in many scenarios, in remote or rural settings, urban areas with limited public transportation, in nursing homes, detention centers, prisons, and for people with physical and mental disabilities limiting their mobility; and

Whereas, The use of telemedicine has grown exponentially during the COVID pandemic to protect both patients and caregivers from spread of infectious disease; and

Whereas, Telemedicine may be especially helpful in addressing disparities in access to medical care based on economic, racial, ethnic, and geographic factors; and

Whereas, There is a worsening shortage of physicians particularly in rural or urban communities that lack comprehensive, supportive, up-to-date medical services and cultural, educational, and recreational amenities outside the workplace; and

Whereas, Current AMA policy H-480.969 requires full and unrestricted licensure in the state of residence where telemedicine is practiced, where the patient is physically located, with certain exceptions; and

Whereas, Current AMA policy H-160.950 requires a physician to be responsible for managing the health care of patients in all practice settings, including medication prescriptive authority, and to be immediately available at all times for supervision and consultation by a nurse practitioner: and

Whereas, Half of the states allow nurse practitioners to practice independently without physician supervision; and

Whereas, 70% of physicians are now employed by large groups, hospitals, private capital groups, insurance companies and ERISA-qualified managed care organizations which often care for patients in many states and employ non-physicians to assist in patient care, using many varying protocols for physician supervision of non-physician professionals, and assessment of an individual physician's competence; and

Whereas, Recent and continuing changes in the ownership and structure of physician practice can raise licensing issues related to conflicts of interest, anti-competitive activity, restraint of trade and interference with interstate commerce related to restriction of physician licensing; and

Whereas, Policy objectives for licensing and interstate health care delivery should incorporate the best practices of individual states, recognizing rapid evolution in the structure of health care delivery including current capabilities of telemedicine in various medical specialties and by non-physician professionals, into a single comprehensive policy that promotes accessible, quality,

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affordable, appropriately accredited and accountable care, distributed to all members of our society; therefore be it

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RESOLVED, That our American Medical Association address the issue of state licensure in a comprehensive manner including studying the best mechanisms to ensure interstate licensure for practitioners practicing in multiple states, optimizing state licensure practices to allow for seamless telemedicine practice across state lines, and addressing long delays in practitioners obtaining state licensures which lead to delays in medical care (Directive to Take Action); and be it further

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RESOLVED, That our AMA research the feasibility of convening a meeting of appropriate stakeholders, including but not limited to state medical boards, medical specialty societies, state medical societies, payers, organizations representing non-physician medical professionals, Centers for Medicare and Medicaid Services-approved accrediting agencies, and patients to develop recommendations to modernize the state medical licensure system including creating mechanisms for multi-state licensure, streamlining the process of obtaining medical licensure, and facilitate practice across state lines (Directive to Take Action); and be it further

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RESOLVED, That our AMA report back on these recommendations by the 2022 Interim Meeting. (Directive to Take Action)

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

Received: 04/06/22

## **RELEVANT AMA POLICY**

#### Guidelines for Integrated Practice of Physician and Nurse Practitioner H-160.950

Our AMA endorses the following guidelines and recommends that these guidelines be considered and quoted only in their entirety when referenced in any discussion of the roles and responsibilities of nurse practitioners: (1) The physician is responsible for the supervision of nurse practitioners and other advanced practice nurses in all settings.

(2) The physician is responsible for managing the health care of patients in all practice settings.

- (3) Health care services delivered in an integrated practice must be within the scope of each practitioner's professional license, as defined by state law.
- (4) In an integrated practice with a nurse practitioner, the physician is responsible for supervising and coordinating care and, with the appropriate input of the nurse practitioner, ensuring the quality of health care provided to patients.
- (5) The extent of involvement by the nurse practitioner in initial assessment, and implementation of treatment will depend on the complexity and acuity of the patients' condition, as determined by the supervising/collaborating physician.
- (6) The role of the nurse practitioner in the delivery of care in an integrated practice should be defined through mutually agreed upon written practice protocols, job descriptions, and written contracts.
- (7) These practice protocols should delineate the appropriate involvement of the two professionals in the care of patients, based on the complexity and acuity of the patients' condition.
- (8) At least one physician in the integrated practice must be immediately available at all times for supervision and consultation when needed by the nurse practitioner.
- (9) Patients are to be made clearly aware at all times whether they are being cared for by a physician or a nurse practitioner.
- (10) In an integrated practice, there should be a professional and courteous relationship between physician and nurse practitioner, with mutual acknowledgment of, and respect for each other's contributions to patient care.
- (11) Physicians and nurse practitioners should review and document, on a regular basis, the care of all patients with whom the nurse practitioner is involved. Physicians and nurse practitioners must work closely enough together to become fully conversant with each other's practice patterns.

Citation: (CMS Rep. 15 - I-94; BOT Rep. 6, A-95; Reaffirmed: Res. 240, A-00; Reaffirmation A-00; Reaffirmed: BOT Rep. 28, A-09; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16, A-13)

#### Independent Practice of Medicine by Advanced Practice Registered Nurses H-35.988

Our AMA, in the public interest, opposes enactment of legislation to authorize the independent practice of medicine by any individual who has not completed the states requirements for licensure to engage in the practice of medicine

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and surgery in all of its branches. Our AMA opposes enactment of the Advanced Practice Registered Nurse (APRN) Multistate Compact, due to the potential of the APRN Compact to supersede state laws that require APRNs to practice under physician supervision, collaboration or oversight.

Citation: Sub. Res. 53, I-82; Reaffirmed: A-84; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: BOT Rep. 9, I-11; Modified: Res. 214, I-17; Modified: BOT Rep. 15, A-18

# Physician Assistants and Nurse Practitioners H-160.947

Our AMA will develop a plan to assist the state and local medical societies in identifying and lobbying against laws that allow advanced practice nurses to provide medical care without the supervision of a physician. The suggested Guidelines for Physician/Physician Assistant Practice are adopted to read as follows (these guidelines shall be used in their entirety):

- (1) The physician is responsible for managing the health care of patients in all settings.
- (2) Health care services delivered by physicians and physician assistants must be within the scope of each practitioner's authorized practice, as defined by state law.
- (3) The physician is ultimately responsible for coordinating and managing the care of patients and, with the appropriate input of the physician assistant, ensuring the quality of health care provided to patients.
- (4) The physician is responsible for the supervision of the physician assistant in all settings.
- (5) The role of the physician assistant in the delivery of care should be defined through mutually agreed upon guidelines that are developed by the physician and the physician assistant and based on the physician's delegatory
- (6) The physician must be available for consultation with the physician assistant at all times, either in person or through telecommunication systems or other means.
- (7) The extent of the involvement by the physician assistant in the assessment and implementation of treatment will depend on the complexity and acuity of the patient's condition and the training, experience, and preparation of the physician assistant, as adjudged by the physician.
- (8) Patients should be made clearly aware at all times whether they are being cared for by a physician or a physician
- (9) The physician and physician assistant together should review all delegated patient services on a regular basis, as well as the mutually agreed upon guidelines for practice.
- (10) The physician is responsible for clarifying and familiarizing the physician assistant with his/her supervising methods and style of delegating patient care.

Citation: BOT Rep. 6, A-95; Reaffirmed: Res 240 and Reaffirmation A-00; Reaffirmed: Res. 213, A-02; Modified: CLRPD Rep. 1, A-03; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16. A-13

# Opposition to the Department of Veterans Affairs Proposed Rulemaking on APRN Practices D-35.979

- 1. Our AMA will express to the U.S. Department of Veterans Affairs (VA) that the plan to substitute physicians by using Advanced Practice Registered Nurses (APRNs) in independent practice, not in physician-led teams, is antithetical to multiple established policies of our AMA and thus should not be implemented.
- 2. Our AMA staff will assess the feasibility of seeking federal legislation that prevents the VA from enacting regulations for veterans' medical care that is not consistent with physician-led health care teams or to mandate that the VA adopt policy regarding the same.
- 3. Our AMA will call upon Congress and the Administration to disapprove or otherwise overturn rules and regulations at the federal level that would expand the scope of practice of APRNs, and comment to the Director of Regulation Management within the Department of Veterans Affairs of this position during the current comment period.
- 4. Our AMA will collaborate with other medical professional organizations to vigorously oppose the final adoption of the VA's proposed rulemaking expanding the role of APRNs within the VA. Citation: Res. 239, A-16

# **COVID-19 Emergency and Expanded Telemedicine Regulations D-480.963**

Our AMA: (1) will continue to advocate for the widespread adoption of telehealth services in the practice of medicine for physicians and physician-led teams post SARS-COV-2; (2) will advocate that the Federal government, including the Centers for Medicare & Medicaid Services (CMS) and other agencies, state governments and state agencies, and the health insurance industry, adopt clear and uniform laws, rules, regulations, and policies relating to telehealth services that: (a) provide equitable coverage that allows patients to access telehealth services wherever they are located, and (b) provide for the use of accessible devices and technologies, with appropriate privacy and security protections, for connecting physicians and patients; (3) will advocate for equitable access to telehealth services, especially for at-risk and under-resourced patient populations and communities, including but not limited to supporting increased funding and planning for telehealth infrastructure such as broadband and internet-connected devices for both physician practices and patients; and (4) supports the use of telehealth to reduce health disparities and promote access to health care.

Citation: Alt. Res. 203, I-20; Reaffirmed: CMS Rep. 7, A-21

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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; Reaffirmed: CMS Rep. 7, A-21

# Established Patient Relationships and Telemedicine D-480.964

Our AMA will:

- 1) 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:
- (2) advocate to the Interstate Medical Licensure Compact Commission and Federation of State Medical Boards for reduced application fees and secondary state licensure(s) fees processed through the Interstate Medical Licensure Compact;
- (3) work with interested state medical associations to encourage states to pass legislation enhancing patient access to and proper regulation of telemedicine services, in accordance with AMA Policy H-480.946, "Coverage of and Payment for Telemedicine"; and
- (4) continue to support state efforts to expand physician licensure recognition across state lines in accordance with the standards and safeguards outlined in Policy H-480.946.

Citation: CMS Rep. 1, I-19; Appended: CMS Rep. 8, A-21

#### State Authority and Flexibility in Medical Licensure for Telemedicine D-480.999

Our AMA will continue its opposition to a single national federalized system of medical licensure.

Citation: (CME Rep. 7, A-99; Reaffirmed and Modified: CME Rep. 2, A-09; Reaffirmed in lieu of Res. 920, I-13; Reaffirmed: BOT Rep. 3, I-14)

#### 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.

Resolution: 215 (A-22) Page 6 of 10

- 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.

Citation: CME Rep. 04, I-18

Resolution: 215 (A-22) Page 7 of 10

#### Telemedicine Encounters by Third Party Vendors D-480.968

- 1. Our AMA will develop model legislation and/or regulations requiring telemedicine services or vendors to coordinate care with the patient's medical home and/or existing treating physicians, which includes at a minimum identifying the patient's existing medical home and/or treating physicians and providing to the treating physician a copy of the medical record, with the patient's consent.
- 2. The model legislation and/or regulations will also require the vendor to abide by laws addressing the privacy and security of patients' medical information
- 3. Our AMA will include in that model state legislation the following concepts based on AMA policy: (a) A valid patient-physician relationship must be established before the provision of telemedicine services; (b) 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; and (c) The standards and scope of telemedicine services should be consistent with related in-person services.
- 4. Our AMA will educate and advocate to AMA members on the use and implementation of telemedicine and other related technology in their practices to improve access, convenience, and continuity of care for their patients. Citation: Res. 234, A-16

#### The Promotion of Quality Telemedicine H-480.969

- (1) It is the policy of the AMA 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. This license category should adhere to the following principles:
- (a) exemption from such a licensure requirement for physician-to-physician consultations;
- (b) 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;
- (c) allowances, by exemption or other means, for out-of-state physicians providing continuity of care to a patient, where there is an established ongoing relationship and previous in-person visits, for services incident to an ongoing care plan or one that is being modified; and
- (d) 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.
- (2) The AMA urges the FSMB and individual states to recognize that a physician practicing certain forms of telemedicine (e.g., teleradiology) must sometimes perform necessary functions in the licensing state (e.g., interaction with patients, technologists, and other physicians) and that the interstate telemedicine approach adopted must accommodate these essential quality-related functions.
- (3) The AMA urges national medical specialty societies to develop and implement practice parameters for telemedicine in conformance with: Policy 410.973 (which identifies practice parameters as "educational tools"); Policy 410.987 (which identifies practice parameters as "strategies for patient management that are designed to assist physicians in clinical decision making," and states that a practice parameter developed by a particular specialty or specialties should not preclude the performance of the procedures or treatments addressed in that practice parameter by physicians who are not formally credentialed in that specialty or specialties); and Policy 410.996 (which states that physician groups representing all appropriate specialties and practice settings should be involved in developing practice parameters, particularly those which cross lines of disciplines or specialties).
- Citation: CME/CMS Rep., A-96; Amended: CME Rep. 7, A-99; Reaffirmed: CME Rep. 2, A-09; Reaffirmed: CME Rep. 6, A-10; Reaffirmed: CME Rep. 6, A-12; Reaffirmed in lieu of Res. 805, I-12; Reaffirmed: BOT Rep. 22, A-13; Reaffirmed in lieu of Res. 920, I-13; Reaffirmed: CMS Rep. 7, A-14; Reaffirmed: BOT Rep. 3, I-14; Reaffirmed: CMS Rep. 1, I-19; Modified: CMS Rep. 8, A-21

## Coverage of and Payment for Telemedicine H-480.946

- 1. Our AMA believes that telemedicine services should be covered and paid for if they abide by the following principles:
- a) 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.

Exceptions to the foregoing include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. If a medical home does not exist, telemedicine providers should facilitate the identification of medical homes and treating physicians where in-person services can be delivered in coordination with the telemedicine services.

Resolution: 215 (A-22) Page 8 of 10

- b) Physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services.
- c) 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.
- d) Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services.
- e) The delivery of telemedicine services must be consistent with state scope of practice laws.
- f) Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.
- g) The standards and scope of telemedicine services should be consistent with related in-person services.
- h) The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes.
- i) The telemedicine service must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine.
- j) The patient's medical history must be collected as part of the provision of any telemedicine service.
- k) The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient.
- I) The provision of telemedicine services must include care coordination with the patient's medical home and/or existing treating physicians, which includes at a minimum identifying the patient's existing medical home and treating physicians and providing to the latter a copy of the medical record.
- m) Physicians, health professionals and entities that deliver telemedicine services must establish protocols for referrals for emergency services.
- 2. Our AMA believes that delivery of telemedicine services must abide by laws addressing the privacy and security of patients' medical information.
- 3. Our AMA encourages additional research to develop a stronger evidence base for telemedicine.
- 4. Our AMA supports additional pilot programs in the Medicare program to enable coverage of telemedicine services, including, but not limited to store-and-forward telemedicine.
- 5. Our AMA supports demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation to address how telemedicine can be integrated into new payment and delivery models.
- 6. Our AMA encourages physicians to verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service.
- 7. Our AMA encourages national medical specialty societies to leverage and potentially collaborate in the work of national telemedicine organizations, such as the American Telemedicine Association, in the area of telemedicine technical standards, to the extent practicable, and to take the lead in the development of telemedicine clinical practice quidelines.

Citation: CMS Rep. 7, A-14; Reaffirmed: BOT Rep. 3, I-14; Reaffirmed in lieu of Res. 815, I-15; Reaffirmed: CME Rep. 06, A-16; Reaffirmed: CMS Rep. 06, I-16; Reaffirmed: Res. 111, A-17; Reaffirmation: A-18; Reaffirmed: CMS Rep. 1, I-19; Reaffirmed: CMS Rep. 8, A-21

## **Evolving Impact of Telemedicine H-480.974**

Our AMA:

- (1) will evaluate relevant federal legislation related to telemedicine;
- (2) urges CMS, AHRQ, and other concerned entities involved in telemedicine to fund demonstration projects to evaluate the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the physician-patient relationship:
- (3) urges professional organizations that serve medical specialties involved in telemedicine to develop appropriate practice parameters to address the various applications of telemedicine and to guide quality assessment and liability issues related to telemedicine;
- (4) encourages professional organizations that serve medical specialties involved in telemedicine to develop appropriate educational resources for physicians for telemedicine practice;
- (5) encourages development of a code change application for CPT codes or modifiers for telemedical services, to be submitted pursuant to CPT processes;
- (6) will work with CMS and other payers to develop and test, through these demonstration projects, appropriate reimbursement mechanisms;
- (7) will develop a means of providing appropriate continuing medical education credit, acceptable toward the Physician's Recognition Award, for educational consultations using telemedicine;
- (8) will work with the Federation of State Medical Boards and the state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries; and
- (9) will leverage existing expert guidance on telemedicine by collaborating with the American Telemedicine Association (www.americantelemed.org) to develop physician and patient specific content on the use of telemedicine services--encrypted and unencrypted.

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Citation: CMS/CME Rep., A-94; Reaffirmation A-01; Reaffirmation A-11; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed in lieu of Res. 805, I-12; Appended: BOT Rep. 26, A-13; Modified: BOT Rep. 22, A-13; Reaffirmed: CMS Rep. 7, A-14; Reaffirmed: CME Rep. 06, A-16; Reaffirmation: A-18

## Addressing Equity in Telehealth H-480.937

Our AMA:

- (1) recognizes access to broadband internet as a social determinant of health;
- (2) encourages initiatives to measure and strengthen digital literacy, with an emphasis on programs designed with and for historically marginalized and minoritized populations;
- (3) encourages telehealth solution and service providers to implement design functionality, content, user interface, and service access best practices with and for historically minoritized and marginalized communities, including addressing culture, language, technology accessibility, and digital literacy within these populations;
- (4) supports efforts to design telehealth technology, including voice-activated technology, with and for those with difficulty accessing technology, such as older adults, individuals with vision impairment and individuals with disabilities;
- (5) encourages hospitals, health systems and health plans to invest in initiatives aimed at designing access to care via telehealth with and for historically marginalized and minoritized communities, including improving physician and non-physician provider diversity, offering training and technology support for equity-centered participatory design, and launching new and innovative outreach campaigns to inform and educate communities about telehealth;
- (6) supports expanding physician practice eligibility for programs that assist qualifying health care entities, including physician practices, in purchasing necessary services and equipment in order to provide telehealth services to augment the broadband infrastructure for, and increase connected device use among historically marginalized, minoritized and underserved populations;
- (7) supports efforts to ensure payers allow all contracted physicians to provide care via telehealth;
- (8) opposes efforts by health plans to use cost-sharing as a means to incentivize or require the use of telehealth or inperson care or incentivize care from a separate or preferred telehealth network over the patient's current physicians; and
- (9) will advocate that physician payments should be fair and equitable, regardless of whether the service is performed via audio-only, two-way audio-video, or in-person.

Citation: CMS Rep. 7, A-21

#### 1.2.12 Ethical Practice in Telemedicine

Innovation in technology, including information technology, is redefining how people perceive time and distance. It is reshaping how individuals interact with and relate to others, including when, where, and how patients and physicians engage with one another.

Telehealth and telemedicine span a continuum of technologies that offer new ways to deliver care. Yet as in any mode of care, patients need to be able to trust that physicians will place patient welfare above other interests, provide competent care, provide the information patients need to make well-considered decisions about care, respect patient privacy and confidentiality, and take steps to ensure continuity of care. Although physicians fundamental ethical responsibilities do not change, the continuum of possible patient-physician interactions in telehealth/telemedicine give rise to differing levels of accountability for physicians.

All physicians who participate in telehealth/telemedicine have an ethical responsibility to uphold fundamental fiduciary obligations by disclosing any financial or other interests the physician has in the telehealth/telemedicine application or service and taking steps to manage or eliminate conflicts of interests. Whenever they provide health information, including health content for websites or mobile health applications, physicians must ensure that the information they provide or that is attributed to them is objective and accurate.

Similarly, all physicians who participate in telehealth/telemedicine must assure themselves that telemedicine services have appropriate protocols to prevent unauthorized access and to protect the security and integrity of patient information at the patient end of the electronic encounter, during transmission, and among all health care professionals and other personnel who participate in the telehealth/telemedicine service consistent with their individual roles.

Physicians who respond to individual health queries or provide personalized health advice electronically through a telehealth service in addition should:

- (a) Inform users about the limitations of the relationship and services provided.
- (b) Advise site users about how to arrange for needed care when follow-up care is indicated.
- (c) Encourage users who have primary care physicians to inform their primary physicians about the online health consultation, even if in-person care is not immediately needed.

Physicians who provide clinical services through telehealth/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. In the context of telehealth/telemedicine they further should:

(d) Be proficient in the use of the relevant technologies and comfortable interacting with patients and/or surrogates electronically.

Resolution: 215 (A-22) Page 10 of 10

- (e) Recognize the limitations of the relevant technologies and take appropriate steps to overcome those limitations. Physicians must ensure that they have the information they need to make well-grounded clinical recommendations when they cannot personally conduct a physical examination, such as by having another health care professional at the patients site conduct the exam or obtaining vital information through remote technologies.
- (f) Be prudent in carrying out a diagnostic evaluation or prescribing medication by:
- (i) establishing the patients identity;
- (ii) confirming that telehealth/telemedicine services are appropriate for that patients individual situation and medical needs:
- (iii) evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction; and
- (iv) documenting the clinical evaluation and prescription.
- (g) When the physician would otherwise be expected to obtain informed consent, tailor the informed consent process to provide information patients (or their surrogates) need about the distinctive features of telehealth/telemedicine, in addition to information about medical issues and treatment options. Patients and surrogates should have a basic understanding of how telemedicine technologies will be used in care, the limitations of those technologies, the credentials of health care professionals involved, and what will be expected of patients for using these technologies.
- (h) As in any patient-physician interaction, take steps to promote continuity of care, giving consideration to how information can be preserved and accessible for future episodes of care in keeping with patientspreferences (or the decisions of their surrogates) and how follow-up care can be provided when needed. Physicians should assure themselves how information will be conveyed to the patients primary care physician when the patient has a primary care physician and to other physicians currently caring for the patient.

Collectively, through their professional organizations and health care institutions, physicians should:

- (i) Support ongoing refinement of telehealth/telemedicine technologies, and the development and implementation of clinical and technical standards to ensure the safety and quality of care.
- (j) Advocate for policies and initiatives to promote access to telehealth/telemedicine services for all patients who could benefit from receiving care electronically.
- (k) Routinely monitor the telehealth/telemedicine landscape to:
- (i) identify and address adverse consequences as technologies and activities evolve; and
- (ii) identify and encourage dissemination of both positive and negative outcomes.

AMA Principles of Medical Ethics: I,IV,VI,IX

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: 502

(A-22)

Introduced by: New York

Subject: **Ensuring Correct Drug Dispensing** 

Reference Committee E Referred to:

Whereas, Medication errors affect millions of people every year with the clinical and economic consequences of those errors having been widely documented; and

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Whereas, Much is known about hospital medication errors because of their well-established reporting systems for continuous monitoring; and

Whereas, In a hospital a dispensing error can be detected and prevented by nursing personnel at the administration stage; and

Whereas, The New York Times published an article entitled "How Chaos at Chain Pharmacies Is Putting Patients at Risk" which stated that pharmacists at companies such as CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces which made it difficult to perform their jobs safely and can lead to "dispensing errors"; and

Whereas, Currently, in some states, any drug dispensed must bear a label on its container which identifies the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription; and

Whereas, When a prescription is filled in a retail pharmacy, the last checkpoint for safety is the patient or caregiver who may not have the training and knowledge to know that the dispensed drug is actually the medication prescribed; therefore be it

RESOLVED, That our American Medical Association request that the United States Food and Drug Administration work with the pharmaceutical and pharmacy industries to facilitate the ability of pharmacies to ensure that a color photo of a prescribed medication and its dosage is attached to the sales receipt to ensure that the drug dispensed is that which has been prescribed. (Directive to Take Action)

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

Received: 03/22/22

Resolution: 502 (A-22)

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#### **RELEVANT AMA POLICY**

# **Epidemiology of Drug Errors H-120.963**

The AMA will continue its collaborations with the Food and Drug Administration and the US Pharmacopoeial Convention, Inc., along with its own ongoing initiatives, to identify and eliminate causes of medication errors.

Citation: Sub. Res. 519, I-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: CSAPH Rep. 01, A-16

# Supporting Safe Medical Products as a Priority Public Health Initiative H-120.958

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 on 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 coding system for prescription medicine packaging in an effort to improve patient safety; and (5) seek opportunities to work collaboratively with other stakeholders 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.

Citation: Res. 416, A-99; Appended: Res. 504, I-01; Reaffirmation A-10; Modified: CSAPH Rep. 01, A-20

Resolution: 513 (A-22)

Introduced by: Oklahoma

Subject: Education for Patients on Opiate Replacement Therapy

Referred to: Reference Committee E

Whereas, We are in a time of potentially increased respiratory illness, given the threat of COVID-19 and flu season in the United States; and

Whereas, We are simultaneously in a time of increased use of opiate replacement therapy for the treatment of opiate use disorder and chronic pain; and

Whereas, Anecdotally, a death scenario occurs when patients in their 60s and 70s who are on relatively high dose maintenance opioid replacement therapy, take their usual dose after onset of a respiratory illness, and

Whereas, AMA Policy D-95.987, "Prevention of Drug-Related Overdose," is to educate physicians and at-risk patients, but it fails to specifically address the needs of older patients who are at risk of death from opiate maintenance therapy when the onset of respiratory illness occurs; therefore be it

RESOLVED, That our American Medical Association amend Policy D-95.987, "Prevention of Drug-Related Overdose," by addition to read as follows:

- 1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related 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 a drug-related overdose; and (b) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.
- 3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.
- 4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.

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5. Our AMA implement an education program for patients on opiate replacement

therapy and their family/caregivers to increase understanding of their increased

risk of death with concurrent opiate maintenance therapy and the onset of a

serious respiratory illness such as SARS-CoV-2. (Modify Current HOD Policy)

#### References:

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https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20030348

Fiscal Note: Not yet determined

Received: 04/26/22

#### **RELEVANT AMA POLICY**

# **Prevention of Drug-Related Overdose D-95.987**

- 1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related 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 a drug-related overdose; and (b) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.
- 3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.
- 4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies. 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; Modified: Res. 506, I-21

Resolution: 601 (A-22)

Introduced by: New York

Subject: Development of Resources on End of Life Care

Referred to: Reference Committee F

Whereas, The questions regarding life and death have been debated by scholars, philosophers, religious leaders and doctors for centuries and technology has blurred the distinction between a quality human life and biological life on a cellular or organ basis; and

Whereas, Economic, social and religious views influence modern definitions of human and biological life, making technology in modern medicine a double-edged sword, favoring the betterment of patients and their quality of life and care; and

Whereas, Physicians have been sworn to do no harm, yet this is increasingly challenging with today's competing forces of technology, shifting social morae's and the economics and legislation of health care; and

Whereas, Confronted/ burdened with the more complicated questions of when life begins and ends, physicians have not always been able to transition patients effectively from life to death, which has contributed to decreased use of tools such as palliative care and hospice care; and

Whereas, End-of-life care as defined by the World Health Organization (WHO) "is the term used to describe the support and medical care given during the time surrounding death"; and

Whereas, Palliative Care is the treatment of patients with serious illnesses and disease with the goal to help the patient feel better, prevent or alleviate symptoms and side effects of disease and treatment, treating the whole patient including the emotional, social, practical, and spiritual costs of that illnesses, striving to improve a patient's quality of life as they deal with serious illness; and

Whereas, Hospice is the treatment of patients at the end of life or with a terminal illness, generally for patients who have less than six months to live and which uses many elements of palliative care to keep patients comfortable during their transition from life to death; and

Whereas, Physicians need to educate themselves on what the treatment goals offer and the reasonableness of the outcome, while all physicians should understand what palliative and hospice care offer a patient in terms of treatment, palliative care is an appropriate bridge to care; and

Whereas, There needs to be more certificate programs for physicians on palliative care until such time as there are enough fellowship trained end of life physicians, education is critical with respect to hospice care which does not mean "no care" but should redefine the scope of care: and

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Whereas, Currently, the delivery of end of life care is fragmented with services provided in the hospital, skilled nursing facility or community with each setting having different resources, definitions and protocols and no seamless way to transfer patients from one setting to the next and back again; and

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Whereas, The current "one size fits all" approach does little to address the spectrum of end of life issues but reinforces the need for a centralized depository of end of life orders that is easily accessible; therefore be it

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RESOLVED, That our American Medical Association develop educational resources for physicians, allied health professionals and patients on end of life care (Directive to Take Action); and be it further

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14 RESOLVED, That our AMA work with all stakeholders to develop proper quality metrics to evaluate and improve palliative and hospice care. (Directive to Take Action)

Fiscal Note: Moderate - between \$5,000 - \$10,000

Received: 03/22/22

Resolution: 608

(A-22)

Introduced by: Resident and Fellow Section

Subject: Transparency of Resolution Fiscal Notes

Referred to: Reference Committee F

Whereas, AMA resolutions include a fiscal note to share the projected cost of the resolution resolved clauses, if adopted; and

Whereas, The fiscal note is often categorized minimal, modest or moderate or sometimes, more specifically states an estimated cost in dollars; and

Whereas, Little justification or detail is provided to explain fiscal notes; and

Whereas, Providing the rationale behind the fiscal note to the House of Delegates would promote understanding, transparency, standardization and enable the House to utilize the AMA's resources more judiciously; therefore be it

RESOLVED, That our American Medical Association amend current policy G-600.061, "Guidelines for Drafting a Resolution or Report," by addition and deletion to read as follows:

(d) A fiscal note setting forth the estimated resource implications (expense increase, expense reduction, or change in revenue) of the any proposed policy, program, study or directive to take action shall be generated and published by AMA staff in consultation with the sponsor- prior to its acceptance as business of the AMA House of Delegates. Estimated changes in expenses will include direct outlays by the AMA as well as the value of the time of AMA's elected leaders and staff. A succinct description of the assumptions used to estimate the resource implications must be included in the AMA House of Delegates Handbook to justify each fiscal note. When the resolution or report is estimated to have a resource implication of \$50,000 or more, the AMA shall publish and distribute a document explaining the major financial components or cost centers (such as travel, consulting fees, meeting costs, or mailing). No resolution or report that proposes policies, programs, studies or actions that require financial support by the AMA shall be considered without a fiscal note that meets the criteria set forth in this policy. (Modify Current HOD Policy)

Fiscal Note: Estimated cost to implement resolution is \$5,810 annually.

Received: 04/08/22

#### **RELEVANT AMA POLICY**

#### Guidelines for Drafting a Resolution or Report G-600.061

Resolutions or reports with recommendations to the AMA House of Delegates shall meet the following guidelines:

1. When proposing new AMA policy or modification of existing policy, the resolution or report should meet the following criteria:

Page 2 of 2

- (a) The proposed policy should be stated as a broad guiding principle that sets forth the general philosophy of the Association on specific issues of concern to the medical profession;
- (b) The proposed policy should be clearly identified at the end of the resolution or report;
- (c) Recommendations for new or modified policy should include existing policy related to the subject as an appendix provided by the sponsor and supplemented as necessary by AMA staff. If a modification of existing policy is being proposed, the resolution or report should set out the pertinent text of the existing policy, citing the policy number from the AMA policy database, and clearly identify the proposed modification. Modifications should be indicated by underlining proposed new text and lining through any proposed text deletions. If adoption of the new or modified policy would render obsolete or supersede one or more existing policies, those existing policies as set out in the AMA policy database should be identified and recommended for rescission. Reminders of this requirement should be sent to all organizations represented in the House prior to the resolution submission deadline;
- (d) A fiscal note setting forth the estimated resource implications (expense increase, expense reduction, or change in revenue) of the proposed policy, program, or action shall be generated by AMA staff in consultation with the sponsor. Estimated changes in expenses will include direct outlays by the AMA as well as the value of the time of AMA's elected leaders and staff. A succinct description of the assumptions used to estimate the resource implications must be included in each fiscal note. When the resolution or report is estimated to have a resource implication of \$50,000 or more, the AMA shall publish and distribute a document explaining the major financial components or cost centers (such as travel, consulting fees, meeting costs, or mailing). No resolution or report that proposes policies, programs, or actions that require financial support by the AMA shall be considered without a fiscal note that meets the criteria set forth in this policy.
- 2. When proposing to reaffirm existing policy, the resolution or report should contain a clear restatement of existing policy, citing the policy number from the AMA policy database.
- 3. When proposing to establish a directive, the resolution or report should include all elements required for establishing new policy as well as a clear statement of existing policy, citing the policy number from the AMA policy database, underlying the directive.
- 4. Reports responding to a referred resolution should include the resolves of that resolution in its original form or as last amended prior to the referral. Such reports should include a recommendation specific to the referred resolution. When a report is written in response to a directive, the report should sunset the directive calling for the report.
- 5. The House's action is limited to recommendations, conclusions, and policy statements at the end of report. While the supporting text of reports is filed and does not become policy, the House may correct factual errors in AMA reports, reword portions of a report that are objectionable, and rewrite portions that could be misinterpreted or misconstrued, so that the "revised" or "corrected" report can be presented for House action at the same meeting whenever possible. The supporting texts of reports are filed.
- 6. All resolutions and reports should be written to include both "MD and DO," unless specifically applicable to one or the other.
- 7. Reports or resolutions should include, whenever possible or applicable, appropriate reference citations to facilitate independent review by delegates prior to policy development.
- 8. Each resolution resolve clause or report recommendation must be followed by a phrase, in parentheses, that indicates the nature and purpose of the resolve. These phrases are the following:
- (a) New HOD Policy:
- (b) Modify Current HOD Policy;
- (c) Consolidate Existing HOD Policy;
- (d) Modify Bylaws;
- (e) Rescind HOD Policy;
- (f) Reaffirm HOD Policy; or
- (g) Directive to Take Action.
- 9. Our AMA's Board of Trustees, AMA councils, House of Delegates reference committees, and sponsors of resolutions will try, whenever possible, to make adjustments, additions, or elaborations of AMA policy positions by recommending modifications to existing AMA policy statements rather than creating new policy.

Citation: CLRPD Rep. 4, A-99; Modified by BOT Rep. 15, A-00; Consolidated: CLRPD Rep. 3, I-01; Modified: CLRPD Rep. 2, A-02; Modified: CLRPD Rep. 6, A-03; Reaffirmed: BOT Rep. 19, A-04; Appended: Res. 606, A-05; Appended: Res. 611, A-07; Modified: CCB/CLRPD Rep. 1, A-12; Modified: Speakers Rep., A-18

Resolution: 703

(A-22)

Introduced by: Maryland, Mississippi

Subject: Mandating Reporting of All Antipsychotic Drug Use in Nursing Home

Residents

Referred to: Reference Committee G

Whereas, The federal government does not publicly disclose the use of antipsychotic drugs given to nursing home residents diagnosed with schizophrenia; and

Whereas, Antipsychotic drugs have historically been used as chemical restraints to keep nursing home residents docile, circumventing the costs associated with additional staffing required to manage nursing home residents; and

Whereas, Because the Food and Drug Administration has issued "black box" warnings regarding the risks of antipsychotic use among elderly patients with dementia, high rates of antipsychotic drug use can lower a nursing home's star rating from the federal government, thus damaging the reputation and desirability of the nursing home;<sup>1</sup> and

Whereas, The percentage of nursing home residents diagnosed with schizophrenia has increased in 2021;<sup>2</sup> and

Whereas, Nearly one-third of nursing home residents reported in the Centers for Medicare and Medicaid Services (CMS) Minimum Data Set (MDS) as having schizophrenia did not have any evidence of this diagnosis in their Medicare claims history, meaning they were likely prescribed antipsychotic drugs but were excluded because of their diagnosis;<sup>3</sup> and

Whereas, Current AMA policy "will ask CMS to cease and desist in issuing citations or financial penalties for medically necessary and appropriate use of antipsychotics for the treatment of dementia-related psychosis; and ask CMS to discontinue the use of antipsychotic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications"; 4 therefore be it

Resolution: 703 (A-22)

Page 2 of 2

RESOLVED, That American Medical Association Policy D-120.951, "Appropriate Use of Antipsychotic Medications in Nursing Home Patients," be amended by addition and deletion to read as follows:

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Our AMA will: (1) meet with the Centers for Medicare & Medicaid Services (CMS) for a determination that acknowledges that antipsychotics can be an appropriate treatment for dementia-related psychosis if non-pharmacologic approaches have failed and will ask CMS to cease and desist in issuing citations or financial penalties for medically necessary and appropriate use of antipsychotics for the treatment of dementia-related psychosis; and (2) ask CMS to discontinue the use of antipsychotic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications; and (3) ask CMS to require the reporting of all antipsychotic drugs used and the diagnoses for which they are prescribed. (Modify Current HOD Policy)

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

Received: 03/01/22

# **RELEVANT AMA POLICY**

Appropriate Use of Antipsychotic Medications in Nursing Home Patients D-120.951 Our AMA will: (1) meet with the Centers for Medicare & Medicaid Services (CMS) for a determination that acknowledges that antipsychotics can be an appropriate treatment for dementia-related psychosis if non-pharmacologic approaches have failed and will ask CMS to cease and desist in issuing citations or financial penalties for medically necessary and appropriate use of antipsychotics for the treatment of dementia-related psychosis; and (2) ask CMS to discontinue the use of antipsychotic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications.

Res. 523, A-12; Appended: Res. 708, A-19

<sup>&</sup>lt;sup>1</sup> Five-Star Quality Rating System | CMS https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/FSQRS (accessed 2021 -09 -21).

<sup>&</sup>lt;sup>2</sup> MDS 3.0 Frequency Report | CMS https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report (accessed 2021 -09 -21).

<sup>&</sup>lt;sup>3</sup> CMS Could Improve the Data It Uses to Monitor Antipsychotic Drugs in Nursing Homes, OEI-07-19-00490. 22.

<sup>&</sup>lt;sup>4</sup> D-120.951 Appropriate Use of Antipsychotic Medications in Nursi | AMA https://policysearch.ama-assn.org/policyfinder/detail/Appropriate%20Use%20of%20Antipsychotic%20Medications%20in%20Nursing%20Home%20Patients %20D-120.951?uri=%2FAMADoc%2Fdirectives.xml-0-77.xml (accessed 2021 -09 -21).

Resolution: 720

(A-22)

Introduced by: Illinois

Subject: Mitigating the Negative Impact of Step Therapy Policies and Nonmedical

Switching of Prescription Drugs on Patient Safety

Referred to: Reference Committee G

Whereas, Insurance companies use pharmaceutical step therapy programs and non-medical drug switching policies as means to control costs; and

Whereas, These policies can serve to try to replace a physician's judgment and interfere with the doctor-patient relationship; and

Whereas, These policies can restrict patient access to effective treatments, putting patient health and safety in jeopardy by subjecting patients to potential adverse effects, and absorbing practice resources with burdensome approvals and documentation requirements; and

Whereas, The process of nonmedical drug switching mandates that a patient go off their current therapies for no other reason than to save money, which can include increasing out-of-pocket costs, moving treatments to higher cost tiers or terminating coverage of a particular drug; and

Whereas, The American College of Physicians (ACP) has recognized the need to balance costs and that any such programs should contain flexibilities so that physicians can, based on their knowledge of a patient's status and co-morbid conditions, be able to easily deviate from the usual approach to optimize patient care and minimize disruptions to effective care; and

Whereas, The ACP has adopted recommendations to help physicians and patients who are subjected to these types of policies; therefore be it

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Resolution: 720 (A-22)

Page 2 of 2

RESOLVED, That our American Medical Association adopt policy supporting the recommendations of the American College of Physicians with respect to insurance step therapy and nonmedical drug switching policies, including:

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All step therapy and medication switching policies should aim to minimize care disruption, harm, side effects and risks to the patient.

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All step therapy and nonmedical drug switching policies should be designed with patients at the center, while accounting for unique needs and preferences.

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All step therapy and nonmedical drug switching protocols should be designed with input from frontline physicians and community pharmacists; feature transparent, minimally burdensome processes that consider the expertise of a patient's physician; and include a timely appeals process.

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Data concerning the effectiveness and potential adverse consequences of step therapy and nonmedical drug switching programs should be made transparent to the public and studies by policymakers. Alternative strategies to address the rising cost of prescription drugs that do not inhibit patient access to medications should be explored. (New HOD Policy)

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

Received: 04/08/22