

Reference Committee J

CMS Report(s)

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

Resolution(s)

- 801 Reimbursement for Post-Exposure Protocol for Needlestick Injuries
- 802 Ensuring Fair Pricing of Drugs Developed with the United States Government
- 803 Encourage Federal Efforts to Expand Access to Scheduled Dialysis for Undocumented People
- 804 Protecting Seniors from Medicare Advantage Plans
- 805 Fair Medication Pricing for Patients in United States: Advocating for a Global Pricing Standard
- 806 Support for Housing Modification Policies
- 807 Addressing the Need for Low Vision Aid Devices
- 808 Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs
- 809 AMA Principles of Medicaid Reform
- 810 Hospital Medical Staff Policy
- 811 Require Payers to Share Prior Authorization Cost Burden
- 812* Autopsy Standards as Condition of Participation
- 813* Public Reporting of PBM Rebates
- 814* PBM Value-Based Framework for Formulary Design
- 815* Step Therapy

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-19

Subject: Established Patient Relationships and Telemedicine
(Resolution 215-I-18)

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

At the 2018 Interim Meeting, the House of Delegates referred Resolution 215-I-18, “Extending the Medical Home to Meet Families Wherever They Go,” which was introduced by the American Academy of Pediatrics. The Board of Trustees assigned this item to the Council on Medical Service for a report back at the 2019 Interim Meeting. Resolution 215-I-18 asked that our American Medical Association (AMA) “develop model legislation to permit primary care physicians, who work in medical homes/primary care practices that satisfy the National Committee for Quality Assurance Patient-Centered Medical Home Recognition Program guidelines, and who have documented a face-to-face patient-care relationship, to provide telehealth services for the patient when the patient travels to any of the fifty states.”

This report provides an overview of state-based medical licensure and telemedicine; describes the Interstate Medical Licensure Compact (the Compact); summarizes relevant AMA policy; and makes recommendations.

BACKGROUND

Telemedicine is a key health care delivery innovation that has the potential to improve access to care and reduce health care costs. The AMA advocates for policies that encourage the adoption of telemedicine, while strongly supporting the current state-based medical licensure structure and the ability of states to enforce their medical practice laws that are in place to protect patients.

Although technological developments have enabled the application of telemedicine across a range of care settings, including patient-centered medical home practices, barriers to its widespread use remain. The financial burden of implementing telemedicine was cited as one such barrier in a recent study, which found that 15.4 percent of physicians worked in practices utilizing telemedicine to interact with patients, and 11.2 percent worked in practices that used telemedicine for interactions between physicians and health care professionals.¹

Referred Resolution 215-I-18 highlighted concerns historically raised by physicians that the state-based licensure process has served as an additional barrier for physicians trying to expand telemedicine practices. Unlike some countries that have national oversight of medical practice, states are responsible for regulating the practice of medicine in the US. State authority to protect the health of its citizens was granted in 1791 under the 10th Amendment of the US Constitution, with formal licensing of physicians through state medical boards dating back to the 1800s.² The primary goals of state medical boards are to protect patients, ensure quality health care, and foster the professional practice of medicine. The prevailing standard for state medical licensure found in the medical practice acts of each state affirms that the practice of medicine is determined to occur

1 where the patient is located, so that the full resources of the state are available for the protection of
2 that patient. Without such protection, a patient who receives services that fall short of the standard
3 of care would have limited recourse to seek redress and relief under the state's medical practice and
4 patient safety statutes and regulations.

5
6 Licensure requirements established by state medical boards vary with respect to telemedicine but,
7 according to the Federation of State Medical Boards (FSMB), 49 state boards—as well as the
8 medical boards of the District of Columbia, Puerto Rico, and the Virgin Islands—require
9 physicians practicing telemedicine to be licensed in the state in which the patient is located,³
10 consistent with AMA policy. Fourteen state medical boards issue a special purpose license,
11 telemedicine license or certificate, or license to practice medicine across state lines.⁴

12
13 Historically, the process of obtaining licenses to practice medicine in multiple states has been
14 burdensome and time-consuming for physicians, and some states formed interstate agreements to
15 practice medicine across state lines. The AMA has long supported solutions that make it easier for
16 physicians to obtain licenses to practice across multiple states, while preserving the ability of states
17 to protect patient health and oversee the care provided to patients within their borders. For many
18 years, the AMA urged policymakers to address the cost, time and paperwork burdens associated
19 with licensure, which were compounded when a physician sought licensure in more than one state.⁵
20 Accordingly, the AMA strongly supported development and implementation of the Compact as a
21 licensure solution that would make it easier and faster for physicians to obtain licenses to practice
22 in multiple states.⁶

23 24 *Interstate Medical Licensure Compact*

25
26 The Compact, developed over many years and officially launched in 2017, established a new
27 pathway to expedite the licensing of physicians already licensed to practice in one state, who seek
28 to practice medicine in one or more other states. This expedited process helps facilitate license
29 portability and allows physicians to practice medicine—including telemedicine—in a safe and
30 accountable manner that expands access to care without compromising patient protections. At the
31 time this report was prepared, the Compact was an agreement among the following 29 states, the
32 District of Columbia and the Territory of Guam: Alabama, Arizona, Colorado, Georgia, Idaho,
33 Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana,
34 Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Pennsylvania, South Dakota,
35 Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming.⁷

36
37 The Compact provides a licensing option under which qualified physicians seeking to practice in
38 multiple states are eligible for expedited licensure in all states participating in the Compact.
39 Licensing fees vary and remain the purview of each state's medical board. For a state to join the
40 Compact, the state legislature must enact authorizing legislation. A license obtained through the
41 expedited procedure provided for by the Compact provides the same licensing currently provided
42 for physicians by state medical boards—the only difference is that the process of obtaining a
43 license is significantly streamlined. Physicians can apply for licenses through the Compact on the
44 [Compact's website](#).

45
46 Importantly, the Compact creates another pathway for licensure and does not otherwise change a
47 state's medical practice act. Of priority to the AMA, facilitating expedited medical licensure
48 through the Compact ensures that states retain their roles in regulating the practice of medicine
49 and protecting patient welfare. The Compact adopts the prevailing standard that the practice of
50 medicine occurs where the patient is located at the time of the physician-patient encounter.

1 A physician practicing under a license facilitated by the Compact is thus bound to comply with the
2 statutes, rules and regulations of each Compact state wherein he/she chooses to practice medicine.
3 The Compact serves as a leading alternative to proposals to change the site of practice from where
4 the patient is located to where the physician is located for purposes of telemedicine, which would
5 usurp state authority to regulate the practice of medicine.

6 7 AMA POLICY AND RESOURCES

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9 The recommendations contained in [Council on Medical Service Report 7-A-14](#) established Policy
10 H-480.946, which outlines safeguards and standards to support the appropriate coverage of and
11 payment for telemedicine services. In the report, the Council prioritized the need for AMA policy
12 to support future innovation in the use of telemedicine while ensuring patient safety, quality of care
13 and the privacy of patient information, as well as protecting the patient-physician relationship and
14 promoting improved care coordination and communication with medical homes.

15
16 A key safeguard included in Policy H-480.946 stipulates that physicians and other health
17 practitioners delivering telemedicine services must be licensed in the state where the patient
18 receives services, or be providing these services as otherwise authorized by that state's medical
19 board. In addition, the policy requires physicians and other health practitioners delivering
20 telemedicine services to abide by state licensure laws, state medical practice acts and other
21 requirements in the state where the patient receives services, and maintains that the delivery of
22 telemedicine services must be consistent with state scope of practice laws. The Council included
23 these safeguards in the recommendations of its report because the Council believed that the key
24 tenets in the delivery of in-person services hold true for the delivery of telemedicine services.
25 Policy H-480.946 also states that a valid patient-physician relationship must be established before
26 the provision of telemedicine services, through:

- 27
28
 - A face-to-face examination, if a face-to-face encounter would otherwise be required in the
29 provision of the same service not delivered via telemedicine; or
 - A consultation with another physician who has an ongoing patient-physician relationship
30 with the patient. The physician who has established a valid physician-patient relationship
31 must agree to supervise the patient's care; or
 - Meeting standards of establishing a patient-physician relationship included as part of
32 evidence-based clinical practice guidelines on telemedicine developed by major medical
33 specialty societies, such as those of radiology and pathology.

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37 Additionally, the policy maintains that prior to the delivery of any telemedicine service, physicians
38 need to verify that their medical liability insurance covers telemedicine services, including
39 telemedicine services provided across state lines, if applicable.

40
41 Long-standing AMA policy also maintains that medical boards of states and territories should
42 require a full and unrestricted license in that state for the practice of telemedicine, unless there are
43 other appropriate state-based licensing methods, with no differentiation by specialty, for physicians
44 who wish to practice telemedicine in that state or territory (Policy H-480.969). The policy also
45 states that this license category should adhere to the following principles:

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 - Application to situations where there is a telemedical transmission of individual patient
48 data from the patient's state that results in either; (i) provision of a written or otherwise
49 documented medical opinion used for diagnosis or treatment or; (ii) rendering of treatment
50 to a patient within the board's state;

- Exemption from such a licensure requirement for traditional informal physician-to-physician consultations (“curbside consultations”) that are provided without expectation of compensation;
- Exemption from such a licensure requirement for telemedicine practiced across state lines in the event of an emergent or urgent circumstance, the definition of which for the purposes of telemedicine should show substantial deference to the judgment of the attending and consulting physicians as well as to the views of the patient; and
- Application requirements that are non-burdensome, issued in an expeditious manner, have fees no higher than necessary to cover the reasonable costs of administering this process, and that utilize principles of reciprocity with the licensure requirements of the state in which the physician in question practices.

Policy D-480.999 opposes a single national federalized system of medical licensure. Policy H-480.974 directs our AMA to work with the FSMB and state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries. Policy D-480.969 states that our AMA will work with the FSMB to draft model state legislation to ensure that telemedicine is appropriately defined in each state’s medical practice statutes and its regulation falls under the jurisdiction of the state medical board. Policies H-275.978 and H-275.955 urge licensing jurisdictions to adopt laws and regulations facilitating the movement of licensed physicians between states. Policy D-275.994 supports the Compact and directs the AMA to work with interested medical associations, the FSMB and other interested stakeholders to ensure expeditious adoption by the states of the Interstate Compact for Medical Licensure.

Policies H-480.974, H-480.968 and H-480.969 encourage national medical specialty societies to develop appropriate and comprehensive practice parameters, standards and guidelines addressing the clinical and technological aspects of telemedicine. Policy H-480.968 urges national private accreditation organizations to require that medical care organizations that establish ongoing arrangements for medical care delivery from remote sites require practitioners at those sites to meet no less stringent credentialing standards and participate in quality review procedures that are at least equivalent to those at the site of care delivery.

The AMA has substantial scope of practice policy, including Policies D-160.995, H-270.958, and H-160.949. Principles for the supervision of nonphysician providers when telemedicine is used are outlined in Policy H-160.937. This policy states that in all settings and circumstances, physician supervision is required when nonphysician providers deliver services via telemedicine, and the extent of supervision provided by the physician should conform to the applicable medical practice act in the state where the patient receives services. Policy H-160.937 further states that nonphysician providers who deliver services via telemedicine should do so according to the applicable nonphysician practice acts in the state where the patient receives such services. Code of Medical Ethics Opinion 1.2.12 states that physicians who provide clinical services through telemedicine must uphold the standards of professionalism expected in in-person interactions, follow appropriate ethical guidelines of relevant specialty societies and adhere to applicable law governing the practice of telemedicine.

Consistent with AMA policy, AMA model state legislation ensures that, with certain exceptions (eg, curbside consultations, volunteer emergency medical care), physicians and other health practitioners practicing telemedicine are licensed in the state where the patient receives services or are providing these services as otherwise authorized by that state’s medical board. A Continuing Medical Education (CME) module, “[Adopting Telemedicine in Practice](#),” outlines steps physicians should take before adopting telemedicine into practice and is available on the [AMA Ed Hub](#).

1 DISCUSSION
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3 The Council appreciates the intent of referred Resolution 215-I-18 and understands the frustrations
4 of the authors. It is increasingly challenging for physician practices to compete with large
5 commercial entities that are contracting with payers to provide telemedicine services, including
6 primary care services. Commercial direct-to-consumer telemedicine enables patients to receive care
7 from their homes, offices or mobile devices; however, these encounters are provided outside of a
8 patient's medical home and can lead to fragmented care. Where there is an established patient
9 relationship, a physician should be able to use telemedicine to provide quality emergent or urgent
10 care for a patient's existing condition when that patient is traveling in another state.
11

12 The Council also discussed potential unintended consequences of the model legislation requested
13 via referred Resolution 215-I-18, which would create an exception for primary care physicians who
14 work in accredited patient-centered medical homes and would ultimately be very disruptive to
15 existing laws and regulations. The Council is concerned that such legislation, if implemented,
16 could result in national oversight of telemedicine provided across state lines, and that any national
17 oversight would be subject to influence by a variety of stakeholders including physicians, but also
18 commercial telemedicine providers and retail health clinics. Additionally, the Council believes it
19 would be difficult to limit the suggested exception to primary care physicians. It is possible that
20 direct-to-consumer telemedicine providers would be able to become medical homes, which could
21 in turn lead to other unintended consequences, such as the overprescribing of antibiotics.⁸
22

23 The Council believes that patient safety must remain a primary consideration during discussions of
24 proposals to enhance patient access to care through telemedicine, and that maintaining AMA policy
25 in support of state licensing boards having authority over medical services where patients are
26 located prioritizes patient protections. The Council notes that treating physicians not licensed by
27 the state where a patient is located may not receive public health department alerts, including
28 notice of local outbreaks such as measles or food borne illness.
29

30 The Council discussed the concerns raised by referred Resolution 215-I-18 and believes that the
31 Compact is a sensible and viable approach to facilitating multistate licensure without undermining
32 state jurisdiction over medical practice and patient health. The Council acknowledges that the
33 licensing option available under the Compact is not yet available to all physicians because not all
34 states have become members of the Compact. However, within two years after its official launch,
35 over half of all states joined the Compact and it was used by more than 3,000 physicians to secure
36 more than 5,400 medical licenses in Compact member states.⁹ The Council recognizes the
37 importance of persuading remaining states to join the Compact, which will ultimately facilitate
38 multistate licensure for most physicians who want it, and recommends that our AMA work with
39 state medical associations to encourage states that are not part of the Compact to consider joining it
40 as a means of enhancing patient access to and proper regulation of telemedicine services.
41

42 With respect to the travel considerations raised in referred Resolution 215-I-18, the Council
43 discussed the ability of physicians to provide telemedicine services to their patients while they are
44 traveling to another state and points to the practical exemptions from state licensure requirements
45 already encompassed in AMA policy—for emergent or urgent circumstances and “curbside
46 consultations.” Physicians who wish to provide telemedicine services to patients in a state where
47 they are not licensed are encouraged to direct inquiries to that state's medical board.
48

49 Finally, the Council believes that state-based exceptions and carve-outs of not only AMA
50 telemedicine policy, but also state licensure laws, will further complicate oversight and regulation

1 and could potentially diminish the standards and patient safeguards that are centerpieces of AMA
2 policy. Accordingly, the Council also recommends reaffirming Policies H-480.946 and H-480.969.

3 4 RECOMMENDATIONS

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6 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
7 215-A-18, and the remainder of the report be filed:

- 8
9 1. That our American Medical Association (AMA) work with state medical associations to
10 encourage states that are not part of the Interstate Medical Licensure Compact to consider
11 joining the Compact as a means of enhancing patient access to and proper regulation of
12 telemedicine services. (Directive to Take Action)
13
14 2. That our AMA reaffirm Policy H-480.946, which delineates standards and safeguards that
15 should be met for the coverage and payment of telemedicine, including that physicians and
16 other health practitioners delivering telemedicine services must be licensed in the state where
17 the patient receives services. (Reaffirm HOD Policy)
18
19 3. That our AMA reaffirm Policy H-480.969, which maintains that state medical boards should
20 require a full and unrestricted license in that state for the practice of telemedicine, with no
21 differentiation by specialty, unless there are other appropriate state-based licensing methods,
22 and with exemptions for emergent or urgent circumstances and “curbside consultations.”
23 (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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¹ Kane CK and Gillis K. The use of telemedicine by physicians: Still the exception rather than the rule. *Health Affairs* 37, No. 12 (December 2018). Available online at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05077>.

² Federation of State Medical Boards. Understanding Medical Regulation in the United States. Available online at: <https://www.fsmb.org/siteassets/education/pdf/best-module-text-intro-to-medical-regulation.pdf>.

³ Federation of State Medical Boards. Telemedicine Policies: Board by Board Overview. Jan. 23, 2018. Available online at: http://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf.

⁴ Ibid.

⁵ American Medical Association. Statement for the Record to the Federal Trade Commission’s Economic Liberty Task Force. Streamlining Licensing Across State Lines: Initiatives to Enhance Occupational License Portability. July 20, 2017. Available online at: https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-7-20-STATEMENT-FOR-THE-RECORD-Streamlining-Licensing-Across-State-Lines_final2.pdf.

⁶ American Medical Association. Statement for the Record to the Federal Trade Commission’s Economic Liberty Task Force. Streamlining Licensing Across State Lines: Initiatives to Enhance Occupational License Portability. July 20, 2017. Available online at: https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-7-20-STATEMENT-FOR-THE-RECORD-Streamlining-Licensing-Across-State-Lines_final2.pdf.

⁷ The Interstate Medical Licensure Compact website: <https://imlcc.org/>.

⁸ Ray KN, Shi Z, Gidengil CA, Poon SJ, Uscher-Pines L and Mehrotra A. Antibiotic prescribing during pediatric direct-to-consumer telemedicine visits. *Pediatrics* 143, No. 5 (May 2019).

⁹ The Interstate Medical Licensure Compact. Press Release dated April 27, 2019.

REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-19)
Addressing Financial Incentives to Shop for Lower-Cost Health Care
(Reference Committee J)

EXECUTIVE SUMMARY

The Council on Medical Service presents this report to examine the practice of employers and insurance companies increasingly implementing programs (ie, Financial Incentive Programs or FIPs) that offer patients financial incentives when they use shopping tools to compare prices on health care items and services and choose lower-cost options. This report examines the potential benefits and risks of FIPs, analyzes examples of current FIPs, and offers guidance on how FIPs could be improved.

Virtues of FIPs include promoting price transparency, empowering patients to pursue health care that minimizes financial burden and reducing societal health care costs. At the same time, it is critical that patients be empowered to make fully informed decisions about their health care, that they are never coerced into accepting lower-cost care if it could jeopardize their health, and that programs that influence patient decision-making be equally transparent about quality and cost. To protect patient access to high-quality care, the Council recommends a set of guiding principles that it encourages health care payers (employers, insurance companies, etc.) and third-party vendors to incorporate into the design and implementation of FIPs. These guiding principles focus on protecting physician involvement in FIPs, the patient-physician relationship, quality assurance and transparency, and patient choice. To further promote these ideals, the Council recommends that the American Medical Association (AMA) encourage state medical associations and national medical specialty societies to seek opportunities to collaborate in the design and implementation of FIPs to empower physicians and patients to make high-value referral choices, and to encourage objective studies of the impact of FIPs.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-19

Subject: Addressing Financial Incentives to Shop for Lower-Cost Health Care

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

1 While encouraging patients to pursue lower-cost health care, employers and insurance companies
2 are increasingly implementing programs (ie, Financial Incentive Programs or FIPs) that offer
3 patients financial incentives when they use shopping tools to compare prices on health care items
4 and services and choose lower-cost options.¹ The Council on Medical Service presents this
5 Council-initiated report to examine the emergence and impact of FIPs, as well as the potential
6 benefits and risks of FIPs, and to offer guidance on how FIPs could be improved.

8 BACKGROUND

10 Care can be deemed “shoppable” when it is a common service that can be researched in advance,
11 multiple providers of that service are available in a market, and sufficient data about the prices and
12 quality of services are available.² Estimates vary as to what proportion of health care spending can
13 be deemed “shoppable,” with some estimates at 10 percent,³ and others as high as 33 to 43
14 percent.⁴

16 FIPs appeal to employers and insurers because they encourage patients to price shop without
17 exposing them to increased out-of-pocket costs.⁵ Additional virtues of FIPs include promoting
18 price transparency, empowering patients to pursue health care that minimizes financial burden and
19 reducing societal health care costs. While considering these potential benefits of FIPs, it is critical
20 to ensure that patients are empowered to make fully informed decisions about their health care, that
21 they are never coerced into accepting lower-cost care if it could jeopardize their health, and that
22 programs that influence patient decision-making be equally transparent about quality and cost.

24 FIPs in the private sector can be used by employers as part of employee benefit packages, or health
25 insurance companies can implement FIPs for their enrollees. In the public sector, some states have
26 implemented FIPs as part of state employees’ benefits. The Council discusses various models that
27 have emerged to encourage and assist patients shopping for lower-cost health care. The models
28 vary with respect to the level of voluntary versus potentially coercive impact on patients. With this
29 report, the Council emphasizes the protection of patients and the patient/physician relationship; and
30 recommends a series of principles to address the potential of FIPs to further fragment patient care.

32 POTENTIAL BENEFITS AND RISKS OF FIPs

34 *Potential Benefits*

36 FIPs could benefit patients, payers, and the health care system in several ways. Both
37 underinsurance and cost-related non-adherence pose significant challenges to patients and
38 providers. Even when a service is covered by a health plan, patients may incur significant costs in

the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo necessary care.⁶ Similarly, cost-related non-adherence refers to a state in which patients are unable to pursue recommended medical care due to financial barriers.⁷ For example, greater out-of-pocket costs for medication to treat certain chronic conditions have been found to reduce initiation and adherence, lower the likelihood of achieving desired health outcomes, and sometimes, increase utilization of acute care services.⁸ In contrast, studies have demonstrated that reducing or eliminating cost-sharing leads to improvements in medication adherence⁹ and reductions in socioeconomic and racial disparities.¹⁰ Accordingly, FIPs could potentially increase patients' access to medical care that may have been financially out-of-reach for them. Additionally, when patients make cost-effective treatment choices, those savings can benefit payers and the health care system. Moreover, even if patients do not alter their treatment plans, having information about the cost of planned medical care provides much needed transparency. Finally, if the care being incentivized by FIPs is, in fact, high-quality care, these programs could be consistent with longstanding American Medical Association (AMA) policy supporting value-based insurance design, as an opportunity to align clinical and financial incentives for patients to pursue high-value care.

FIPs could also be significantly enhanced by including referring/prescribing physicians in the "shopping" experience at the point of care. Treating physicians' referral recommendations play a critical role in patients' choices regarding follow-up care. FIPs that embrace the importance of physician referrals could benefit patients, physicians and other elements of the health care system. If patients' FIP benefits could be made available to treating physicians in real time during patient consultations, patients and their trusted physicians could work together to choose the best referral and/or prescription option, considering both quality and cost of care. Such fully informed referrals could enhance efficiency, quality, and cost of care.

Potential Risks

FIPs raise many questions that must be answered to determine whether they are truly in patients' best interests. As an initial matter, FIPs raise several administrative questions. Health care is uniquely complex and cannot simply be shopped like retail goods. Key limits on shopping for health care include:

Patient Limits: Even if a service is shoppable for some patients, for other patients, shopping for that service may not be convenient, practical or advisable.¹¹ Similarly, prescription drugs can be shoppable in some cases, but not in others. Some patients find less expensive drugs just as efficacious as more expensive alternatives, but specific formulations are required by others. While some patients may find that a lower-priced prescription drug could be appropriate, it might require additional burden for the patient (such as more frequent dosing) and/or the provider (such as required monitoring and/or testing). In such cases, patients must fully understand and be willing to accept the additional burden.

Care Coordination and Quality of Care: If shopping for lower-cost care leads patients to obtain care from a variety of physicians and facilities, absent an integrated records system, there is a potential for fragmentation of care, which creates additional challenges for patients and physicians in receiving and providing quality care.

Administrative Burden: If, after receiving a referral or prescription from their physicians, patients shop for and choose to pursue lower-cost care, both the patients and their physicians may face time-consuming administrative burdens. Patients may need to reach out to their referring

physicians for new prescriptions and/or new referrals, and they may have to seek copies of their medical records to facilitate care coordination.

FIPs also raise concerns about quality of care and unintended consequences, and these become especially fraught when working with already vulnerable patient populations, such as those with low incomes and/or costly chronic conditions, who may be unduly persuaded by enticing financial incentives. Here the question of whether patients are truly presented with meaningful choices versus the extent to which they are somewhat coerced into accepting a non-preferred care option becomes more complicated. Key considerations include continuity of care and the tradeoff between quality and cost.

Continuity of Care: It is unclear whether FIPs will interfere in patient-physician relationships and/or attempt to substitute for medical advice. Patients should be empowered to reach out to whomever they would like in researching their care options. However, if patients have received referrals or prescriptions from their physicians and have not made efforts to shop for alternative options, programs that proactively reach out to such patients to suggest alternative courses of treatment risk harming the trust built between patients and their physicians and risk substituting their judgement for medical advice. Additionally, it is not clear how the “health professionals” providing patient assistance through some FIPs are trained, but even if providing referrals is within their scope of practice, these “health professionals” could disrupt existing patient-physician relationships.

Quality/Cost Tradeoffs: Any program that encourages physicians or patients to make quality tradeoffs to reduce cost raises significant questions about unintended consequences. While some care, even if that care is of less than ideal quality, could be better than cost-related non-adherence, the obvious preference is to direct patients to appropriate care while minimizing financial burden. For patients experiencing significant financial burden, either due to expensive medical conditions or due to other social determinants of health, it is especially important to acknowledge and safeguard against crossing the fine line between an optional financial incentive and implicit coercion to accept the least expensive care.

While the FIPs described in this report claim to base their decisions on care quality, it is not clear what metrics or data are used to evaluate quality, nor is it clear if their metrics align with well-established, evidence-based quality criteria developed by national medical specialty societies. Accordingly, it is possible that these programs could steer patients to care that is of lesser quality than the original physician referral. Transparency regarding FIPs quality data and analyses is essential.

INTRODUCTION TO CURRENT FIPs

Generally, shopping programs are available through preferred provider organization (PPO)-style plans that offer patients broader choices of providers from whom they can receive care. Patients enrolled in Health Maintenance Organizations (HMOs) and/or narrow-network plans are restricted to a smaller set of medical providers and may be unable to access higher quality and lower cost health care.¹² Additionally, patient cost-sharing varies significantly based on insurance benefit design, and some design features will provide greater or lesser incentives for patients to shop for lower-cost care.¹³

The decision to implement an FIP can come from the private and/or public sector. In the private sector, employers can choose to implement FIPs as part of their employees’ benefits packages, or health insurance companies can implement FIPs for their enrollees. In the public sector, some

states have chosen to implement FIPs as part of state employees' benefits packages (eg, New Hampshire) or via legislation that requires some private insurers to offer pay-to-shop incentives (eg, Maine).¹⁴ Multiple tools have emerged to encourage and assist patients shopping for a broad spectrum of care.

Sapphire Digital: More than 350 health plans and employers, representing over 95 million members, use the Sapphire Digital platform to incentivize patients to shop for care.¹⁵ Sapphire Digital's SmartShopper program works by integrating directly with an employer's benefit program.¹⁶ SmartShopper reaches patients through several channels: call centers, web chat assistants, direct mail campaigns, and an online platform where patients can compare prices. SmartShopper is aimed at patients, but it requires partnerships with local providers, employers, and payers.¹⁷ The FIP provides cash incentives to encourage patients to shop for what the company describes as "routine care" including, imaging services, labs, specialty drugs, preventive exams and outpatient surgeries. The extent to which these services are truly routine, however, is subjective. Approximately 200 procedures can be shopped through the SmartShopper program, with about 50 services being responsible for the bulk of the savings.¹⁸ After comparing prices, if patients choose to receive care from one of the identified lower-cost providers, they will be mailed a check, with incentives on average ranging from \$25 to \$500 per individual service. In 2018, the most shopped medical procedures were lab/blood work, mammogram, magnetic resonance imaging (MRI), colonoscopy, and computerized tomography (CT) scan.¹⁹

Critically, it is unclear what quality metrics Sapphire Digital uses to determine whether the lower-cost services it incentivizes are in fact "better value" and "high-quality."²⁰ Sapphire Digital provides shoppers with quality data from Quantros which has been described as, "a patent pending proprietary composite scoring system which integrates outcome quality measures, such as readmission, complication and mortality rates, into a single, multidimensional composite quality score. The data are risk-adjusted and rendered as an easy-to-understand rating for individual physicians, hospitals and health systems."²¹ Previously, Sapphire Digital had described its quality data as incorporating "structure" and "patient experience" measures.²²

Sapphire Digital recently took health care shopping a step further when it launched its Medical Expertise Guide (MEG) in late 2018.²³ MEG builds upon the SmartShopper tool in two critical ways: first, it focuses specifically on influencing patients' choices for surgical procedures; and second, rather than relying on patients to engage with the tool because they are interested in shopping for care, MEG enables Sapphire Digital to predict which patients might need care and proactively reaches out to those patients. The program's engagement strategy is based on predictive analytics and modeling, used to identify patients on a clinical path that could lead to expensive surgery. In describing their methods for identifying high-quality care, Sapphire Digital explains that MEG applies quality measures such as infection and complication rates, patient reviews, predictive analytics, and "proprietary confidence measures." MEG also provides assistance from "highly-trained health care professionals."²⁴ This novel technology has the potential for both significant benefits and risks.

UnitedHealthcare (UHC): In addition to incentivizing patients to shop for lower-cost health care services, FIPs can incentivize patients to choose lower-cost prescription drugs. UHC recently launched its My ScriptRewards program that allows patients to earn up to \$500 in prepaid debit cards that can be used to pay medical expenses when they choose "doctor-approved, guideline-recommended and cost-effective medications" to treat HIV.²⁵ UHC explains that the Department of Health and Human Services (HHS) has recommended several HIV treatment regimens, and the cost among these regimens can vary significantly. UHC has selected two regimens (Cimduo® + Tivicay® (two-pill regimen) and Cimduo + Isentress®/Isentress HD® (three-pill regimen)) and

1 incentivizes patients to choose one of these lower-cost regimens by offering these regimens with no
2 patient cost-sharing, plus the prepaid debit card rewards.

3
4 With the lower cost of UHC's preferred regimens, however, come some key distinctions between
5 UHC's preferred HIV treatments and other options. Critically, HHS guidelines issued in late 2018
6 selected Biktarvy, a treatment that is not eligible for the UHC incentive, as a preferred regimen,
7 whereas UHC's preferred regimens do not appear on the list of HHS recommended initial
8 treatments.²⁶ Moreover, UHC's preferred regimens require patients to take two or three pills a day,
9 whereas Biktarvy is a once-a-day pill regimen. UHC does not explicitly force patients to accept one
10 of the lower-cost prescription options and stresses the importance of patients working with their
11 physicians to determine whether one of the lower-cost treatment regimens is right for them.
12 However, if the lower-cost regimens are not appropriate, the only recourse is to reach out to UHC
13 to determine which alternative regimens are covered under patients' pharmacy benefits,²⁷ and
14 patients or providers may be forced to explicitly opt out of the My ScriptRewards program in order
15 to fill a non-preferred antiretroviral prescription.²⁸ UHC plans to expand its My ScriptRewards
16 program to additional high-cost specialty drug categories in the future.²⁹

17
18 Walmart: In contrast to FIPs focused on identifying lower-cost care, some payers are creating
19 financial incentives that preference demonstrated quality over cost. Concerned that employees were
20 being misdiagnosed, leading to unnecessary surgery and spending, Walmart Inc., the nation's
21 largest private employer, created a program to encourage patients to go to specific imaging centers
22 based on diagnostic accuracy, not price.³⁰ Walmart employees do not have to choose a preferred
23 imaging center, but if they do not, they pay additional cost-sharing. Walmart's imaging program is
24 aligned with its efforts over the past decade to create financial incentives for patients to obtain care
25 at designated hospitals where it believes patients will achieve better results. As part of its Centers
26 of Excellence program, Walmart has selected hospitals across the country that it believes have the
27 expertise and resources to provide its members with the highest-quality care for several medical
28 conditions, including various surgeries and cancer diagnoses.³¹ For many of these treatments,
29 patients travel to one of the designated Centers of Excellence, where their care is covered 100
30 percent and travel and lodging costs are covered for the patient and a companion caregiver.

31
32 Anthem/UHC: A similar but clearly distinguishable insurance benefit design feature imposes prior
33 authorization requirements and/or denies coverage when patients choose a higher-priced site of
34 service. Such benefit design features jeopardize physician and patient choice. Anthem and UHC
35 provide examples of this type of program. In addition to Anthem's preapproval process to review
36 the medical necessity of a non-emergency outpatient MRI or CT scan, an Anthem subsidiary also
37 evaluates where the scan should be performed, and provides the requesting physician with a list of
38 eligible imaging centers.³² Citing the "huge cost disparities for imaging services, depending on
39 where members receive their diagnostic tests," Anthem's program ultimately prevents many
40 patients from receiving MRIs and CT scans at hospital-owned, outpatient facilities, instead
41 requiring them to use independent imaging centers.³³ Similarly, starting in 2019, UHC began
42 conducting site of care reviews, in addition to their prior authorization reviews, when specific
43 advanced diagnostic imaging procedures are requested at an outpatient hospital setting (no
44 additional review is required if the test is to be performed at a freestanding diagnostic radiology
45 center or office setting).³⁴

IMPACT OF HEALTH CARE SHOPPING PROGRAMS

Objective Data

Despite the increasing popularity of FIPs, there is little objective evidence of their impact.³⁵ A working paper from the National Bureau of Economic Research highlights the crucial role of the referring physician. The study suggests that rather than focusing on patient cost-sharing, payers could more effectively help patients pursue lower-cost health care services by providing price information to physicians and incentivizing them to make cost-efficient referrals.³⁶ The study found that patients did not “shop” for care, even when the care at issue was a non-invasive MRI scan, when they were exposed to significant out-of-pocket costs, when they were provided ready access to a price transparency tool, and when they had the opportunity to reduce the price they would pay without traveling a long distance.³⁷ Instead, the study found that referring physicians influence where patients will receive further care far more than patient exposure to out-of-pocket costs, with referring physician influence accounting for 51 percent of variance, and out-of-pocket cost exposure accounting for 2.4 percent of the variance.³⁸ The data studied were comprised of insurance claims data provided by a large national insurer that covers tens of millions of lives annually and is active in all 50 states. However, the main analysis uses data from 2013. The study authors infer that given the weight patients ascribe to the advice of their referring physicians versus the influence of out-of-pocket cost in the context of a lower-limb MRI scan, patients are even less likely to actively price shop for more complex services. Supporting these conclusions, a 2016 analysis by the Health Care Cost Institute, which is funded in part by Aetna, Humana, Kaiser Permanente, and UHC, found only “modest” potential gains from the consumer price shopping aspect of price transparency efforts.³⁹

In another recent study, the Health Care Service Corporation (the fourth-largest health plan in the United States) collaborated with academic researchers to analyze the impact of the SmartShopper program.⁴⁰ Critically, this study did not examine any impacts on quality of care; rather, it was focused on financial impacts and changes in utilization. While the study identified some cost savings for employers and patients, the financial impact was limited.⁴¹ The study estimated a 5.2 percent reduction in annual spending on reward-eligible services, a savings of \$2.3 million per year, or approximately \$8 per patient per year. The study authors noted that, to receive a reward, patients may not be able to receive care from the provider their physician initially recommended, and patients may feel more comfortable seeking a second referral for imaging services, rather than invasive procedures. Moreover, switching providers is particularly complex for surgical procedures, and patients may be more concerned about quality of surgical services. Additionally, the study noted that the availability of lower priced providers may play a role in the results observed. The study authors suggested that the small reduction in utilization among patients in receipt of any reward eligible services could be due to patients using the price comparison tool, becoming aware of the still high out-of-pocket cost of reward eligible services, and choosing not to pursue care. The study concludes that while rewards programs are appealing to employers, they may not be the most effective way to reduce spending.

Another recent study specifically focused on quality of care variations that exist among sites of care providing MRIs.⁴² A first of its kind study analyzed MRI reports following complete lumbar MRI examinations of the same patient, performed at 10 different regional imaging centers, over a period of three weeks. All of the study centers had valid accreditation from the American College of Radiology. The study found “marked variability” in the reported interpretive findings and “an alarmingly high number” of interpretive errors in the MRI reports.⁴³ Specifically, no interpretive findings were reported in all 10 MRI reports, and only 1 finding (out of 49 total findings) was reported in 9 out of 10 reports. Moreover, the high average miss rate across the examinations

means that important pathologies are routinely under detected, and the high false positive rates for specific pathologies indicate that some diagnostic findings may be routinely over detected. These findings have clear and critical implications for appropriate diagnosis and treatment. Moreover, since payers heavily rely on MRI reports during utilization and authorization review processes, an inaccurate diagnosis on MRI can lead to significant delays in appropriate care.⁴⁴ In the context of incentive programs, knowing that such significant variation exists among equally accredited providers of a non-invasive imaging examination raises serious questions about the quality of care evaluations FIPs perform before making referral recommendations that may differ from the patient's treating clinician.

Data from Sapphire Digital

In contrast to the objective research studies that question the impact of patients shopping for lower-cost health care, Sapphire Digital claims its tools have achieved more significant cost savings across the continuum of care. As of 2018, Sapphire Digital claims that, over the course of four years, its program saved employers over \$56 million, and employers paid \$6.7 million in cash incentives to their employees.⁴⁵ Sapphire Digital stated that, on average, patients save \$606 per procedure shopped on SmartShopper. In 2016, Sapphire Digital published an analysis that extrapolated potential health care system wide savings of \$17.6 billion on colonoscopies alone.⁴⁶ Data provided by plans that have implemented SmartShopper can support Sapphire Digital's claims. For example, HealthTrust, a non-profit organization that provides insurance benefits to public employees and began using SmartShopper in 2014, saved \$1.5 million by the end of 2015, \$2.8 million by the end of 2016, and \$2.75 million in the first 10 months of 2017.⁴⁷ However, despite increases in engagement, as of 2018, only 10 percent of HealthTrust members regularly used SmartShopper.

AMA POLICY

FIPs relate to a wide variety of AMA policy. Policy H-450.941 expresses the AMA's uncompromising commitment to primacy of the patient-physician relationship free from intrusion from third parties. The policy specifically supports initiatives that protect patient access and that do not contain requirements that permit third party interference in the patient-physician relationship, and it strongly opposes attempts to steer patients towards certain physicians primarily based on cost of care factors. Policy H-450.947 sets forth extensive pay-for-performance principles and guidelines. Especially relevant elements of Policy H-450.947 include a focus on patient-centered, evidence-based care; allowances for variations in individual patient care based on a physician's clinical judgement; providing proactive explanations of programs to the patients impacted; and programs that do not create conditions that limit access to improved care or directly or indirectly disadvantage patients and their physicians based on geographic, ethnic, cultural, or socioeconomic groups, their medical conditions, or the setting where care is delivered.

AMA policy regarding drug pricing also informs discussion of FIPs. Policy H-110.997 supports programs that contain the rising costs of prescription drugs, with caveats to ensure that physicians have input into such programs, that all patients have access to all prescription drugs necessary to treat their illnesses, and that physicians have the freedom to prescribe the most appropriate drug(s) and method(s) of delivery for individual patients. Policy H-125.991 guides drug formularies and therapeutic interchange, discouraging switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen, while encouraging mechanisms such as incentive-based formularies.

1 AMA policies on the patient-centered medical home underscore the patient/physician relationship
2 as essential for maintaining continuity of care (Policies H-160.919 and H-160.918). In addition, the
3 Council notes the relevance of AMA Policy H-450.937 regarding medical tourism, which
4 advocates that employers, insurance companies, and other entities that facilitate or incentivize
5 medical care outside the US adhere to several principles, including that such incentives must be
6 voluntary and ensure continuity of care and necessary follow-up care.

7
8 AMA policy strongly supports value-based care. Policy H-110.986 provides principles to guide
9 value-based pricing programs for pharmaceuticals, including: (a) value-based prices of
10 pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of
11 pharmaceuticals should be evidence-based and be the result of valid and reliable data; (c) processes
12 to determine value-based prices of pharmaceuticals must be transparent, easily accessible to
13 physicians and patients, and provide practicing physicians and researchers a central and significant
14 role; and (d) value-based pricing of pharmaceuticals should allow for patient variation and
15 physician discretion. Policy H-155.960 supports value-based decision-making and recognizes the
16 role of physician leadership and importance of collaboration among physicians, patients, insurers,
17 employers, unions, and government in successful cost-containment and quality-improvement
18 initiatives. Policy D-185.979 supports value-based insurance design plans and encourages national
19 medical specialty societies to collaborate with payers to promote alignment of patient financial
20 incentives with utilization of high-value services. Policy H-185.935 guides use of reference pricing
21 and supports consideration of reference pricing strategies for elective services for which there is
22 evidence of a significant variation in cost that does not correspond to a variation in quality of care.

23 24 DISCUSSION

25
26 Patients, physicians, and health care payers alike benefit when it is possible to identify high-quality
27 health care that minimizes patient financial burden and ensures continuity of care. With payers
28 increasingly looking to FIPs as an avenue for reducing patient costs, it is essential that health care
29 quality not be sacrificed in the process, and that fragmentation of care is minimized. To protect
30 these and other critical elements of high-quality care, the Council recommends a set of guiding
31 principles for use in the development and implementation of FIPs.

32
33 Physicians are committed to providing and helping their patients obtain evidence-based, high-
34 quality, cost-effective care. Accordingly, patients will benefit if physicians are involved in the
35 development and implementation of patient incentives. Physicians should also be consulted by FIPs
36 to identify high-value referral options. FIP benefit information should be integrated into health care
37 information technology with real-time access to empower patients and physicians to make optimal
38 referral and prescription choices efficiently, reduce subsequent administrative burden, and promote
39 improved quality and cost of care.

40
41 FIPs must avoid adding to the fragmentation of patient care by informing referring and/or primary
42 care physicians when their patients have selected an FIP service and by providing a full record of
43 the service encounter. In addition, it is critical that patient care plans are first developed and
44 discussed between patients and their physicians. FIPs should make it clear that only the treating
45 physician can determine whether a lower-cost option is appropriate. Patients should be encouraged
46 to consult with their physicians prior to deviating from established patient care plans.

47
48 It is also essential that FIPs remind patients that they can choose their physician or facility,
49 consistent with their health plan benefits. FIPs should provide transparency regarding the quality
50 data they use in making referral recommendations so that patients and physicians can be confident
51 that lower-cost care meets their quality expectations. Similarly, FIPs should provide transparency

of their quality ratings of participating physicians and facilities and provide physicians with directions for appealing exclusion from lists of preferred lower-cost physicians. The Council also recommends that patients and physicians should have access to a process for publicly reporting unsatisfactory care with FIP options.

FIPs should provide meaningful transparency of both prices and vendors. Patients should fully understand any cost-sharing, other burdens or trade-offs, and incentives associated with receiving care from FIP-preferred physicians and facilities.

To further promote the ideals articulated in the principles, the Council recommends that health insurers that contract with FIPs should indemnify patients for any additional medical expenses that result as follow-up in cases where the FIP service is inadequate, such as a scan that is not useful to the referring physician. The insurer should cover the follow-up scan with no patient cost-sharing. The Council also recommends that state and medical associations and national medical specialty societies apply these principles and seek opportunities to collaborate in the design and implementation of FIPs to empower physicians and patients to make high-value referral choices and recommends objective studies of the impact of FIPs. With FIPs at the intersections of local health care and nation-wide large employer benefit plans, as well primary care referrals to specialists, the AMA and the Federation of Medicine have complementary roles to play in promoting optimal patient care.

Finally, given the lack of data on the impact of current FIPs, the Council recommends objective studies on various aspects of FIPs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the following continuity of care principles for any financial incentive program (FIP):
 - a) Collaborate with the physician community in the development and implementation of patient incentives.
 - b) Collaborate with the physician community to identify high-value referral options based on both quality and cost of care.
 - c) Provide treating physicians with access to patients' FIP benefits information in real-time during patient consultations, allowing patients and physicians to work together to select appropriate referral options.
 - d) Inform referring and/or primary care physicians when their patients have selected an FIP service prior to the provision of that service.
 - e) Provide referring and/or primary care physicians with the full record of the service encounter.
 - f) Never interfere with a patient-physician relationship (eg, by proactively suggesting health care items or services that may or may not become part of a future care plan).
 - g) Inform patients that only treating physicians can determine whether a lower-cost care option is medically appropriate in their case and encourage patients to consult with their physicians prior to making changes to established care plans. (New HOD Policy)

- 1 2. That our AMA support the following quality and cost principles for any FIP:
 - 2 a) Remind patients that they can receive care from the physician or facility of their choice
 - 3 consistent with their health plan benefits.
 - 4 b) Provide publicly available information regarding the metrics used to identify, and quality
 - 5 scores associated with, lower and higher-cost health care items, services, physicians and
 - 6 facilities.
 - 7 c) Provide patients and physicians with the quality scores associated with both lower and
 - 8 higher-cost physicians and facilities, as well as information regarding the methods used to
 - 9 determine quality scores.
 - 10 d) Respond within a reasonable timeframe to inquiries of whether the physician is among the
 - 11 preferred lower-cost physicians; the physician's quality scores and those of lower-cost
 - 12 physicians; and directions for how to appeal exclusion from lists of preferred lower-cost
 - 13 physicians.
 - 14 e) Provide a process through which patients and physicians can publicly report unsatisfactory
 - 15 care experiences with referred lower-cost physicians or facilities.
 - 16 f) Provide meaningful transparency of prices and vendors.
 - 17 g) Inform patients of the health plan cost-sharing and any financial incentives associated with
 - 18 receiving care from FIP-preferred, other in-network, and out-of-network physicians and
 - 19 facilities.
 - 20 h) Inform patients that pursuing lower-cost and/or incentivized care, including FIP incentives,
 - 21 may require them to undertake some burden, such as traveling to a lower-cost site of
 - 22 service or complying with a more complex dosing regimen for lower-cost prescription
 - 23 drugs. (New HOD Policy)
 - 24
- 25 3. That our AMA support requiring health insurers to indemnify patients for any additional
- 26 medical expenses resulting from needed services following inadequate FIP-recommended
- 27 services. (New HOD Policy)
- 28
- 29 4. That our AMA oppose FIPs that effectively limit patient choice by making alternatives other
- 30 than the FIP-preferred choice so expensive, onerous and inconvenient that patients effectively
- 31 must choose the FIP choice. (New HOD Policy)
- 32
- 33 5. That our AMA encourage state medical associations and national medical specialty societies to
- 34 apply these principles in seeking opportunities to collaborate in the design and implementation
- 35 of FIPs, with the goal of empowering physicians and patients to make high-value referral
- 36 choices. (New HOD Policy)
- 37
- 38 6. That our AMA encourage objective studies of the impact of FIPs that include data collection
- 39 on dimensions such as:
 - 40 a) Patient outcomes/the quality of care provided with shopped services;
 - 41 b) Patient utilization of shopped services;
 - 42 c) Patient satisfaction with care for shopped services;
 - 43 d) Patient choice of health care provider;
 - 44 e) Impact on physician administrative burden; and
 - 45 f) Overall/systemic impact on health care costs and care fragmentation. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-19

Subject: Improving Risk Adjustment in Alternative Payment Models

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

1 Medicare and other payers are shifting away from the fee-for-service (FFS) model toward
2 alternative payment models (APMs). A goal of APMs is to better deliver high quality care in a
3 cost-efficient manner to improve outcomes. APMs can eliminate barriers to care coordination that
4 are often present in traditional payment systems. For example, FFS generally does not support the
5 resources that would be required to take after-hours calls from patients to help them avoid
6 emergency visits; provide self-management education to help patients manage their conditions at
7 home; or conduct proactive outreach to ensure patients get needed preventive services.

8
9 Often, the complex FFS patient will have additional insurance claims filed for their additional
10 needed services. APMs that pay for services in a more aggregated way, such as a bundled payment
11 for an episode of care or a monthly payment for each patient, need to have a means of adjusting
12 payments to account for patients that need more services. Risk adjustment can serve as a tool to
13 make APM payments better reflect differences in patient characteristics and need for services.

14
15 It is important to note that risk adjustment is distinct from both the assumption of financial risk and
16 risk associated with professional liability. In an APM with downside financial risk, APM providers
17 may be accountable for providing care within a capped payment amount and need to either absorb
18 or repay spending in excess of that amount. Risk adjustment, the focus of this report, is a
19 mechanism for adjusting payment rates, budgets, or both, based on the health status and expected
20 spending on a patient population. Improved risk adjustment models will have positive spillover
21 effects in other areas of payment policy, importantly in the Merit-based Incentive Payment System
22 (MIPS), which adjusts FFS payments up or down according to performance in four categories.
23 Similar to APMs, MIPS scores should be risk adjusted to account for variations in patient
24 complexity, sociodemographic factors, and costs outside of the physician's control. As many small
25 and specialty practices will stay in MIPS, better risk adjustment is needed to avoid unfairly
26 penalizing those who care for the sickest and most vulnerable.

27
28 This report, initiated by the Council, provides background on risk adjustment; outlines refinement
29 strategies; summarizes relevant policy; details American Medical Association (AMA) work on
30 adjustment improvements; and presents policy recommendations to improve risk adjustment.

31 32 BACKGROUND

33
34 Risk is the process of modifying payments and benchmarks and allowing payers to estimate future
35 spending. Risk adjustment systems assign patients a risk score based on demographic factors and
36 health status. Demographic factors may include age, gender, dual eligibility for Medicare and
37 Medicaid (a proxy for socioeconomic status or disability), and whether the patient resides in the
38 community or in a health care facility. Patient health status is usually based on the diagnosis codes

submitted on claims in a calendar year. The importance of accurate risk adjustment is increasing as organizations such as Accountable Care Organizations (ACOs) and other APMs bear financial risk for managing a patient population as well as understanding the needs of individual patients and tailoring care delivery to each patient.

Despite the rising importance of risk adjustment, there are fundamental problems with current risk adjustment methodologies. Most risk adjustment systems only predict about 20-30 percent of the variation in services and spending across patients and are designed to predict spending on a large insured patient population, not adjust for differences in patient needs.¹ For example, risk adjustment that significantly weighs factors such as age and gender communicates a limited picture of the patient. Such simplistic design can reinforce inappropriate spending, penalize efforts to reduce overuse, and cause providers to focus spending reduction efforts on the wrong patients.² Additionally, the current risk adjustment methodologies do not adequately address treatment and outcome differences related to patient characteristics. They do not consider the complexity of a patient's disease nor social risk factors that are outside of the physician's control, such as lack of transportation or food insecurity. Basing risk scores solely on diagnosis, age and gender, for example, can lead to the same scores being assigned to patients who have drastically different needs. Poorly designed risk adjustment likely distorts comparisons of physician spending.

Moreover, most risk adjustment systems use historical information on patient characteristics and not the most current information. Many systems rely on ICD codes via retrospective review of claims data. Basing risk adjustment on prior claims data means that it accounts for the health conditions patients experienced in previous years but not for significant changes in the patient's health status or permanent conditions.³ Some risk adjustment methods do not account for a patient's disease stage, such as cancer or a patient's functional status, and they often do not account for factors that influence whether a patient is an appropriate candidate for a procedure or treatment. For instance, risk adjustment systems do not distinguish between patients with different cancer stage diagnoses nor do they account for how the patient's disease affects activities of daily living or whether they have a caregiver at home.

Importantly, most risk adjustment systems do not account for social determinants of health (SDOH). The link between non-medical factors and poor health outcomes is well documented; however, non-medical factors largely are absent from risk adjustment methods.⁴ To enhance fairness in performance assessment, some hospitals have implemented peer group methodology aimed at creating groups of similar hospitals for comparison purposes to account for hospitals that treat a significant number of patients with SDOH challenges. However, peer group comparisons do not take place at a more micro level, and risk adjustment methods are not sophisticated enough to reliably differentiate between poor quality of care and high medical and social risk. These methodological flaws have the unfortunate effect of inappropriately penalizing physicians who care for patients with SDOH challenges. Ultimately, not accounting for SDOH can make it harder for physicians caring for vulnerable patients to maintain a sustainable practice and therefore can reduce access to care for these populations exacerbating the challenge of getting vulnerable populations the care they need.

VARIOUS RISK ADJUSTMENT STRATEGIES

Risk Stratification

Risk stratification is the process of segmenting patients into groups of similar complexity and care needs.⁵ The first step in risk stratification is to identify high-risk patients. After stratifying patients into groups, practices can more easily make targeted care management decisions and identify those

1 patients that may have particular care needs. Consequently, the usefulness of stratification models
2 relies on data availability, which should encompass the patient's own assessment of his or her
3 health including SDOH. To date, most risk stratification models use a diagnosis-based formula and
4 do not include many SDOH that materially affect patient's health and ability to follow a particular
5 treatment plan.

6
7 One popular method of risk stratification is Medicare Advantage's (MA) Hierarchical Condition
8 Categories (HCC). Both MA plans and Medicare Shared Savings Program (MSSP) ACOs use the
9 HCC methodology,⁶ which relies on ICD-10 coding to assign risk scores derived from
10 retrospective claims data review. The algorithm takes into account demographic factors like age
11 and gender, and insurance companies use HCC coding to assign patients a risk adjustment factor
12 (RAF). In turn, insurers then use the RAF score to help portray patients' conditions and predict
13 future costs.⁷

14 15 *Outlier Payments or Individual Stop Loss Insurance*

16
17 Outlier payments are additional payments paid for by insurers to physicians or organizations to
18 account for encounters and patients that are exceptionally costly. Outlier payments function as a
19 form of stop-loss insurance. Stop-loss insurance protects the provider against significantly higher
20 than intended patient costs. This strategy is particularly useful when available for providers who
21 care for vulnerable populations. Because many SDOH are not yet included in risk stratification
22 systems and overall risk adjustment systems, the ability to access outlier payments after caring for
23 individuals with known high costs is critical for practice financial viability. The strategy also
24 ensures access to care and appropriate treatment for high-risk populations.

25 26 *Risk Corridors or Aggregate Stop Loss Insurance*

27
28 Risk corridors are another mechanism that can protect against adverse selection and insufficient
29 physician payments. Risk corridors function by limiting losses and gains beyond an allowable
30 range.⁸ Risk corridors set a target spending amount, and insurers pay into the program to
31 compensate those physicians with patient costs exceeding the target. Risk corridors mirror
32 aggregate stop loss insurance in that physicians are protected against higher than expected total
33 spending.

34 35 *Payment Adjustment for External Price Changes*

36
37 Adjustment for external price changes is an important protection for physicians operating in a
38 value-based payment delivery system. Under this mechanism, the physician payment is adjusted
39 for changes in the prices of drugs or services from other providers that are beyond the control of
40 the provider accepting the APM payment.⁹ Physicians must only be responsible for the services
41 that they deliver and cannot be held financially or otherwise accountable for spending outside of
42 their control. Payment adjustments protect physicians from spending costs outside of their control.

43 44 **AMA POLICY**

45
46 AMA policy promotes physician-led payment reform programs that serve as models for others
47 working to improve patient care and lower costs (Policy D-385.963). Policy H-390.844 emphasizes
48 the importance of physician leadership and accountability to deliver high quality and value to
49 patients. The AMA advocates for providing opportunities for physicians to determine payment
50 models that work best for their patients, their practices, and their regions (Policy H-390.844).

1 Policy D-390.953 directs the AMA to advocate with the Centers for Medicare & Medicaid Services
2 (CMS) and Congress for APMs developed with specialty and state medical societies.
3 With respect to risk adjustment, Policy H-165.842 states that health insurance coverage of high-risk
4 individuals should be subsidized through mechanisms such as risk adjustment. Policy H-395.908
5 states that the AMA will work with CMS and interested organizations to design systems that
6 identify new data sources to enable adequate analyses of clinical and non-clinical factors that
7 contribute to a patient's health and success of treatment, such as disease stage and SDOH factors. It
8 also calls to account for differences in patient needs, such as functional limitations, changes in
9 medical conditions compared to historical data, and ability to access health care services. Policy
10 H-395.908 further calls for the AMA to explore an approach in which physicians managing patient
11 care can contribute additional information, such as disease severity, that may not be available in
12 existing risk adjustment methods to more accurately determine the appropriate risk stratification.
13 Policy H-390.849 calls for adequate risk adjustment methodologies and encourages attribution
14 processes that emphasize voluntary agreements between patients and physicians. The policy also
15 states that reformed payment rates must be sufficient to maintain a sustainable medical practice and
16 that payment reform implementation should be undertaken within a reasonable timeframe and with
17 adequate assistance.

18 19 AMA ACTIVITY

20
21 Risk adjustment and risk stratification for APMs have been important components of AMA
22 advocacy on ACOs and other APMs. The AMA has long called for Medicare to allow ACO
23 patients' risk scores to increase over time if their health care needs warrant, and the 2018 Pathways
24 to Success ACO regulation finally permits such an increase for the first time since the program's
25 inception. The AMA also has discussed new approaches to risk stratification and risk adjustment in
26 physician-focused APMs at its APM workshops. AMA comments to the Physician-focused
27 Payment Model Technical Advisory Committee and the Center for Medicare and Medicaid
28 Innovation on proposed APMs have repeatedly urged improved approaches to risk adjustment and
29 urged Medicare to provide organizations developing APM proposals with claims and other data
30 analyses that they can use to improve their risk adjustment methods.

31
32 The AMA also is advocating for improvements to the risk adjustment methodologies in MIPS. For
33 instance, the AMA supports and is engaged in developing episode-based cost measures which
34 account for Medicare Parts A and B spending around a clinically cohesive set of medical services
35 rendered to treat a given medical condition. With AMA input, CMS has developed risk adjustment
36 methods for the episodes that account for patient characteristics that can influence spending outside
37 of the control of the clinician. These measures were first introduced in 2019, and more evidence
38 and testing are needed to determine the accuracy and validity of these measures and their
39 methodologies. In addition, the AMA has advocated for the elimination of the flawed total cost of
40 care measure, which holds physicians accountable for costs outside of their control.

41
42 The AMA continues to support the complex patient bonus in MIPS, which applies at the final score
43 to adjust for patient complexity. The complex patient bonus is based on the physician's attributed
44 beneficiaries' average HCC risk score and the proportion of dually eligible patients. This serves as
45 a proxy to capture the clinical complexity of the patient panels for a physician or practice.
46 However, this approach does not sufficiently identify patients with social risk factors that can affect
47 a patient's access to medications, treatments, and other services. While adjustment based on the
48 clinical complexity of the patients served through the complex patient bonus is a step toward
49 addressing disparities, CMS must continue to explore and incorporate additional risk factors and
50 strategies.
51

1 Additionally, the AMA's Integrated Health Model Initiative (IHMI) has developed a data model
2 related to the common data elements and terminologies for communicating SDOH. The AMA is
3 collaborating with the largest SDOH standards project in the health information technology
4 community, known as the Gravity Project hosted by the Social Interventions Research and
5 Evaluation Network at the University of California – San Francisco (SIREN).¹⁰ IHMI and
6 UnitedHealth Group (UHG) plan to jointly develop a set of use cases that leverage this common
7 data set and publish this use case via the Gravity project. Once the data are standardized and there
8 are sufficient data in the form of patient outcomes related to the standardized SDOH, data driven
9 predictive risk analyses can be formulated. At this point, SDOH risk calculation can be achieved
10 and is based on published research and limited and non-standardized data sets. The goal is to
11 ensure the industry-backed and accepted SDOH data set is complete and suitable for clinician
12 decision making to improve patient outcomes. Moreover, IHMI is working on the creation of 23
13 new ICD-10 codes related to SDOH such as access to nutritious food and the financial ability to
14 pay for medications.

15 DISCUSSION

16
17
18 Adverse selection of high-risk patients is an impediment to equitable patient care and successful
19 payment reform. Evidence confirms that factors such as functional impairment and socioeconomic
20 status are strongly associated with increased costs and hospital readmissions, and the exclusion of
21 such factors from risk adjustment systems negatively affects the financial viability of physicians
22 and organizations serving high-risk individuals. Thus, poorly designed risk adjustment systems are
23 a harm to vulnerable populations who may experience decreased access to care.¹¹ The Council
24 reiterates that this report is about risk adjustment, not the assumption of risk. However, it
25 recognizes that the two concepts are linked in that physicians must have better risk adjustment
26 methods available if they are to be expected to access risk arrangements.¹² The Council believes
27 that proper risk adjustment is essential if providers are to be held accountable for outcomes.

28
29 Throughout the transition to value-based care, the AMA has been vocal that physician
30 accountability must be limited to aspects of spending and quality that they can reasonably
31 influence. Accordingly, the Council recommends supporting payment adjustment for external price
32 changes that are beyond the physician's control and supporting accountability measures that
33 exclude services that the physician does not deliver, or order, or otherwise have the ability to
34 influence. The AMA also continues to advocate for reduced administrative burden, particularly that
35 related to electronic health records, and the Council reaffirms this commitment.

36
37 Additionally, a payment formula that relies solely on medical problems but ignores social risk and
38 functional status can have the effect of underpaying those who care for vulnerable populations and
39 exacerbate health disparities.¹³ Clinical coding must be coupled with risk adjustment systems, and
40 the two concepts must work in concert to find ways to distinguish between disease states and
41 functional status. Meaningful risk adjustment must allow for variance within existing general
42 diagnoses to capture characteristics specific to individual patients. To that end, the Council
43 recommends supporting risk stratification that varies payment rates based on patient characteristics,
44 including SDOH. Further, the Council recommends supporting outlier payments that increase
45 payment if spending on an individual exceeds a pre-defined threshold or supporting individual
46 stop-loss insurance paid by insurers. Similarly, the Council recommends supporting risk corridors
47 that increase payment if spending on all patients exceeds a pre-defined percentage above the
48 payments or supporting aggregate stop loss insurance. If physicians received extra payments for
49 caring for high-risk and vulnerable populations, these payments could help not only sustain
50 physician practices but also fund services that improve health equity.

Improving risk adjustment and its functions will become increasingly relevant to the viability of practices and the overall health care system. Thorough and accurate risk adjustment not only helps physicians garner the appropriate payment to support practice sustainability, but also helps physicians become more successful in managing their patients. The Council believes that the goal of proper risk adjustment and delivery system reform is tailored interventions and better patient outcomes, and it believes that its recommendations are a step in the right direction. The Council will continue to monitor the rapidly evolving area of risk adjustment methodologies.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-385.908 stating that the AMA will work with the Centers for Medicare & Medicaid Services and interested organizations to design systems that identify data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as disease stage and socio-demographic factors; account for differences in patient needs, such as functional limitations, changes in medical conditions, and ability to access health care services; and explore an approach in which the physician managing a patient's care can contribute additional information, such as disease severity, that may not be available in existing risk adjustment methods to more accurately determine the appropriate risk stratification. (Reaffirm HOD Policy)
2. That our AMA reaffirm Policy D-478.995 advocating for appropriate, effective, and less burdensome documentation requirements in the use of electronic health records so that capturing patient characteristics and risk adjustment measures do not add to physician and practice administrative burden. (Reaffirm HOD Policy)
3. That our AMA support risk stratification systems that use fair and accurate payments based on patient characteristics, including socioeconomic factors, and the treatment that would be expected to result in the need for more services or increase the risk of complications. (New HOD Policy)
4. That our AMA support risk adjustment systems that use fair and accurate outlier payments if spending on an individual patient exceeds a pre-defined threshold or individual stop loss insurance at the insurer's cost. (New HOD Policy)
5. That our AMA support risk adjustment systems that use risk corridors that use fair and accurate payment if spending on all patients exceeds a pre-defined percentage above the payments or support aggregate stop loss insurance at the insurer's cost. (New HOD Policy)
6. That our AMA support risk adjustment systems that use fair and accurate payments for external price changes beyond the physician's control. (New HOD Policy)
7. That our AMA support accountability measures that exclude from risk adjustment methodologies any services that the physician does not deliver, order, or otherwise have the ability to influence. (New HOD Policy)

Fiscal Note: Less than \$500

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REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-19)
Mechanisms to Address High and Escalating Pharmaceutical Prices
(Reference Committee J)

EXECUTIVE SUMMARY

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and concluded that additional policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for pharmaceuticals.

The Council has long prioritized the importance of competition and transparency in the pharmaceutical marketplace, but recognizes that there are multiple situations in which payers have weakened bargaining power, due to lack of competition for some drugs. In addition, there is often limited recourse following an unjustifiable price hike of a prescription medication, leaving patients questioning whether they will be able to continue to afford their medication. As such, the Council recommends policies to promote reasonable pricing behavior in the pharmaceutical marketplace, as an alternative to price controls.

First, the Council recommends principles to guide the use of arbitration in determining the price of prescription drugs, which build upon existing policy in favor of drug price negotiation, and opposed to price controls. Arbitration should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases. Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability. Importantly, arbitration provides an incentive for drug manufacturers and payers to arrive at a negotiated price.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that upholds market-based principles and preserves patient access to necessary medications.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-19

Subject: Mechanisms to Address High and Escalating Pharmaceutical Prices

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, determining whether additional policy was needed to guide future AMA advocacy efforts. In its review, the Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for pharmaceuticals.

This report provides background on the impacts of high and escalating prescription drug prices and costs; outlines emerging approaches to address pharmaceutical pricing; and presents policy recommendations.

THE IMPACTS OF HIGH AND ESCALATING PRESCRIPTION DRUG PRICES AND COSTS

Retail prescription drugs account for 10 percent of total health spending,¹ with estimates suggesting that spending on prescription drugs is closer to 15 percent of total health spending when other factors, including the non-retail drug markets and gross profits of other stakeholders involved in drug distribution, payment, and reimbursement are included.² Of significance, spending on specialty drugs is approaching one-half of drug spending.³ The most recent National Health Expenditure projections showed that retail prescription drug spending was estimated to have increased by 3.3 percent to \$344.5 billion in 2018, with a 4.6 percent increase in spending expected in 2019. Drivers behind the rate of growth in prescription drug spending include a higher number of new drug introductions, increased utilization of prescription drugs, and an increase in drug price growth. The projected annual growth in prescription drug spending is expected to average 6.1 percent from 2020 through 2027. Contributions to future growth in spending in the prescription drug sector include increased prescription drug utilization resulting from employer and insurer efforts to remove barriers associated with medications for chronic conditions; expected market release of more expensive drugs for conditions including cancer, diabetes, and Alzheimer's disease; the aging of the population; and modifications to pharmacotherapy guidelines.⁴

Approximately 5.8 billion prescriptions were dispensed in the US in 2018, 90 percent of which were dispensed as generics. The retail price differentials between specialty, brand-name and generic drugs are noteworthy. Examining the retail prices of drugs widely used by older Americans, in 2017 the average annual retail price of therapy for specialty drugs was \$78,781, dropping to \$6,798 for brand-name drugs, and \$365 for generics.⁵ Overall, the list price of the

1 average brand drug was \$657.08 for a 30-day prescription in 2018, a noteworthy increase from
 2 \$364.92 in 2014. The average prices of brand-name drugs at pharmacies before coupons and
 3 discounts are applied were \$229 lower than list prices in 2018 for a 30-day prescription.⁶ Average
 4 generic pharmacy prices for a 30-day prescription were relatively stable from 2014 to 2018,
 5 increasing to \$19.10 from \$18.50.⁷

6
 7 Health plans, payers, employers, physicians and patients are facing the increasing financial burden
 8 posed by prescription drugs, both brand and generic. In the Medicare program, between 2007 and
 9 2017, Part D program spending has seen an annual growth rate of 5.6 percent, and amounted to
 10 \$79.9 billion in 2017. Premiums paid by Part D enrollees for basic benefits (not including low-
 11 income subsidy enrollees) amounted to \$14 billion in 2017, which has increased by 13 percent on
 12 average annually since 2007. High-cost enrollees are a primary contributor to Part D spending
 13 growth, with the associated spending growth for high-cost enrollees resulting from higher drug
 14 prices.⁸ Under Medicare Part B, drug spending has increased on average by 9.6 percent annually
 15 between 2009 and 2017, with the largest driver of this growth in spending being price growth – a
 16 combination of increasing prices for existing drugs as well as the introduction of new high-cost
 17 drugs in the market. In 2017, \$18 billion of total Part B spending was for drugs administered in
 18 physician offices, approximately \$12.3 billion was for drugs administered in hospital outpatient
 19 departments, and \$1.8 billion was for drugs provided by suppliers.⁹

20
 21 Rising and high prescription drug prices are impacting Medicaid budgets and state budgets overall.
 22 Under the Medicaid drug benefit, drug manufacturers pay rebates to states in return for Medicaid
 23 reimbursement for their prescription drugs. Drug manufacturers are required to pay an additional
 24 rebate amount if the average manufacturer price (AMP) for a drug rises faster than inflation. From
 25 2014 to 2017, Medicaid outpatient prescription drug spending before rebates increased from \$45.9
 26 billion to \$63.6 billion.¹⁰ The \$34.9 billion collected in rebates brought net Medicaid spending on
 27 prescription drugs down significantly in fiscal year (FY) 2017. The proportion of spending geared
 28 to brand-name versus generic drugs in Medicaid increased – from 76.6 percent in FY 2014 to 80.5
 29 percent in FY 2017. This growth resulted from an increase in average spending per claim for brand
 30 drugs – from \$294 per claim in FY 2014 to \$411 per claim in FY 2017. Of note, the share of
 31 spending on specialty drugs has significantly increased in Medicaid – accounting for approximately
 32 44 percent of spending in FY 2017.¹¹

33
 34 Employer-sponsored health plans as well as health plans sold in the individual market have also
 35 had to absorb the higher costs of prescription drugs, which often translate to higher premiums,
 36 higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the
 37 higher costs of specialty and certain generic drugs. In 2018, 88 percent of employees were enrolled
 38 in plans with three, four or more cost-sharing tiers for prescription drugs.¹² This year, almost all
 39 standalone Medicare Part D plans have a benefit design with five tiers for generic and brand-name
 40 drugs and cost-sharing that deviates from the standard 25 percent coinsurance for all covered drugs
 41 between the deductible and the initial coverage limit.¹³

42
 43 The higher costs of prescription drugs are in part passed down to health plan enrollees, and impact
 44 physician practices. Ultimately, prescription drug costs can impact the ability of physicians to place
 45 their patients on the best treatment regimen, due to the regimen being unaffordable for the patient,
 46 or being subject to coverage limitations and restrictions, as well as utilization management
 47 requirements, by the patient's health plan. In the worst-case scenario, patients entirely forgo
 48 necessary treatments involving drugs and biologics due to their high cost.

49
 50 In 2018, overall out-of-pocket costs for prescription drugs reached \$61 billion, an increase from
 51 \$56 billion in 2014. Across Medicare, Medicaid and commercial health plans, 8.8 percent of

1 patients pay more than \$500 per year out-of-pocket for prescriptions. Medicare beneficiaries have a
2 notably higher incidence rate of high out-of-pocket expenses for prescription drugs, with almost 20
3 percent paying more than \$500 out-of-pocket.¹⁴ Nonpreferred generic tiers in many cases have
4 higher copayments than patients have become accustomed to for generic medications. In addition,
5 plans with specialty drug cost-sharing tiers often require coinsurance amounts of 25 to 50 percent,
6 versus requiring a fixed copayment. Considering the costs of many specialty medications, patients
7 could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of
8 specialty drugs in Medicare could cause the number of Part D enrollees who reach the catastrophic
9 coverage threshold to grow substantially, resulting in increases in Medicare spending to plans for
10 reinsurance.

11
12 Increasing patient cost-sharing is associated with declines in medication adherence, which in turn
13 can lead to poorer health outcomes. Among those currently taking prescription drugs,
14 approximately a quarter of adults and seniors have reported difficulties in affording their
15 prescription drugs. Approximately 30 percent of all adults have reported not taking their
16 medications as prescribed at some point in the past year due to cost. Drilling down further, 19
17 percent of adults have not filled a prescription in the past year due to cost, 18 percent chose to take
18 an over-the-counter medication instead, and 12 percent cut pills in half or skipped doses. Of
19 significance, almost 10 percent of all adults reported that their condition worsened from not taking
20 their medication as prescribed.¹⁵

21
22 Notably, out-of-pocket costs for prescription drugs are linked to the rate at which patients newly
23 prescribed a drug either do not pick up their prescription or switch to another product. The rate at
24 which such patients, enrolled in either Medicare or a commercial health plan, abandon their
25 prescription increases significantly once out-of-pocket costs reach \$50. At this point, 31.2 percent
26 of commercially insured patients and 27.6 percent of Medicare patients abandon their
27 prescriptions.¹⁶

28
29 High prescription drug costs, and any declines in medication adherence that may result, can also
30 impact physicians participating in alternative payment models (APMs). For example, Part B drug
31 costs are included in calculations of APM financial risk, even though physicians cannot influence
32 or control drug prices. In addition, physicians in APMs can be affected if poor medication
33 adherence leads to complications or exacerbations that in turn lead to emergency department visits
34 and/or hospital admissions.

35 36 EMERGING APPROACHES TO ADDRESS HIGH AND ESCALATING DRUG PRICES

37
38 Escalating and increasingly unaffordable drug prices have caused the Administration, members of
39 Congress and policy experts to put forward innovative proposals to put downward pressure on
40 prices, or more closely tie a drug's price to its value. Whereas proposals that would allow for
41 binding arbitration and contingent exclusivity periods could build upon existing market-based
42 approaches to address pharmaceutical prices and costs, caution would have to be exercised in
43 implementing proposals that leverage international price indices, so as to not merely import
44 international price controls into the US.

45 46 *Utilizing Binding Arbitration*

47
48 An emerging policy option that has been put forward to address high and escalating drug prices is
49 using binding arbitration in the event of failed drug price negotiations in order to settle on the final
50 price of the drug. Supporters argue that binding arbitration has the potential to build upon the
51 negotiations that currently take place along the pharmaceutical supply chain that determine

coverage of and payment for prescription drugs. In the US, binding arbitration is currently used in public-sector labor-management negotiations, and Major League Baseball uses the approach in the event of failed negotiations for baseball players' salaries. While negotiated prices between the pharmaceutical company and the payer/government entity in question would remain the preferred solution, arbitration has the potential to help equalize the bargaining power of both parties of the negotiation, while incentivizing negotiating parties to negotiate in good faith. If negotiations fail to conclude with a price agreeable to both parties, they could submit to final offer arbitration or conventional arbitration.

In final offer arbitration, the arbitrator would be given final bids by the drug manufacturer and the payer/government entity in question. Such bids would be accompanied by data justifying the price put forward by each party, and there would be potential for an independent third party to offer a third price, which can be informed by value-based price benchmarks, comparative effectiveness research, and cost-effectiveness analysis. The arbitrator under final offer arbitration would be required to choose one of three prices: 1) the bid of the drug manufacturer; 2) the bid of the payer/government entity; or 3) the price submitted by the independent third party, if applicable. Alternatively, under conventional arbitration, the arbitrator would not be tied to any of the bids or options put forward; they could select any price they believe is fair.¹⁷

Case Study: Germany

Germany uses arbitration as one potential pathway to determine the price of a drug in the German market. After a drug is approved by the European Medicines Agency, allowing for the drug to be sold in Germany, a drug manufacturer unilaterally sets the drug's price, applicable for 12 months. At the same time, the manufacturer also is required to submit a report outlining the benefits of the drug to the Federal Joint Committee, comprised of physicians, dentists, hospitals, and health insurers (sickness funds). The Federal Joint Committee forwards the report to the non-governmental Institute for Quality and Efficiency in Health Care (IQWiG), which conducts an assessment of the clinical effectiveness and benefits of the new drug compared with one or more comparator therapies. After the IQWiG submits its finding, the Federal Joint Committee issues a final decision regarding the level of benefit of the new drug relative to existing therapies that treat the condition in question. Such benefits can include prolonged life expectancy, reduction in side effects, health status improvement, shortening of disease duration and quality of life improvement. A drug is then assigned one of six benefit ratings:

1. Major added benefit
2. Considerable added benefit
3. Minor added benefit
4. Nonquantifiable added benefit
5. No evidence of added benefit
6. Lower benefit than comparator(s)

Depending on a drug's benefit rating, and whether there is a reference group to guide a reference price of a drug, a drug manufacturer can either enter into negotiations with Germany's sickness funds (health insurers), or be assigned to a therapeutic class subject to reference pricing – pricing based on other drugs in the same therapeutic class, including generics. Drugs that enter into negotiations have six months from the Federal Joint Committee decision to agree to a price. If they cannot agree on a price, an arbitration panel is required to set a price within three months, which is binding for the following year. Either party can challenge the decision, which would then trigger IQWiG conducting a cost-benefit analysis. In addition, new findings can serve as cause for the parties to revisit an agreement or arbitration decision after one year.^{18,19,20}

Relevant AMA Policy

Policy D-330.954 supports federal legislation which gives the Secretary of Health and Human Services (HHS) the authority to negotiate contracts with manufacturers of covered Part D drugs; and states that the AMA will work toward eliminating Medicare prohibition on drug price negotiation and prioritize its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS. Policy H-155.962 states that our AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.

Policy H-110.986 supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion. Policy H-110.986 also supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. Policy H-460.909 outlines principles for creating a centralized comparative effectiveness research entity.

Leveraging an International Pricing Index

Recent proposals put forward by the Administration and members of Congress attempt to lower US drug costs by tying them to international prices, and/or would use an average of international prices, or an international reference price, to help define whether a price of a drug is excessive. In October of 2018, the Administration released an Advance Notice of Proposed Rulemaking (ANPRM) for a proposal entitled “International Pricing Index Model for Part B Drugs.” The ANPRM did not represent a formal proposal, but outlined the Administration’s current thinking and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. At the time that this report was written, a proposed rule on the international pricing index model was expected to be released, which has the potential to differ markedly from what was outlined in the ANPRM.

The ANPRM outlined a new payment model for physician-administered drugs paid under Medicare Part B that will transition Medicare payment rates for certain Part B drugs to lower rates that are tied to international reference prices – referred to as the “international pricing index” – except where the average sales price (ASP) is lower. The international reference price would partly be based on an average of prices paid by other countries. To accomplish this, the proposal would create a mandatory demonstration through the Centers for Medicare & Medicaid Innovation (CMMI), which would apply to certain randomly selected geographic areas, representing approximately 50 percent of Medicare Part B drug spending. Initially, the program would apply only to sole-source drug products and some biologics for which there is robust international pricing data available.

1 In geographic areas included in the demonstration, CMS would contract with private-sector
2 vendors that will negotiate for, purchase, and supply providers with drug products that are included
3 in the demonstration. CMS would directly reimburse the vendor for the included drugs, starting
4 with an amount that is more heavily weighted toward the ASP instead of the international pricing
5 index, and transitioning toward a target price that is heavily based on the international pricing
6 index. Providers would select vendors from which to receive included drugs, but would not be
7 responsible for buying from and billing Medicare for the drug product.

8
9 An alternative international drug price index has been put forward, which differs from that
10 introduced in the ANPRM: the Market-Based International Index (MBII). Unlike the international
11 price index included in the ANPRM, the MBII excludes developed countries with single-payer
12 health systems that use price controls. Therefore, unlike the index provided for the ANPRM, the
13 MBII does not include Canada, Finland, Greece, Italy, Spain, Sweden and the United Kingdom.
14 The MBII benchmark has two tiers. The first tier represents 60 percent of the benchmark, and
15 includes the Netherlands, Singapore and Switzerland – countries with truly market-based health
16 systems – as well as Denmark, which does not regulate drug prices. The second tier, which
17 constitutes 40 percent of the benchmark, includes Austria, Belgium, the Czech Republic, France,
18 Germany, Ireland, Japan, Portugal, and Slovakia – countries that have a mix of private and public
19 health insurance.²¹

20
21 Legislation has also been introduced in Congress that would use international drug prices to
22 determine whether a drug's price is excessive, trigger additional interventions, and serve as an
23 upper limit in drug price negotiations. Senator Bernie Sanders (I-VT) and Representative Ro
24 Khanna (D-CA) have introduced S 102/HR 465, the Prescription Drug Price Relief Act of 2019.
25 Notably, under the bill, the price of a prescription drug would be considered "excessive" if the
26 domestic average manufacturing price exceeds the median price for the drug in Canada, the United
27 Kingdom, Germany, France, and Japan. Even if a drug's price does not meet this criterion, or if
28 pricing information is unavailable in at least three of the five countries, a drug's price could still be
29 considered excessive if it is higher than reasonable in light of factors outlined in the legislation,
30 including cost, revenue, and the size of the affected patient population. If brand-name drugs are
31 found to be excessively priced, the drug would be included on a public excessive price database.
32 Open, nonexclusive licenses would be issued for the drug; and review of corresponding
33 applications for generic drugs and biosimilar biological products would be expedited to facilitate
34 competition as well as the entry of lower-cost options into the marketplace.^{22,23}

35
36 In addition, Congressman Frank Pallone (D-NJ) has introduced HR 3, the Lower Drug Costs Now
37 Act of 2019. The legislation would incorporate an international price average as part of authorizing
38 the Secretary of HHS to negotiate drug prices, limited to drugs that lack competition and have the
39 greatest financial impact to the Medicare program and the US health system as a whole, as well as
40 insulin. The Secretary of HHS would directly negotiate with drug manufacturers to establish a
41 maximum fair price for drugs selected for negotiation, which would be applied to Medicare, with
42 flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate
43 even lower prices. In addition, the drug manufacturer would be required to offer the negotiated
44 price to private group and individual health insurance plans. An "average international market
45 price" would be established to serve as an upper limit for the price reached in any negotiation, if
46 practicable for the drug at hand, defined as no more than 120 percent of the drug's volume-
47 weighted net average price in six countries – Australia, Canada, France, Germany, Japan and the
48 United Kingdom. There would be a financial penalty if a pharmaceutical manufacturer does not
49 participate in or comply with the negotiations.

50

Relevant AMA Policy and Advocacy

Pursuant to AMA Policy, the AMA submitted comments in response to the “International Pricing Index Model for Part B Drugs” in December 2018. Policy H-155.962 opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. Policy H-110.983 advocates that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- it must be genuinely voluntary and not penalize practices that choose not to participate;
- it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
- it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate health care inflation rate;
- it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of (CAP)-acquired drugs at multiple office locations;
- it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Tying Pharmaceutical Pricing to Market Exclusivity

Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the US, or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for Food & Drug Administration (FDA) review and meet the statutory requirements. Biologic manufacturers have 12 years of exclusivity for innovator (brand-name) products. Innovator biologics also have additional patent protection that generally exceeds exclusivity period by a few years.²⁴

Exclusivity periods for pharmaceuticals are not tied to the list price at which they enter the market, nor to the rate at which they increase in price from year to year. The Council notes that two potential options have been proposed to more closely tie drug market exclusivity to pricing behavior. First, a policy strategy has been put forward to implement contingent exclusivity periods for new brand drugs. Under this policy option, drug manufacturers with a newly approved drug would be able to set their list price at whatever they wish, but the length of the exclusivity period would depend on whether their list price is reasonable, ie, if it aligns with the drug’s value. Multiple options could be utilized to assess a drug’s value, including cost per quality-adjusted life

year (QALY), or a value-based price benchmark. Contingent exclusivity periods, therefore, could potentially lengthen the exclusivity period for drugs with lower cost per QALY, and reduce the exclusivity period for drugs priced too highly to align with their value. For example, in the case of an innovator biologic, a biologic with a low cost per QALY could see its exclusivity period extended to 15 years from 12 years, whereas a biologic priced too high relative to its value could have its exclusivity period set to 7 years.²⁵

Second, Senator Richard Durbin (D-IL) and Representative Jared Golden (D-ME) introduced S 366/HR 1188, the Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act, which would shorten (but not automatically void) the Food, Drug, and Cosmetic Act market exclusivity period for prescription drugs that experience sudden increases in price. Under the FLAT Prices Act, an increase of the wholesale acquisition cost of a prescription drug of more than 10 percent over a one-year period, more than 18 percent over a 2-year period, or more than 25 percent over a three-year period would result in a reduction of market exclusivity of 180 days. For every five percent increase over these thresholds, the market exclusivity would be reduced an additional 30 days. Manufacturers would be required to report such price increase within 30 days of meeting the criteria for a price increase. Failure to report within the allotted time would result in 30 days of reduced exclusivity daily until the report is submitted. The Secretary of HHS would have discretion to grant a waiver to a manufacturer if the Secretary determines that the price increase is justified and does not unduly restrict patient access to the drug or impact public health.^{26,27}

Relevant AMA Policy

Policy H-110.987 supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations. The policy also supports drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase; legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment. In addition, it advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase. Finally, it states that our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.

Policy H-110.986 supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help

1 assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based
2 pricing of pharmaceuticals should allow for patient variation and physician discretion.

3
4 Policy H-110.986 also supports the inclusion of the cost of alternatives and cost-effectiveness
5 analysis in comparative effectiveness research. Finally, it supports direct purchasing of
6 pharmaceuticals used to treat or cure diseases that pose unique public health threats, including
7 Hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

8 9 DISCUSSION

10
11 Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have
12 imposed on patients, on physician practices, and the broader health care system. Patients delay,
13 forgo, or ration their medication when treatments are cost-prohibitive, putting their health at risk.
14 At a time of significantly increasing drug prices, and the launch of products with high list prices,
15 the Council believes that more needs to be done to improve access to and lower the costs of
16 prescription drugs, without stifling innovation.

17
18 The Council has long prioritized the importance of competition and transparency in the
19 pharmaceutical marketplace, and believes that negotiation of drug prices between drug
20 manufacturers and payers should continue to be the preferred mechanism to determine how drugs
21 are covered and paid for. That being said, the Council recognizes that there are multiple situations
22 in which payers have weakened bargaining power, due to a drug's lack of competition in the
23 marketplace. In addition, there is often limited recourse following an unjustifiable price hike of a
24 prescription medication, leaving patients questioning whether they will be able continue to afford
25 their medication. As such, the Council recommends policies to promote reasonable pricing
26 behavior in the pharmaceutical marketplace, as an alternative to price controls.

27
28 First, the Council recommends principles to guide the use of arbitration in determining the price of
29 prescription drugs, which build upon existing policy in favor of drug price negotiation, and
30 opposed to price controls. Of note, arbitration can serve a role in many circumstances, from
31 negotiating drug prices in Medicare Part D, to any negotiations that take place following a drug
32 product's market entry, as executed in Germany. The Council believes that arbitration should be
33 used for pharmaceuticals that have insufficient competition; have high list prices; or have
34 experienced unjustifiable price increases. Using arbitration will help rebalance the importance of
35 prescription drug affordability with the need for innovation, as an alternative to the status quo,
36 which allows unilateral price setting of drugs by manufacturers without regard to patient access and
37 affordability. Importantly, arbitration provides an incentive for drug manufacturers and
38 payers/government entities to arrive at a negotiated price.

39
40 To ensure that there is a pathway to use arbitration in Medicare Part D, the Council recommends
41 the reaffirmation of Policy D-330.954, which supports removing the current prohibition that
42 restricts the Secretary of HHS from being able to negotiate drug prices in Part D. In whatever
43 setting arbitration for drug prices is used, the Council underscores that the process should be
44 overseen by objective, independent entities, which would have the authority to select neutral
45 arbitrators or an arbitration panel, with strong conflict-of-interest protections built in.

46
47 The Council believes that as part of the arbitration process, and to guide the results, the use of
48 comparative effectiveness research and cost-effectiveness analysis will be critical. Related, the
49 arbitration process should include the submission of a value-based price benchmark for the drug in
50 question to inform the arbitrator's decision, pursuant to Policy H-110.986.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug product to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that uphold market-based principles and preserve patient access to necessary medications. In addition, the Council recommends reaffirmation of Policy H-110.983 outlining standards for any revised Medicare Part B Competitive Acquisition Program, which is relevant considering recent proposals to incorporate an international pricing index in Medicare Part B.

The Council believes that the recommendations of this report add to the already large body of AMA policies that address the high cost of prescription medications, which guide AMA advocacy efforts to improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. Pursuant to these policies, the AMA supports: (1) requiring manufacturer and pharmaceutical supply chain transparency; (2) increasing competition and curtailing anti-competitive practices; (3) ensuring prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow including in the electronic health record; and (4) streamlining and modernizing the utilization control methods used by health insurers in response to higher prescription drug costs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
 - a. The arbitration process should be overseen by objective, independent entities;
 - b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;
 - 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 cost-effectiveness analysis addressing the drug in question;
 - e. The arbitration process should include the submission of a value-based price benchmark for the drug in question to inform the arbitrator's decision;
 - f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer/government entity;
 - g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases; and

- 1 h. The arbitration process should include a mechanism for either party to appeal the
2 arbitrator's decision. (New HOD Policy)
3
- 4 2. That our AMA advocate that any use of international price indices and averages in determining
5 the price of and payment for drugs should abide by the following principles:
6
 - 7 a. Any international drug price index or average should exclude countries that have single-
8 payer health systems and use price controls;
 - 9 b. Any international drug price index or average should not be used to determine or set a
10 drug's price, or determine whether a drug's price is excessive, in isolation;
 - 11 c. The use of any international drug price index or average should preserve patient access to
12 necessary medications; and
 - 13 d. The use of any international drug price index or average should limit burdens on physician
14 practices. (New HOD Policy)
15
- 16 3. That our AMA support the use of contingent exclusivity periods for pharmaceuticals, which
17 would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its
18 list price at the time of market introduction. (New HOD Policy)
19
- 20 4. That our AMA reaffirm Policy H-110.983, which advocates that any revised Medicare Part B
21 Competitive Acquisition Program meet certain outlined standards to improve the value of the
22 program by lowering the cost of drugs without undermining quality of care. (Reaffirm HOD
23 Policy)
24
- 25 5. That our AMA reaffirm Policy H-110.986, which outlines principles for value-based pricing
26 programs, initiatives and mechanisms for pharmaceuticals, and supports the inclusion of the
27 cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
28 (Reaffirm HOD Policy)
29
- 30 6. That our AMA reaffirm Policy H-460.909, which outlines principles for creating a centralized
31 comparative effectiveness research entity. (Reaffirm HOD Policy)
32
- 33 7. That our AMA reaffirm Policy D-330.954, which states that our AMA will work toward
34 eliminating Medicare prohibition on drug price negotiation. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-19)

Introduced by: Medical Student Section

Subject: Reimbursement for Post-Exposure Protocol for Needlestick Injuries

Referred to: Reference Committee J

Whereas, Needlestick injuries (NSI) occur in a clinical setting and introduce the risk of transmitting bloodborne pathogens such as Hepatitis B, Hepatitis C, and HIV¹; and

Whereas, The Centers for Disease Control and Prevention (CDC) estimates that about 385,000 sharps-related injuries occur annually among health care workers with medical students also at risk of sustaining NSIs^{2,3}; and

Whereas, Due to the risk of contracting aforementioned bloodborne pathogens, the protocol for NSIs is to receive the appropriate post-exposure prophylaxis (PEP) as a means of disease prevention with appropriate diagnostic follow up^{2,3}; and

Whereas, According to recommendations from the International Antiviral Society, the protocol for PEP of HIV specifically for health care workers includes at least 4 weeks of three antiretroviral drug regimen with appropriate laboratory and clinical follow up³; and

Whereas, A systematic review that analyzed the costs associated with NSIs among healthcare workers found these costs to range from \$650 to \$750, while also noting extraneous factors, such as time lost at work, that led to variations in costs⁴; and

Whereas, The review also noted that frequent changes in the indicated antiretroviral therapy further leads to a greater variation and increase in costs, with an approximated median cost of \$1,187⁴; and

Whereas, A cost analysis published by the Kaiser Family Foundation indicated that since 2014, the prices of branded common and specialty drugs have risen by 60% and 57%, respectively⁵; and

Whereas, In addition to presenting a significant financial implication, aforementioned processes related to PEP potentially create a severe emotional burden on those who sustain such an injury^{1,2,4}; and

Whereas, Many NSIs often go unreported, with studies citing the fear of punishment, the financial costs, and the “time consuming process” as a major factor for not immediately reporting an injury^{2,6-8}; and

Whereas, Health care workers that sustain NSI are required to undergo appropriate protocol for exposure, of which all related costs are financially covered under their employer’s workers’ compensation program⁹; and

Whereas, While these programs vary by state, medical students are often exempt from the mandatory coverage of workers' compensation that their institution offer to health care workers since they are not considered employees¹⁰; and

Whereas, As an exception to this, the state of Utah amended policy 53B-14-401 to include medical students within its definition of "interns" stating that interns can become recipients of medical benefits from workers' compensation in the event of occupational injuries and diseases¹¹; and

Whereas, Although a majority of medical schools require medical students to have a form of health insurance prior to matriculation, the comprehensive costs associated with NSIs are not explicitly stated, and insurance providers inconsistently provide complete coverage of these costs⁴; and

Whereas, Existing AMA policy addresses the costs and debts associated with undergraduate medical education (H-305.925); therefore be it

RESOLVED, That our American Medical Association encourage medical schools to ensure medical students can be reimbursed for the costs associated with post-exposure protocol for blood or body substance exposure sustained during clinical rotations either by their insurance provider or the state's workers' compensation fund, where applicable (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage state societies to work with their respective workers' compensation fund to include medical students as recipients of medical benefits in the event of blood or body substance exposure during clinical rotations. (Directive to Take Action)

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

Received: 08/28/19

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RELEVANT AMA POLICY

Insurance Coverage for Medical Students and Resident Physicians H-295.942

1. Our AMA urges all medical schools to pay for or offer affordable policy options and, assuming the rates are appropriate, require enrollment in disability insurance plans by all medical students;

2. Our AMA urges all residency programs to pay for or offer affordable policy options for disability insurance, and strongly encourage the enrollment of all residents in such plans;
 3. Our AMA urges medical schools and residency training programs to pay for or offer comprehensive and affordable health insurance coverage, including but not limited to medical, dental, and vision care, to medical students and residents which provides no less than the minimum benefits currently recommended by the AMA for employer-provided health insurance and to require enrollment in such insurance.
 4. Our AMA urge carriers offering disability insurance to: (a) offer a range of disability policies for medical students and residents that provide sufficient monthly disability benefits to defray any educational loan repayments, other living expenses, and an amount sufficient to continue payment for health insurance providing the minimum benefits recommended by the AMA for employer-provided health insurance; and (b) include in all such policies a rollover provision allowing continuation of student disability coverage into the residency period without medical underwriting.
 5. Our AMA: (a) actively encourages medical schools, residency programs, and fellowship programs to provide access to portable group health and disability insurance, including human immunodeficiency virus positive indemnity insurance, for all medical students and resident and fellow physicians; (b) will work with the ACGME and the LCME, and other interested state medical societies or specialty organizations, to develop strategies and policies to ensure access to the provision of portable health and disability insurance coverage, including human immunodeficiency virus positive indemnity insurance, for all medical students, resident and fellow physicians; and (c) will prepare informational material designed to inform medical students and residents concerning the need for both disability and health insurance and describing the available coverage and characteristics of such insurance.
- Citation: (BOT Rep. W, I-91; Reaffirmed: BOT Rep. 14, I-93; Appended: Res. 311, I-98; Modified: Res. 306, A-04; Modified: CME Rep. 2, A-14)

HIV Postexposure Prophylaxis for Medical Students During Electives Abroad D-295.970

1. Our AMA recommends that US medical schools ensure that medical students who engage in clinical rotations abroad have immediate access to HIV prophylaxis.
 2. Our AMA encourages medical schools to provide information to medical students regarding the potential health risks of completing a medical rotation abroad, and on the appropriate precautions to take to minimize such risks.
- Citation: (Res. 303, A-02; Reaffirmed: CCB/CLRPD Rep. 4, A-12)

Pre-Exposure Prophylaxis (PrEP) for HIV H-20.895

1. Our AMA will educate physicians and the public about the effective use of pre-exposure prophylaxis for HIV and the US PrEP Clinical Practice Guidelines.
 2. Our AMA supports the coverage of PrEP in all clinically appropriate circumstances.
 3. Our AMA supports the removal of insurance barriers for PrEP such as prior authorization, mandatory consultation with an infectious disease specialist and other barriers that are not clinically relevant.
 4. Our AMA advocates that individuals not be denied any insurance on the basis of PrEP use.
- Citation: Res. 106, A-16; Modified: Res. 916, I-16; Appended: Res. 101, A-17

Prophylaxis for Medical Students Exposed to Bloodborne Pathogens D-365.999

1. Our AMA will work with the Department of Health and Human Services to seek that references to "staff" in the proposed conditions of participation for hospitals expressly include "students and/or trainees" before they are finalized.
2. Our AMA is unsuccessful in achieving the desired outcome in Recommendation 1, our AMA will work with OSHA to obtain a clarifying interpretation of the current OSHA requirements that would have the effect of broadening the application of their bloodborne pathogen standards to include medical students and trainees.
3. Our AMA is unsuccessful in fulfilling Recommendation 2, our AMA will develop model legislation to establish new standards to ensure appropriate prophylaxis and counseling are made available to medical students and trainees exposed to bloodborne pathogens.
4. Our AMA will make a concerted effort to encourage medical schools to require, as part of their affiliation agreements with medical centers, that CDC and other applicable guidelines and standards be applied also to medical students and trainees. Additionally, Our AMA draft and disseminate model contract language for medical schools to use when contracting with hospitals. And further, Our AMA incorporate an effective enforcement mechanism into the model contract language.

Health and Disability Coverage for Health Care Workers at Risk for HIV and Other Serious Infectious Diseases H-20.906

1. Health Insurance

A currently held health insurance policy of a healthcare worker should not be terminated, coverage reduced or restricted, or premiums increased solely because of HIV infection.

2. Disability Coverage

a) Each health care worker should consider the risks of exposure to infectious agents posed by his/her type of practice and the likely consequences of infection in terms of changes needed in that practice mode and select disability insurance coverage accordingly. The policy selected should contain a reasonable definition of "sickness" or "disability," an own-occupation clause, and guaranteed renewability, future insurability, and partial disability provisions;

b) In making determinations of disability, carriers should take into consideration the recommendations of the professional and institutional staff with whom an infected health care worker is associated, including the worker's own personal physician;

c) Since there are a variety of disability insurance coverages available and a diversity of practice modes, each health care professional should individually assess his/her risk of infection and that of his/her employees and select disability coverage accordingly.

Citation: (BOT Rep. 21, I-00; Reaffirmed: CSAPH Rep. 1, A-10)

Principles of and Actions to Address Medical Education Costs and Student Debt H-305.925

The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue, our American Medical Association (AMA) will:

1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.

2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs--such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector--to promote practice in underserved areas, the military, and academic medicine or clinical research.

3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.

4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.

5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.

6. Work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of trainees with educational debt.

7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.

8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.

9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).

10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.

11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.

12. Encourage medical schools to (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education; (b) Engage in fundraising activities to increase the availability of scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, low-interest loan programs; (c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students; (d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students; (e) Counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation; (f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen; (g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees; (h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; (i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.

13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.

14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals: (a) Eliminating the single holder rule; (b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training; (c) Retaining the option of loan forbearance for residents ineligible for loan deferment; (d) Including, explicitly, dependent care expenses in the definition of the "cost of attendance"; (e) Including room and board expenses in the definition of tax-exempt scholarship income; (f) Continuing the federal Direct Loan Consolidation program, including the ability to "lock in" a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs; (g) Adding the ability to refinance Federal Consolidation Loans; (h) Eliminating the cap on the student loan interest deduction; (i) Increasing the income limits for taking the interest deduction; (j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001; (k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating; (l) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.

15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.

16. Continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.

17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.

18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.

19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.

20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will: (a) Advocate that all resident/fellow physicians have access to PSLF during their training years; (b) Advocate against a monetary cap on

PSLF and other federal loan forgiveness programs; (c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed; (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note; (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer; (f) Advocate that the profit status of a physicians training institution not be a factor for PSLF eligibility; (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed; (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas; (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.

21. Advocate for continued funding of programs including Income-Driven Repayment plans for the benefit of reducing medical student load burden.

22. Formulate a task force to look at undergraduate medical education training as it relates to career choice, and develop new policies and novel approaches to prevent debt from influencing specialty and subspecialty choice.

Citation: CME Report 05, I-18; Appended: Res. 953, I-18; Reaffirmation: A-19; Appended: Res. 316, A-19;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-19)

Introduced by: Medical Student Section

Subject: Ensuring Fair Pricing of Drugs Developed with the United States Government

Referred to: Reference Committee J

Whereas, The United States spends almost twice as much on healthcare as other comparable high income countries despite similar utilization rates, driven in part by higher spending on prescription drugs than other comparable nations^{1,2,3,4,5,6,7}; and

Whereas, The United States spends between 30% and 190% more on pharmaceutical drugs per capita as compared to other comparable high income countries despite similar utilization rates^{3,4,5,6}; and

Whereas, Many drugs cost significantly more in the United States than in other comparable industrialized countries, imposing an undue financial burden on American consumers of pharmaceutical compounds, particularly the uninsured, Medicare beneficiaries, and those whose insurance plans do not cover medicines they need^{3,4,5,6,7,8}; and

Whereas, The United States government is the world's largest funder of the basic science research that supports the development of new pharmaceutical compounds^{9,10,11}; and

Whereas, The United States government licenses drugs discovered in its laboratories to for-profit entities in order to facilitate commercialization^{12,13,14}; and

Whereas, Numerous examples exist of drugs funded in whole or in part by the US government being sold in the United States for higher prices than in other comparable industrialized countries^{3,15,16,17,18,19,20,21,22,23}; and

Whereas, Pharmaceutical companies and industry advocacy groups excuse high prices by explaining they are necessary for research and development of new drugs^{25,26,27}; and

Whereas, A report by the US Government Accountability Office found that pharmaceutical sales increased by 45% globally over the period from 2006 to 2015 and two thirds of pharmaceutical companies saw their profit margins increase over that time period, while annual research and development investment in the United States increased by only 8% over the period from 2008 to 2014²⁸; and

Whereas, Pharmaceutical companies have a higher average profit margin than all comparable industries, including software development which is often cited as a similar industry with high upfront R&D costs and low relative distribution costs^{28,29}; and

Whereas, The United States pays an estimated 70% of all pharmaceutical profits obtained from OECD nations despite only accounting for 34% of the OECD's GDP³⁰; and

1 Whereas, While the 1980 Bayh-Dole Act grants US government agencies the authority to
2 unilaterally revoke licenses to companies or order that additional licenses be granted in order to
3 ensure access (so-called “march in rights”), this extraordinary power has never been used to
4 ensure fair pricing^{31,32,33}; and

5
6 Whereas, The NIH has repeatedly decided that it does not have the statutory authority to use its
7 march-in rights to force licensees to set fair prices for American consumers as this is under the
8 purview of Congress^{34,35,36}; and

9
10 Whereas, 29 European countries currently use a model called international reference pricing
11 (IRP) to set drug prices whereby insurers and/or socialized healthcare programs agree to pay a
12 maximum price for drugs set to an index of prices paid by comparable nations or use such an
13 index as a benchmark for negotiations to set prices^{37,38}; and

14
15 Whereas, Studies of the effectiveness of IRP have found that it lowers prices, increases
16 utilization of drug classes to which the model is applied, and reduces expenditures with no
17 negative effects on health outcomes^{39,40,41,42,43}; and

18
19 Whereas, One of the most common concerns regarding IRP is that it may incentivize
20 pharmaceutical companies to delay or eliminate product launches in countries with a lower
21 willingness to pay^{44,45,46,47}; and

22
23 Whereas, Analyses of IRP’s effects on pharmaceutical product launch delay have found the
24 effect is weak and is limited to countries with a lower willingness to pay^{48,49,50}; and

25
26 Whereas, The United States is one of the nations with the highest willingness to pay in
27 aggregate, implying IRP’s tendency to delay pharmaceutical product launch in lower-income
28 countries would likely not apply to the United States^{8,9,47,48}; and

29
30 Whereas, The Institute for Medicare and Medicaid Innovation in the Department of Health and
31 Human Services (HHS) has proposed a new model for Medicare Part B reimbursement for
32 single-source pharmaceuticals and biologics to be phased into 50% of Medicare Part B plans
33 between 2020 to 2025 that shifts the reimbursement structure to an IRP model, using 126% of
34 the average price paid for a drug in 16 comparable OECD countries for which drug pricing
35 information is widely and publicly available as a benchmark^{2,49,50,51}; and

36
37 Whereas, Over the five years of its implementation, the proposed model is expected to save
38 \$17.2 billion overall including \$3.4 billion in direct out-of-pocket savings without changing
39 Medicare Part B’s benefit structure^{50,51}; and

40
41 Whereas, The AMA has expressed concern that the involuntary nature of the trial program may
42 pose risks to patient access to necessary medications should third party vendors be unable to
43 negotiate prices for drugs that fall at or under Medicare’s target price for reimbursement⁵²; and

44
45 Whereas, Existing AMA Policy (H-110.997, H-110.988, H-110.987, D-110.993, H-110.991,
46 D-110.988, H-110.998, D-330.954) highlights the AMA’s continuing commitment to lowering
47 prescription drug costs, so long as physician freedom of choice is preserved and appropriate
48 incentives for pharmaceutical research and development are maintained; therefore be it

1 RESOLVED, That our American Medical Association amend Policy H-110.987 by addition to
2 read as follows:

3
4 **Pharmaceutical Costs, H-110.987**

- 5 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive
6 behavior by pharmaceutical companies attempting to reduce competition from generic
7 manufacturers through manipulation of patent protections and abuse of regulatory exclusivity
8 incentives.
9 2. Our AMA encourages Congress, the FTC and the Department of Health and Human
10 Services to monitor and evaluate the utilization and impact of controlled distribution channels
11 for prescription pharmaceuticals on patient access and market competition.
12 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical
13 industry.
14 4. Our AMA will continue to monitor and support an appropriate balance between incentives
15 based on appropriate safeguards for innovation on the one hand and efforts to reduce
16 regulatory and statutory barriers to competition as part of the patent system.
17 5. Our AMA encourages prescription drug price and cost transparency among
18 pharmaceutical companies, pharmacy benefit managers and health insurance companies.
19 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional
20 rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
21 7. Our AMA supports legislation to shorten the exclusivity period for biologics.
22 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies
23 and national medical specialty societies to develop principles to guide advocacy and
24 grassroots efforts aimed at addressing pharmaceutical costs and improving patient access
25 and adherence to medically necessary prescription drug regimens.
26 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local
27 and national advocacy initiatives that bring attention to the rising price of prescription drugs
28 and help to put forward solutions to make prescription drugs more affordable for all patients.
29 10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical
30 manufacturers to provide public notice before increasing the price of any drug (generic,
31 brand, or specialty) by 10% or more each year or per course of treatment and provide
32 justification for the price increase; (b) legislation that authorizes the Attorney General and/or
33 the Federal Trade Commission to take legal action to address price gouging by
34 pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c)
35 the expedited review of generic drug applications and prioritizing review of such applications
36 when there is a drug shortage, no available comparable generic drug, or a price increase of
37 10% or more each year or per course of treatment.
38 11. Our AMA advocates for policies that prohibit price gouging on prescription medications
39 when there are no justifiable factors or data to support the price increase.
40 12. Our AMA will provide assistance upon request to state medical associations in support of
41 state legislative and regulatory efforts addressing drug price and cost transparency.
42 13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical
43 products where manufacturers engage in anti-competitive behaviors or unwarranted price
44 escalations.
45 14. Our AMA will support trial programs using international reference pricing for
46 pharmaceuticals as an alternative drug reimbursement model for Medicare, Medicaid,
47 and/or any other federally-funded health insurance programs, either as in individual
48 solution or in conjunction with other approaches. (Modify Current HOD Policy)

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

Received: 08/28/19

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RELEVANT AMA POLICY

Cost of Prescription Drugs H-110.997

Our AMA:(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs; (2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in

making these choices; (3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products; (4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies; (5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies; (6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and (7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.

Citation: BOT Rep. O, A-90 Sub. Res. 126 and Sub. Res. 503, A-95 Reaffirmed: Res. 502, A-98 Reaffirmed: Res. 520, A-99 Reaffirmed: CMS Rep. 9, I-99 Reaffirmed: CMS Rep.3, I-00 Reaffirmed: Res. 707, I-02 Reaffirmation A-04 Reaffirmed: CMS Rep. 3, I-04 Reaffirmation A-06 Reaffirmed in lieu of Res. 814, I-09 Reaffirmed in lieu of Res. 201, I-11 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988

1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.
3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.
4. Our AMA supports measures that increase price transparency for generic prescription drugs.

Citation: Sub. Res. 106, A-15 Reaffirmed: CMS 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

Pharmaceutical Costs H-110.987

1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
 12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
 13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
- Citation: CMS Rep. 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Appended: Res. 201, A-17 Reaffirmed in lieu of: Res. 207, A-17 Modified: Speakers Rep. 01, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Appended: BOT Rep. 14, A-19 Reaffirmed: Res. 105, A-19

Reducing Prescription Drug Prices D-110.993

Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.

Citation: CMS Rep. 3, I-04 Modified: CMS Rep. 1, A-14 Reaffirmation A-14 Reaffirmed in lieu of Res. 229, I-14

Price of Medicine H-110.991

Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.

Citation: CMS Rep. 6, A-03 Appended: Res. 107, A-07 Reaffirmed in lieu of: Res. 207, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Reaffirmation: A-19 Appended: Res. 126, A-19

Prescription Drug Price and Cost Transparency D-110.988

1. Our AMA will continue implementation of its TruthinRx grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmacy benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.
2. Our AMA will report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign.

Citation: Alt. Res. 806, I-17

Cost of New Prescription Drugs H-110.998

Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs.

Citation: Res. 112, I-89 Reaffirmed: Res. 520, A-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of Res. 229, I-14

Prescription Drug Prices and Medicare D-330.954

1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Citation: Res. 211, A-04 Reaffirmation I-04 Reaffirmed in lieu of Res. 201, I-11 Appended: Res. 206, I-14 Reaffirmed: CMS Rep. 2, I-15 Appended: Res. 203, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 803
(I-19)

Introduced by: Medical Student Section

Subject: Encourage Federal Efforts to Expand Access to Scheduled Dialysis for Undocumented People

Referred to: Reference Committee J

Whereas, There are 6,480 undocumented immigrants with end-stage renal disease (ESRD) living in the United States¹; and

Whereas, Scheduled hemodialysis is the standard of care in patients with ESRD and is an effective treatment for prolonging survival and improving quality of life^{2,3}; and

Whereas, Undocumented immigrants with ESRD are more likely to be employed than US citizens with ESRD,^{4,5} and they contribute more to the Medicare Trust Fund than they withdraw⁶; and

Whereas, Despite this substantial financial contribution to the US economy, undocumented immigrants are unable to obtain health benefits through Medicaid and Medicare, which cover dialysis for beneficiaries with ESRD¹; and

Whereas, In most states, there is no public funding for undocumented immigrants to receive scheduled dialysis so they must resort to emergency-only dialysis, meaning they must wait until they develop critical illness before presenting to the emergency department, where they undergo dialysis and are often admitted to a medical ward^{1,7,8}; and

Whereas, While emergency departments are mandated to provide emergent dialysis through the 1986 Emergency Medical Treatment and Active Labor Act (EMTALA),^{9,10} they can provide only 1-2 sessions per week (rather than the recommended 3 sessions per week) and even then, high demand compromises the availability of dialysis chairs⁸; and

Whereas, Without consistent access to dialysis, many patients have experienced multiple cardiac arrests and severe psychosocial distress leading to debilitating, long-term health consequences that add further cost and burden to the healthcare system⁸; and

Whereas, Emergency-only hemodialysis patients experienced a 5-year mortality rate >14-fold higher than patients undergoing scheduled maintenance dialysis, more ICU admissions, and an almost 10-fold greater use of acute-care days^{11,12}; and

Whereas, Compared with emergency-only dialysis, scheduled dialysis involves cost savings of \$72,000 per person per year; extending dialysis coverage to 6,480 undocumented immigrants nationwide could lead to cost savings of more than \$400 million over 1 year¹³; and

Whereas, 11 states and the District of Columbia offer scheduled hemodialysis to undocumented immigrants through state emergency Medicaid programs⁸; and

Whereas, H.R. 2644 Chronic Kidney Disease Improvement in Research and Treatment Act of 2017 was proposed “to understand the progression of kidney disease and the treatment of kidney failure in minority populations and improve access to kidney disease treatment for those in underserved rural and urban areas^{14,15}; and

Whereas, The Renal Physicians Association’s position on dialysis of undocumented individuals states that “the federal government has a responsibility to provide care for all patients within the borders of the United States, and the financial burden of care provided to citizens and noncitizens is both a federal and state responsibility... difficult access to or denial of dialysis services will invariably hasten the patient’s demise and ultimate death”¹⁶; therefore be it

RESOLVED, That our American Medical Association support expanded access to scheduled dialysis for undocumented persons with end-stage renal disease. (New HOD Policy)

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

Received: 08/28/19

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RELEVANT AMA POLICY

Health Care Payment for Undocumented Persons D-440.985

Our AMA shall assist states on the issue of the lack of reimbursement for care given to undocumented immigrants in an attempt to solve this problem on a national level.

Citation: Res. 148, A-02; Reaffirmation A-07; Reaffirmed: CMS Rep. 01, A-17; Reaffirmation: A-19

Federal Funding for Safety Net Care for Undocumented Aliens H-160.956

Our AMA will lobby Congress to adequately appropriate and dispense funds for the current programs that provide reimbursement for the health care of undocumented aliens.

Citation: Sub. Res. 207, A-93; Reaffirmed BOT Rep. 17 - I-94; Reaffirmed by Ref. Cmt. B, A-96;

Reaffirmation A-02; Reaffirmation A-07; Reaffirmed: BOT Rep. 22, A-17; Reaffirmation: A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 804
(I-19)

Introduced by: Indiana

Subject: Protecting Seniors from Medicare Advantage Plans

Referred to: Reference Committee J

1 Whereas, Medicare Advantage plans are heavily marketed to seniors by insurance companies,
2 with less than ideal transparency in advertising; and
3

4 Whereas, These plans produce higher insurance company profits at cost to CMS because
5 Advantage plans are paid at a higher rate than traditional Medicare; and
6

7 Whereas, There also is the potential for higher annual and lifetime costs for the patient under an
8 Advantage Plan; and
9

10 Whereas, Presentations by insurance company officials to seniors can overemphasize the value
11 of different options and can create confusion; therefore be it
12

13 RESOLVED, That our American Medical Association encourage AARP, insurance companies
14 and other vested parties to develop simplified tools and guidelines for comparing and
15 contrasting Medicare Advantage plans. (New HOD Policy)

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

Received: 09/27/19

RELEVANT AMA POLICY

<https://policysearch.ama-assn.org/policyfinder/detail/comparing%20Medicare%20Advantage%20Plans?uri=%2FAMADoc%2FHOD.xml-H-285.902.xml>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 805
(I-19)

Introduced by: International Medical Graduates Section

Subject: Fair Medication Pricing for Patients in United States: Advocating for a Global Pricing Standard

Referred to: Reference Committee J

1 Whereas, Patients in the United States spend more on prescription medications than any other
2 industrialized country according to the National Healthcare Expenditure, 333 billion dollars in
3 2017, up from 236 billion dollars in 2007; and
4

5 Whereas, Increases in prescription drug prices have resulted in many patients foregoing
6 medication and putting lives at risk; while other countries such as Britain, the world's 20 top
7 selling medications are three times cheaper than in the United States; and
8

9 Whereas, Data from a study of generic and brand name drug costs published in Health Affairs in
10 January 2019 shows that generic drugs and brand name drugs increased in price from 9 to 21
11 percent per annum from 2005 through 2016; and
12

13 Whereas, Up to 85% of the raw ingredients used in the medications sold in the United States
14 are produced outside of the country while our prices for pharmaceuticals per capita are the
15 highest in the world; and
16

17 Whereas, Recent efforts to create an International Pricing Index to allow the Centers for
18 Medicaid and Medicare to negotiate prices for medications in Part B, which leaves the majority
19 of medications prescribed that are in Medicare Part D and from other sources unaffected; and
20

21 Whereas, New legislation efforts are focusing on the creation of an International Pricing Index
22 that would identify only the 250 most costly medications each year and negotiate prices for only
23 25 of these medications per annum, would continue to leave the majority of medications
24 unaffected; and
25

26 Whereas, The current legislative proposal would cap the price of medications at 120% of an
27 International Pricing Index for only 25 medications each year, which may potentially still result in
28 consumers experiencing an unfair burden of medication prices for the majority of medications;
29 and
30

31 Whereas, The AMA is dedicated to promoting patient-centered quality healthcare that is
32 accessible and affordable; it would be in the best interest for patient care and to minimize cost
33 to better control medication prices; therefore be it

- 1 RESOLVED, That our American Medical Association advocate for legislation to create an
 2 International Pricing Index that would track global medication prices for all prescription
 3 medications and keep U.S. medication costs aligned with prices paid in other countries to help
 4 control costs and reduce unreasonable patient financial barriers to treatment (Directive to Take
 5 Action); and be it
 6
 7 RESOLVED, That our AMA advocate for legislation that would ensure that patients are charged
 8 fairly for prescription medications based on the International Pricing Index and that additional
 9 costs will not be arbitrarily assigned or passed onto patients. (Directive to Take Action)

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

Received: 10/01/19

References:

- 1) "Spending On Prescription Drugs In The US: Where Does All The Money Go?", Health Affairs Magazine; <https://www.healthaffairs.org/doi/10.1377/hblog20180726.670593/full/>
- 2) "Retail prescription drug spending grew by \$90 billion over four years," Modern Healthcare; <https://www.modernhealthcare.com/technology/retail-prescription-drug-spending-grew-90-billion-over-four-years>
- 3) "The Contribution Of New Product Entry Versus Existing Product Inflation In The Rising Costs Of Drugs," Health Affairs; <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05147#EX1>
- 4) "International Pricing Index: Outsourcing Negotiations Will Continue the US Drug Cost Crisis", Health Affairs Magazine; <https://www.healthaffairs.org/doi/10.1377/hblog20190307.887201/full/>
- 5) "More Than 300 Groups Seek Halt to CMS Plans for Global Drug Pricing Index", American Journal of managed Care; <https://www.ajmc.com/newsroom/more-than-300-groups-seek-halt-to-cms-plans-for-global-drug-pricing-index>
- 6) "Why are Prescription Drug Prices Rising?" U.S. News & World Report, <https://health.usnews.com/health-care/for-better/articles/2019-02-06/why-are-prescription-drug-prices-rising>
- 7) "How the U.S. Pays 3 Times More for Drugs", Scientific American: <https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/>

RELEVANT AMA POLICY

Price of Medicine H-110.991

Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.

Citation: CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19

Cost of Prescription Drugs H-110.997

Our AMA:

- (1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;
- (2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
- (3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;

- (4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
 - (5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
 - (6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
 - (7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
- Citation: BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Cost Sharing Arrangements for Prescription Drugs H-110.990

Our AMA:

- 1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
 - 2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and
 - 3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.
- Citation: CMS Rep. 1, I-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 1, I-12; Reaffirmed in lieu of Res. 105, A-13; Reaffirmed in lieu of: Res. 205, A-17; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS Rep. 07, A-18

Drug Issues in Health System Reform H-100.964

The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.

- (2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
- (3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
- (4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.
- (5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
- (6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
- (7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
- (7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
- (8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.
- (9) reaffirms AMA Policies H-115.995 and H-115.997, opposing FDA-mandated patient package inserts for all marketed prescription drugs.
- (10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.
- (11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
- (12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public

disclosure of patient and reporter identities.

(13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.

(14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.

(15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.

(16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.

(17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.

Citation: (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97; Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11)

Controlling Cost of Medical Care H-155.966

The AMA urges the American Hospital Association and all hospitals to encourage the administrators and medical directors to provide to the members of the medical staffs, housestaff and medical students the charges for tests, procedures, medications and durable medical equipment in such a fashion as to emphasize cost and quality consciousness and to maximize the education of those who order these items as to their costs to the patient, to the hospital and to society in general.

Citation: (Sub. Res. 75, I-81; Reaffirmed: CLRPD Rep. F, I-91; Res. 801, A-93; CMS Rep. 12, A-95; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmation A-08; Reaffirmed in lieu of Res. 5, A-12)

Patient and Public Education about Cost of Care H-155.980

The AMA, as a part of its program to strengthen the US health care system, supports intensifying its efforts to better understand patient concerns regarding fees and other costs of health care in all settings, including the cost of medication, and supports attempts to relieve these concerns.

Citation: (Res. 153, I-89; Sub. Res. 42, I-89; Reaffirmed in lieu of Res. 811, I-93; CMS Rep. 12, A-95; Reaffirmed: CMS Rep. 7, A-05; Modified: CMS Rep. 1, A-15)

Medicare Part B Competitive Acquisition Program (CAP) H-110.983

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- (1) it must be genuinely voluntary and not penalize practices that choose not to participate;
- (2) it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
- (3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;
- (4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;
- (5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- (6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- (7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- (8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Citation: Res. 216, I-18

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988

1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.

2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.

3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.

4. Our AMA supports measures that increase price transparency for generic prescription drugs.

Citation: Sub. Res. 106, A-15; Reaffirmed: CMS 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Pharmaceutical Costs H-110.987

1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.

2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.

4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.

5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.

6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.

7. Our AMA supports legislation to shorten the exclusivity period for biologics.

8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.

9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.

10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.

13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.

Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19

Maximum Allowable Cost of Prescription Medications H-155.962

Our AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.

Citation: CMS Rep. 2, A-07; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed: CMS Res. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmation: A-17

Managed Care Cost Containment Involving Prescription Drugs H-285.965

(1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.

(2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-

containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

(3) Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a chance to discuss the change with the patient.

(4) Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.

(5) Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.

(6) Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.

(7) Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.

(8) When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.

(9) Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.

(10) Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting.

(11) In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed.

(12) For physicians who do not have electronic access, hard copies must be available.

Citation: CEJA Rep. 2, A-95; Res. 734, A-97; Appended by Res. 524 and Sub. Res. 714, A-98; Reaffirmed: Res. 511, A-99; Modified: Res. 501, Reaffirmed: Res. 123 and 524, A-00; Modified: Res. 509, I-00; Reaffirmed: CMS Rep. 6, A-03; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmation A-08; Reaffirmation A-10; Reaffirmed in lieu of Res. 822, I-11; Reaffirmation A-14; Reaffirmed: CMS Rep. 05, A-19

Low Cost Drugs to Poor Countries During Times of Pandemic Health Crises H-250.988

Our AMA: (1) encourages pharmaceutical companies to provide low cost medications to countries during times of pandemic health crises; and (2) shall work with the World Health Organization (WHO), UNAID, and similar organizations that provide comprehensive assistance, including health care, to poor countries in an effort to improve public health and national stability.

Citation: (Res. 402, A-02; Reaffirmed: CSAPH Rep. 1, A-12)

1.2.13 Medical Tourism

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequate screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.

Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patients decision to seek health care abroad. (IV, V, VI) Physicians need to be aware of the implications of medical tourism for individual patients and the community.

Collectively, through their specialty societies and other professional organizations, physicians should:

- (a) Support collection of and access to outcomes data from medical tourists to enhance informed decision making.
- (b) Advocate for education for health care professionals about medical tourism.
- (c) Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.
- (d) Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.

Individually, physicians should:

- (e) Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individuals concerns and wishes about care.
- (f) Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.
- (g) Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.
- (h) Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.
- (i) Offer their best professional guidance about a patients decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patients best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.
- (j) Physicians should respond compassionately when a patient who has undergone treatment abroad without the physicians prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider:
 - (i) the nature and duration of the patient-physician relationship;
 - (ii) the likely impact on the individual patients well-being;
 - (iii) the burden declining to provide follow-up care may impose on fellow professionals;
 - (iv) the likely impact on the health and resources of the community.

Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.

AMA Principles of Medical Ethics: IV, V, VI

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2018

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 806
(I-19)

Introduced by: Medical Student Section

Subject: Support for Housing Modification Policies

Referred to: Reference Committee J

Whereas, Falls amongst the elderly population cost approximately 30,000 lives and nearly \$32 billion every year¹; and

Whereas, For US adults ages 65 and older in 2012, there were 24,190 deaths and 3.2 million non-fatal, fall-related injuries²; and

Whereas, US citizens with low socioeconomic status or greater neighborhood disadvantage had higher rates of falls⁷; and

Whereas, Minorities, those with lower levels of education, and those with less social support were less likely to have home modifications⁸; and

Whereas, Blacks were 30-40% less likely than whites to have fall-related injuries when controlling for these differences⁹; and

Whereas, Home modifications led by an occupational therapist had the greatest potential to affect the most elderly when compared to six other fall prevention strategies, including Tai Chi, Otago, medication management, Vitamin D supplements, expedited first eye cataract surgery, and single-vision distance lenses for outdoor activities¹⁰; and

Whereas, Homes are the most likely setting of falls in the elderly with high morbidity and mortality and prevention in the single most effective intervention^{5,18,19}; and

Whereas, Home hazards to the elderly include physical limitations, loose rugs, unstable furniture, obstructed walkways, and poor lighting give way to falls within the home²⁰; and

Whereas, Simple modifications aimed at increasing lighting and tacking down loose rugs or carpets have shown to statistically reduce the risk of falling in the home¹⁶; and

Whereas, Other interventions include grab bars and grips in the bathroom, hand-rails on both sides of the steps, and lever-style handles on doors and faucets, wheelchair ramps, stair lifts, first-floor bathroom or kitchen renovations, and other more extensive renovations²¹; and

Whereas, There are currently three insurance-based funding schemes for housing modifications, including Medicare Advantage, Medicaid's Money Follows the Person Initiative, and the Veteran's Health Administration Home Improvements and Structural Alterations (HISA) benefits; and

Whereas, Housing modifications are comparatively clinically effective, cost effective, and actionable in preventing fall related injuries among the elderly; therefore be it

RESOLVED, That our American Medical Association support legislation for health insurance coverage of housing modification benefits for: (a) the elderly; (b) other populations that require these modifications in order to mitigate preventable health conditions, including but not limited to the disabled or soon to be disabled; and (c) other persons with physical and/or mental disabilities. (New HOD Policy)

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

Date Received: 10/01/19

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RELEVANT AMA POLICY

Community-Based Falls Prevention Programs H-25.988

Our American Medical Association will work with relevant organizations to support community-based falls prevention programs.

Citation: (Res. 408, A-15)

Exercise Programs for the Elderly H-25.995

The AMA recommends that physicians: (1) stress the importance of exercise for older patients and explain its physiological and psychological benefits; (2) obtain a complete medical history and perform a physical examination that includes exercise testing for quantification of cardiovascular and physical fitness as appropriate, prior to the specific exercise prescription; (3) provide appropriate follow-up of patients' exercise programs; and (4) encourage all patients to establish a lifetime commitment to an exercise program.

Citation: (CSA Rep. C, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Health Care for Older Patients H-25.999

The AMA: (1) endorses and encourages further experimentation and application of home-centered programs of care for older patients and recommends further application of other new experiments in providing better health care, such as rehabilitation education services in nursing homes, chronic illness referral centers, and progressive patient care in hospitals; (2) recommends that there be increased emphasis at all levels of medical education on the new challenges being presented to physicians in health care of the older person, on the growing opportunities for effective use of health maintenance programs and restorative services with this age group, and on the importance of a total view of health, embracing social, psychological, economic, and vocational aspects; (3) encourages continued leadership and participation by the medical profession in community programs for seniors; and (4) will explore and advocate for policies that best improve access to, and the availability of, high quality geriatric care for older adults in the post-acute and long term care continuum..

Citation: (Committee on Aging Report, I-60; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmation A-11; Appended: Res. 709, A-13)

Policy Recommendations in the Field of Aging H-25.998

It is the policy of the AMA that: (1) Older individuals should not be isolated;

(2) a health maintenance program is necessary for every individual;

(3) more persons interested in working with the older people in medical and other professional fields are needed;

(4) more adequate nursing home facilities are an urgent health need for some older people in many communities;

(5) further development of service and facilities is required;

(6) extension of research on both medical and socioeconomic aspects of aging is vital;

(7) local programs for older persons, especially those which emphasize the importance of self-help and independence by the senior citizen, should be a major concern of medicine, both collectively and individually; and

(8) local medical society committees along with other leaders in community service, should be equipped to appraise the advantage or disadvantage of proposed housing for older people.

Citation: CMS Rep. A, I-60; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: CMS Rep. 01, A-18;

5.1 Advance Care Planning

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

thought of primarily for terminally ill patients or those with chronic medical conditions, advance care planning is valuable for everyone, regardless of age or current health status. Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions. Importantly, these discussions also give individuals the opportunity to identify who they would want to make decisions for them should they not have decision-making capacity. Proactively discussing with patients what they would or would not want if recovery from illness or injury is improbable also gives physicians opportunity to address patients concerns and expectations and clarify misunderstandings individuals may have about specific medical conditions or interventions. Encouraging patients to share their views with their families or other intimates and record them in advance directives, and to name a surrogate decision maker, helps to ensure that patients own values, goals, and preferences will inform care decisions even when they cannot speak for themselves.

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

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

(a) Regularly encourage all patients, regardless of age or health status, to:

(i) think about their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness or injury, including any preferences they may have about specific medical interventions (such as pain management, medically administered nutrition and hydration, mechanical ventilation, use of antibiotics, dialysis, or cardiopulmonary resuscitation);

(ii) identify someone they would want to have make decisions on their behalf if they did not have decision-making capacity;

(iii) make their views known to their designated surrogate and to (other) family members or intimates.

(b) Be prepared to answer questions about advance care planning, to help patients formulate their views, and to help them articulate their preferences for care (including their wishes regarding time-limited trials of interventions and surrogate decision maker). Physicians should also be prepared to refer patients to additional resources for further information and guidance if appropriate.

(c) Explain how advance directives, as written articulations of patients preferences, are used as tools to help guide treatment decisions in collaboration with patients themselves when they have decision-making capacity, or with surrogates when they do not, and explain the surrogates responsibilities in decision making. Involve the patients surrogate in this conversation whenever possible.

(d) Incorporate notes from the advance care planning discussion into the medical record. Patient values, preferences for treatment, and designation of surrogate decision maker should be included in the notes to be used as guidance when the patient is unable to express his or her own decisions. If the patient has an advance directive document or written designation of proxy, include a copy (or note the existence of the directive) in the medical record and encourage the patient to give a copy to his or her surrogate and others to help ensure it will be available when needed.

(e) Periodically review with the patient his or her goals, preferences, and chosen decision maker, which often change over time or with changes in health status. Update the patients medical records accordingly when preferences have changed to ensure that these continue to reflect the individuals current wishes. If applicable, assist the patient with updating his or her advance directive or designation of proxy forms. Involve the patients surrogate in these reviews whenever possible.

AMA Principles of Medical Ethics: I.IV

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 807
(I-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Addressing the Need for Low Vision Aid Devices

Referred to: Reference Committee J

Whereas, An estimated 1,082,790 patients in the United States live with a vision of 20/200 or worse, constituting severe visual disability, and the incidence of low vision and blindness is expected to more than double in the next 30 years;¹ and

Whereas, Visual disability and blindness negatively impact patients' educational opportunities, income, and economic prospects;² and

Whereas, Visual disability is determined by low vision specialists (optometrist, ophthalmologist, or occupational therapist) based on decreased (relative to age-norms) measures of visual ability, including best corrected visual acuity, contrast sensitivity, and/or visual fields combined with a validated visual functioning questionnaire score (e.g., National Eye Institute Visual Functioning questionnaire or Impact of Visual Impairment Scale); and

Whereas, Vision rehabilitation services provide critical guidance, education, and devices to patients with visual impairment, including low vision aids (LVA) (magnifying lenses, electronic magnifiers, smartphone applications for text reading) that help individuals improve or maximize their remaining vision;² and

Whereas, Vision rehabilitation with LVAs has been shown to have a positive impact on visual functioning in up to 45 to 50 percent of patients with low vision;³ and

Whereas, LVAs offered to veterans through the Veterans Affairs hospital system showed significant improvement in all levels of visual function, including reading, mobility, and visual motor skills;⁴ and

Whereas, Vision rehabilitation service consultation by trained clinicians are currently covered by Medicare;⁵ and

Whereas, Historically, Medicare by statute does not cover LVAs, as the US Center for Medicare and Medicaid Services has interpreted a statute stating that Medicare will not cover eye glasses

¹ Chan T, Friedman DS, Bradley C, Massof R. Estimates of Incidence and Prevalence of Visual Impairment, Low Vision, and Blindness in the United States. *JAMA Ophthalmol.* 2018;136(1):12–19.

² Huber J, Jutai J, Strong G, Plotkin A. The Psychosocial Impact of Closed-Circuit Televisions on Persons with Age-Related Macular Degeneration. *J Vis Impair Blind* 2008;102:690-701.

³ Judith E. Goldstein, OD; Mary Lou Jackson, MD; Sandra M. Fox, OD; James T. Deremeik, CLVT; Robert W. Massof, PhD; for the Low Vision Research Network Study Group. Clinically Meaningful Rehabilitation Outcomes of Low Vision Patients Served by Outpatient Clinical Centers. *JAMA Ophthalmol.* 2015;133(7):762-769.

⁴ Joan A. Stelmack, OD, MPH; X. Charlene Tang, MD, PhD; Domenic J. Reda, PhD; Stephen Rinne, MA; Rickilyn M. Mancil, MA; Robert W. Massof, PhD; for the LOVIT Study Group. Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT). *Arch Ophthalmol.* 2008;126(5):608-617.

⁵ The Blind Guide. Medicare for People with Low Vision. Accessed March 13, 2019. Available at: <https://www.theblindguide.com/medicare-low-vision>.

1 for beneficiaries, except in the setting of vision correction after cataract surgery, to include
2 LVAs;^{6,7} and
3

4 Whereas, LVAs have been shown to be more impactful on low vision patients' visual functioning
5 than either power wheelchairs or support canes, which are currently paid for by Medicare under
6 the durable medical equipment benefit;⁸ and
7

8 Whereas, Visual impairment is more likely to be present in older patients, patients in poverty,
9 and in patients with risk factors such as diabetes, indicating that a large number of patients with
10 visual impairment rely on Medicare and/or Medicaid for health care services coverage;⁹ and
11

12 Whereas, LVAs can cost hundreds to thousands of dollars if purchased out-of-pocket;¹⁰ and
13

14 Whereas, A greater need for services for patients with low vision is expected to rise,
15 necessitating strategic allocation of resources and policy planning;¹¹ therefore be it
16

17 RESOLVED, That our American Medical Association support legislative and regulatory actions
18 promoting insurance coverage and adequate funding for low vision aids for patients with visual
19 disabilities. (Directive to Take Action)

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

Received: 10/02/19

⁶ 42 U.S.C. § 1395y(a)(7), SSA § 1862(a)(7).

⁷ 42 U.S.C. § 1395x(s)(3), SSA § 1861(s)(8).

⁸ Houston, K. Massachusetts Eye and Ear Outcomes Book: Vision Rehabilitation Service, Psychosocial Impact of Assistive Devices Scale (PIADS), Final Analysis. 2019.

⁹ Ko F, Vitale S, Chou CF, Cotch MF, Saaddine J, Friedman DS. Prevalence of nonrefractive visual impairment in US adults and associated risk factors, 1999-2002 and 2005-2008. *JAMA*. 2012;308(22):2361-2368.

¹⁰ Enhanced Vision. DaVinci Pro HD/OCR - Full Page Text-to-Speech. Accessed March 13, 2019. Available at: <https://www.enhancedvision.com/shop/davinci-pro-electronic-desktop-magnifier>.

¹¹ Chan T, Friedman DS, Bradley C, Massof R. Estimates of Incidence and Prevalence of Visual Impairment, Low Vision, and Blindness in the United States. *JAMA Ophthalmol*. 2018;136(1):12-19.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 808
(I-19)

Introduced by: American Academy of Physical Medicine & Rehabilitation

Subject: Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs

Referred to: Reference Committee J

1 Whereas, Seat elevation is an accessory to power wheelchairs that assists an individual with
2 mobility impairment to raise and lower themselves in the seated position through the use of an
3 electromechanical lift system, and standing feature is an accessory that allows an individual to
4 transition from a seated position to a standing position without the need to transfer out of the
5 wheelchair; and

6
7 Whereas, These features provide individuals with significantly improved abilities to perform
8 mobility-related activities of daily living (MRADLs) and to function independently within the
9 home; and

10
11 Whereas, Seat elevation is especially important for assisting individuals with transfers to/from a
12 wheelchair to/from a commode, bed, or other surface with less risk of falls and shoulder and
13 other injuries secondary to long-term wheelchair use; and

14
15 Whereas, Standing feature has been demonstrated to both assist with MRADLs and provide
16 numerous medical benefits, including improved circulation, promotion of bone density, improved
17 GI tract function, improved mobility and lower limb function, reduced risk of contractures, and
18 reduced occurrence of pressure ulcers and skeletal deformities; and

19
20 Whereas, The Centers for Medicare and Medicaid Services' (CMS) National Coverage
21 Determination (NCD) for mobility assistance equipment (MAE) grants coverage for power
22 wheelchairs and other mobility devices when they are determined to be reasonable and
23 necessary for beneficiaries with personal mobility deficits to assist in the performance of
24 MRADLs; and

25
26 Whereas, HCFA Ruling 96-1 clearly states that accessories that are integral to wheelchairs are
27 considered DME and are part of the DME benefit; and

28
29 Whereas, The four DME Medicare Administrative Contractors (MACs) have taken the position
30 that both seat elevation and standing feature are non-covered benefits for Medicare
31 beneficiaries because they are not primarily medical in nature and, therefore, do not meet the
32 definition of DME; and

33
34 Whereas, CMS's position on seat elevation and standing feature stands in stark contrast to its
35 position that the tilt and recline feature in power wheelchairs is, in fact, considered primarily
36 medical in nature and has been since 2006; and

1 Whereas, The DME MACs' position on coverage of standing feature and seat elevation is
2 contrary to the NCD for MAE, ignores CMS national policy, and results in categorical denials
3 regardless of individual need; and
4

5 Whereas, Patients who are not eligible for Medicare, such as patients on Medicaid and patients
6 who receive health care benefits through commercial insurance, experience similar access and
7 coverage barriers, therefore be it
8

9 RESOLVED, That our American Medical Association request that the Centers for Medicare and
10 Medicaid Services (CMS) render a benefit category determination (BCD) that establishes that
11 the seat elevation and standing features of power wheelchairs are primarily medical in nature
12 and qualify under the definition of durable medical equipment (DME) when used in a power
13 wheelchair (Directive to Take Action); and be it further
14

15 RESOLVED, That our AMA urge CMS to require the DME Medicare Administrative Contractors
16 (MACs) to determine an appropriate coverage policy for Medicare beneficiaries in need of the
17 seat elevation and standing features in their power wheelchairs on an individual basis according
18 to the National Coverage Determination (NCD) for mobility assistance equipment (MAE),
19 activate the existing Healthcare Common Procedure Coding System (HCPCS) codes for seat
20 elevation and standing feature in power wheelchairs, and determine appropriate reimbursement
21 levels for these codes in order to facilitate access to these important benefits for Medicare
22 beneficiaries with mobility impairments (Directive to Take Action); and be it further
23

24 RESOLVED, That if CMS is not able or willing to provide access to seat elevation and standing
25 feature through its administrative authority, our AMA advocate before Congress to support
26 legislation that will clarify the DME benefit to include coverage, coding and reasonable
27 reimbursement of standing feature and seat elevation in power wheelchairs for appropriate
28 Medicare beneficiaries with mobility impairments (Directive to Take Action); and be it further
29

30 RESOLVED, That our AMA encourage all health insurance carriers to cover standing feature
31 and seat elevation in power wheelchairs for appropriate beneficiaries with mobility impairments.
32 (Directive to Take Action)

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

Received: 10/03/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 809
(I-19)

Introduced by: Utah

Subject: AMA Principles of Medicaid Reform

Referred to: Reference Committee J

1 Whereas, Medicaid is a state/federal program that pays for healthcare services for low-income
2 pregnant women and adults with and without children, children, individuals who are elderly or
3 have a disability, parents and women with breast or cervical cancer, and
4

5 Whereas, Some low-income individuals eligible for Medicaid may qualify for private health
6 insurance funded by Medicaid; and
7

8 Whereas, Spending on Medicaid is about one-tenth of the federal budget, \$630 million in 2018;
9 and
10

11 Whereas, The average annual growth in Medicaid spending is 5.5 percent, exceeding that of
12 private health insurance; and
13

14 Whereas, Medicaid member obligations do not always encourage use of the most appropriate
15 care and avenues of care; and
16

17 Whereas, Medicaid reimbursement does not always support the most effective and efficient
18 interaction between clinicians and patients; and
19

20 Whereas, Some Medicaid policies regarding enrollment qualification and leaving the program
21 encourage patients to behave in ways that are not in the patients' best interest (e.g., Medicaid
22 spend-down); and
23

24 Whereas, Physician-directed oversight of access, quality, and cost can greatly improve
25 Medicaid; and
26

27 Whereas, Unnecessary and burdensome administrative requirements on clinicians could be
28 evaluated and reduced; therefore be it

1 RESOLVED, That our American Medical Association support the following principles of
2 Medicaid reform:

- 3
- 4 1. Provide appropriate access to care that is the most cost effective and efficient to our
- 5 citizens.
- 6 2. Encourage individuals to be enrolled in private insurance supported by Medicaid funding, if
- 7 possible.
- 8 3. Create the best coverage at the lowest possible cost.
- 9 4. Incentivize Medicaid patient behavior to improve lifestyle, health, and compliance with
- 10 appropriate avenues of care and utilization of services.
- 11 5. Establish a set of specialty specific high-quality metrics with appropriate remuneration and
- 12 incentives for clinicians to provide high quality care.
- 13 6. Seek to establish improved access for Medicaid patients to primary care providers and
- 14 referrals to specialists for appropriate care.
- 15 7. Assure appropriate payment and positive incentives to encourage but not require clinician
- 16 participation in Medicaid for both face-to-face and non-face-to-face encounters, under
- 17 appropriate establishment of clinician-patient relationship.
- 18 8. Include payment incentives to clinicians for after-hours primary care to assist patients with
- 19 an inability to access care during normal business hours.
- 20 9. Avoid tactics and processes that inhibit access to care, delay interventions and prevent
- 21 ongoing maintenance of health.
- 22 10. Eliminate current disincentives (e.g., Medicaid spend-down in order to qualify) to patients
- 23 improving their lives while on Medicaid, to increase successful transition into the private
- 24 insurance market.
- 25 11. Cease any tax, or attempt to tax, any health care profession for the purpose of supporting
- 26 the cost of Medicaid.
- 27 12. Develop a physician directed clinician oversight board at the state level to insure the proper
- 28 access, quality and cost of care under the Medicaid program throughout all geographically
- 29 diverse areas of the states.
- 30 13. Allow clinicians to see patients for more than one procedure in a visit so that patients do not
- 31 have to return for another service at an extra cost to the Medicaid program and extra time
- 32 and effort to the Medicaid patient (e.g., if patient comes because they are sick, allow them to
- 33 have a diabetes check-up at the same time).
- 34 14. Strategically plan to reduce administrative costs and burdens to clinicians, and of the
- 35 Medicaid program itself, by reducing at least, but not limited to, burdensome documentation
- 36 requirements, administrative obstacles, and regulatory impediments. (New HOD Policy) and
- 37 be it further
- 38

39 RESOLVED, That our AMA pursue action to improve the federal requirements for Medicaid
40 programs based on the AMA's principles of Medicaid reform (Directive to Take Action)

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

Received: 10/03/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 810
(I-19)

Introduced by: Utah

Subject: Hospital Medical Staff Policy

Referred to: Reference Committee J

1 Whereas, Hospital medical staff play a critical role in the function and operations of hospitals
2 and in the relationship that physicians have with hospitals; and
3

4 Whereas, The core responsibilities of the organized medical staff are the promotion of patient
5 safety and quality of care; and
6

7 Whereas, Members of the organized medical staff may choose to act as a group for the purpose
8 of communicating and dealing with the governing board and others with respect to matters that
9 concern the interest of the organized medical staff and its members; and
10

11 Whereas, Individual physician involvement in the political process is important to the good of the
12 nation and for wise decision-making regarding healthcare matters; and
13

14 Whereas, Hospital medical staff in a nonprofit setting could endanger the nonprofit status
15 through political actions; and
16

17 Whereas, The hospital medical staff leadership should be focused on high quality medical care
18 delivery and not be politicized; therefore be it
19

20 RESOLVED, That our American Medical Association support and advocate that hospital
21 medical staff leadership should be fully licensed physicians and that if others are included, they
22 should be non-voting or advisory to the hospital medical staff members (Directive to Take
23 Action); and be it further
24

25 RESOLVED, That our AMA support and advocate that the decisions made by hospital medical
26 staffs focus on quality patient care, medical staff standards and the operation of the hospital,
27 and that those decisions not engage the medical staff in external political matters (e.g.,
28 advanced practice clinician scope of practice expansion, etc.) (Directive to Take Action); and be
29 it further
30

31 RESOLVED, That AMA Policy H-225.993, "Medical Staff Policy Determination," be rescinded.
32 (Rescind HOD Policy)

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

Received: 10/03/19

RELEVANT AMA POLICY

Medical Staff Policy Determination H-225.993

The AMA believes that only fully licensed physicians on the medical staff should establish overall medical staff standards and policy for quality medical care, where consistent with local, state and federal laws.

Citation: (Res. 115, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CMS Rep. 7, A-05; Reaffirmed: CMS Rep. 1, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811
(I-19)

Introduced by: Michigan

Subject: Require Payers to Share Prior Authorization Cost Burden

Referred to: Reference Committee J

Whereas, "Pre-authorization" takes up a significant portion of time; and

Whereas, Prior authorization remains a primarily manual, time-consuming process that often delays patient access to indicated therapy or even alters the course of therapy and places excessive burden on providers, including nurses and pharmacists, health care practices, and hospitals; and

Whereas, Prior authorization disrupts workflow and diverts valuable resources away from direct patient care; and

Whereas, Despite estimates varying by type and size of health care practice, one survey found that, on average, in United States medical practices, physicians spent three hours per week interacting with payers, nurses spent 19.1 hours, clerical staff spent 35.9 hours, and lawyers/accountants spent 7.2 hours; and

Whereas, This translates into substantial increase in uncompensated overhead health care costs; and

Whereas, A critical consequence is nonpayment if prior authorization is not obtained in advance of providing the therapy or service; and

Whereas, There are substantial costs with processing prior authorizations for nonformulary drugs on the physician office side of managed care as well as on the insurance side of the process; and

Whereas, There is some evidence that prior authorization requirements reduce non drug-related costs but little evidence that they have a positive impact on clinical or humanistic outcomes; and

Whereas, It has been found that preauthorization is a measurable burden on physician and staff time with the mean annual projected cost per full-time equivalent physician for prior authorization activities ranged from \$2,161 in one study to \$3,430 in another; therefore be it

RESOLVED, That our American Medical Association reaffirm policies H-320.939, "Prior Authorization and Utilization Management Reform," and H-385.951, "Remuneration for Physician Services." (Reaffirm HOD Policy)

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

Received: 10/03/19

Sources:

1. The Journal of Cardiovascular Nursing: May/June 2017 - Volume 32 - Issue 3 - p 209-211
2. Allergy & Asthma Proceedings . Mar/Apr2006, Vol. 27 Issue 2, p119-122
3. J Manag Care Spec Pharm, 2001 Jul;7(4):297-303 4. J Am Board Fam Med January 2013, 26 (1) 93-95
4. J Am Board Fam Med January 2013, 26 (1) 93-95

RELEVANT AMA POLICY

Prior Authorization and Utilization Management Reform H-320.939

1. Our AMA will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.

2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.

3. Our AMA supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm.

Citation: CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19;

Remuneration for Physician Services H-385.951

1. Our AMA actively supports payment to physicians by contractors and third party payers for physician time and efforts in providing case management and supervisory services, including but not limited to coordination of care and office staff time spent to comply with third party payer protocols.

2. It is AMA policy that insurers pay physicians fair compensation for work associated with prior authorizations, including pre-certifications and prior notifications, that reflects the actual time expended by physicians to comply with insurer requirements and that compensates physicians fully for the legal risks inherent in such work.

3. Our AMA urges insurers to adhere to the AMA's Health Insurer Code of Conduct Principles including specifically that requirements imposed on physicians to obtain prior authorizations, including pre-certifications and prior notifications, must be minimized and streamlined and health insurers must maintain sufficient staff to respond promptly.

Citation: (Sub. Res. 814, A-96; Reaffirmation A-02; Reaffirmation I-08; Reaffirmation I-09; Appended: Sub. Res. 126, A-10; Reaffirmed in lieu of Res. 719, A-11; Reaffirmed in lieu of Res. 721, A-11; Reaffirmation A-11; Reaffirmed in lieu of Res. 822, I-11; Reaffirmed in lieu of Res. 711, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812
(I-19)

Introduced by: College of American Pathologists, National Association of Medical
Examiners, United States and Canadian Academy of Pathology, American
Society for Clinical Pathology, American Society of Cytopathology

Subject: Autopsy Standards as Condition of Participation

Referred to: Reference Committee J

1 Whereas, The Centers for Medicare & Medicaid Services (CMS) decision to remove the autopsy
2 standards §482.22 (d) for hospitals was released in the Omnibus Burden Reduction (Conditions
3 of Participation (COP)) Final Rule on September 26, 2019; and
4

5 Whereas, As a condition for Medicare reimbursement, hospitals have been previously required
6 to provide autopsies as part of COP; and
7

8 Whereas, The removal of this standard will contribute to the further decline in the national
9 autopsy rate, limiting the contributions to medical education and research that have the potential
10 to affect the quality of patient care; and
11

12 Whereas, The autopsy plays a unique and indispensable role in supporting the ability of health
13 care professionals to provide and improve high quality patient care; and
14

15 Whereas, Failure to provide autopsies in appropriate circumstances will have an adverse effect
16 on quality assurance and education; and
17

18 Whereas, Removal of this requirement, despite other mechanisms for encouraging hospitals to
19 retain their programs, will further erode the national clinical autopsy rates; therefore be it
20

21 RESOLVED, That our American Medical Association call upon the Centers for Medicare and
22 Medicaid Services to reinstate the Autopsy Standard as a Medicare Condition of Participation.
23 (Directive to Take Action)

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

Received: 10/17/19

RELEVANT AMA POLICY

Importance of Autopsies H-85.954

1. Our AMA supports seeking the cooperation of the National Advisory Council on Aging of the National Institutes of Health in recommending to physicians, hospitals, institutes of scientific learning, universities, and most importantly the American people the necessity of autopsy for pathological correlation of the results of the immeasurable scientific advancements which have occurred in recent years. Our AMA believes that the information garnered from such stringent scientific advancements and correlation, as well as coalitions, should be used in the most advantageous fashion; and that the conclusions obtained from such investigations should be widely shared with the medical and research community and should be interpreted by these groups with the utmost scrutiny and objectivity.
 2. Our AMA: (a) supports the efforts of the Institute of Medicine and other national organizations in formulating national policies to modernize and promote the use of autopsy to meet present and future needs of society; (b) promotes the use of updated autopsy protocols for medical research, particularly in the areas of cancer, cardiovascular, occupational, and infectious diseases; (c) promotes the revision of standards of accreditation for medical undergraduate and graduate education programs to more fully integrate autopsy into the curriculum and require postmortems as part of medical educational programs; (d) encourages the use of a national computerized autopsy data bank to validate technological methods of diagnosis for medical research and to validate death certificates for public health and the benefit of the nation; (e) requests The Joint Commission to consider amending the Accreditation Manual for Hospitals to require that the complete autopsy report be made part of the medical record within 30 days after the postmortem; (f) supports the formalization of methods of reimbursement for autopsy in order to identify postmortem examinations as medical prerogatives and necessary medical procedures; (g) promotes programs of education for physicians to inform them of the value of autopsy for medical legal purposes and claims processing, to learn the likelihood of effects of disease on other family members, to establish the cause of death when death is unexplained or poorly understood, to establish the protective action of necropsy in litigation, and to inform the bereaved families of the benefits of autopsy; and (h) promotes the incorporation of updated postmortem examinations into risk management and quality assurance programs in hospitals.
 3. Our AMA reaffirms the fundamental importance of the autopsy in any effective hospital quality assurance program, and urges physicians and hospitals to increase the utilization of the autopsy so as to further advance the cause of medical education, research and quality assurance.
 4. Our AMA representatives to the Liaison Committee on Medical Education ask that autopsy rates and student participation in autopsies continue to be monitored periodically and that the reasons that schools do or do not require attendance be collected. Our AMA will continue to work with other interested groups to increase the rate of autopsy attendance.
 5. Our AMA requests that the National Committee on Quality Assurance (NCQA) and other accrediting bodies encourage the performance of autopsies to yield benchmark information for all managed care entities seeking accreditation.
 6. Our AMA calls upon all third party payers, including CMS, to provide adequate payment directly for autopsies, and encourages adequate reimbursement by all third party payers for autopsies.
 7. It is the policy of our AMA: (a) that the performance of autopsies constitutes the practice of medicine; and (b) in conjunction with the pathology associations represented in the AMA House, to continue to implement all the recommendations regarding the effects of decreased utilization of autopsy on medical education and research, quality assurance programs, insurance claims processing, and cost containment.
 8. Our AMA affirms the importance of autopsies and opposes the use of any financial incentives for physicians who acquire autopsy clearance.
- Citation: (CCB/CLRPD Rep. 3, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-19)

Introduced by: American College of Rheumatology
American Society of Clinical Oncology

Subject: Public Reporting of PBM Rebates

Referred to: Reference Committee J

1 Whereas, Pharmacy Benefit Managers (PBMs) are third-parties that create drug formularies for
2 insurers; and

3
4 Whereas, PBMs negotiate rebates and discounts with pharmaceutical manufacturers under the
5 pretense of lowering drug costs and insurance costs for consumers and insurers; and

6
7 Whereas, The amount of rebates and discounts made available to PBMs can create a perverse
8 incentive to raise prices for preferred formulary placement or otherwise serve as a mechanism
9 to influence a drug's placement on a formulary; and

10
11 Whereas, There is no legal requirement that PBMs pass these savings back to plans or
12 consumers; and

13
14 Whereas, Under the prevailing regulatory regimes PBMs may reclassify rebates and discounts
15 to retain the benefit of the bargain for themselves; and

16
17 Whereas, The details of these rebates and discounts are not currently made available to the
18 public; and

19
20 Whereas, In states where the details of the rebates and discounts are disclosed to state
21 regulatory bodies, as required in Arkansas, Minnesota, and Utah, they should be made
22 available to the public; therefore be it

23
24 RESOLVED, That our American Medical Association advocate for Pharmacy Benefit Managers
25 (PBMs) and state regulatory bodies to make rebate and discount reports and disclosures
26 available to the public (Directive to Take Action); and be it further

27
28 RESOLVED, That our AMA advocate for the inclusion of required public reporting of rebates
29 and discounts by PBMs in federal and state PBM legislation. (Directive to Take Action)

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

Received: 10/17/19

RELEVANT AMA POLICY

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987

1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. Our AMA supports improved transparency of PBM operations, including disclosing:
 - Utilization information;
 - Rebate and discount information;
 - Financial incentive information;
 - Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
 - Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
 - Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
 - Percentage of sole source contracts awarded annually.
6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.

Citation: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814
(I-19)

Introduced by: American Society of Clinical Oncology

Subject: PBM Value-Based Framework for Formulary Design

Referred to: Reference Committee J

Whereas, The Centers for Medicare and Medicaid Services recently updated the Minimum Specialty Tier Eligibility criteria for drugs covered by in-network specialty pharmacies through Medicare Part D to be drugs that cost more than \$670 a month¹; and

Whereas, In a typical Medicare Part D plan, medications classified as “specialty drugs” are set at the highest specialty benefit tier which is subject to the highest cost-sharing²; and

Whereas, According to the 2018 Express Scripts Drug Trend Report, specialty medications now account for 44.7 percent of total drug spending in the United States³; and

Whereas, In 2017 the median monthly out of pocket drug expenditure for insured cancer patients was roughly \$703--equating to roughly 11% of household income for the average cancer patient⁴; and

Whereas, Many employers and other plan sponsors use pharmacy benefit managers (PBMs) to outsource the complicated work of designing and maintaining formularies in order to generate potential cost savings for payers and plan sponsors--however it is not clear those savings necessarily accrue to patients⁵; and

Whereas, Most PBM companies follow a definition similar to the Magellan Rx definition of “specialty drugs” -- drugs that are high cost (for Magellan Rx this means \$1000+ per 30-day supply), high complexity, and/or high touch oral or injectable medications used to treat complex or chronic conditions⁶; and

Whereas, PBMs obtain revenue from pharmaceutical manufacturers in the form of rebate payments for “preferred” formulary status, which results in increased market-share by encouraging utilization of the drugs chosen⁷; and

Whereas, Despite PBMs negotiating lower drug prices through rebates, this lower price may not translate to patient savings if the price reduction is not enough to trigger the plan to place the drug on a lower cost-sharing tier; and

¹ Centers for Medicare and Medicaid Services. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2, 2018. (Accessed: September 26, 2019). URL: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>

² Silverscript, MedicareRX. Medicare Part D Formulary Tiers. October 10, 2018. (Accessed: September 30, 2019). URL: <https://www.silverscript.com/learn/formulary-tiers>

³ Express Scripts. 2018 Express Scripts Drug Trend Report. 2019. (Accessed September 30, 2019). URL: <https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf>

⁴ Forbes. Even Insured Patients are Overwhelmed by the Cost of Cancer Care. August 10, 2017. (Accessed: September 26, 2019). URL: <https://www.forbes.com/sites/arieneweintraub/2017/08/10/even-insured-patients-are-overwhelmed-by-the-cost-of-cancer-care/#6b80188b51c4>

⁵ American Society of Clinical Oncology. ASCO Policy Statement on Pharmacy Benefit Managers and Their Impact on Cancer Care. August 2018. (Accessed: October 3, 2019). URL: <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2018%20ASCO%20PBM%20Statement.pdf>

⁶ Magellan Rx Management. Specialty Pharmacy Drug List (Accessed: September 24, 2019). URL: https://magellanrx.com/member/external/commercial/common/doc/en-us/MRx_Formulary_Specialty.pdf

⁷ American Society of Clinical Oncology. ASCO Policy Statement on Pharmacy Benefit Managers and Their Impact on Cancer Care.

1 Whereas, The relatively lower price of a drug compared to other treatments does not
2 necessarily equate to value--value ultimately comes down to the relationship between price and
3 meaningful improvements in health outcomes at the level of individual patients; and
4

5 Whereas, The trend toward tiered formularies burdens vulnerable patients with high levels of
6 coinsurance, does not guarantee that they are receiving the most effective possible treatment,
7 and places them in the cross hairs of a drug pricing problem that they did not create⁸; therefore
8 be it
9

10 RESOLVED, That our American Medical Association emphasize the importance of physicians'
11 choice of the most appropriate pharmaceutical treatment for their patients in its advocacy;
12 (Directive to Take Action) and be it further
13

14 RESOLVED, That our AMA advocate for pharmacy benefit managers (PBMs) and health plans
15 to use a value-based decision-making framework that is transparent and includes applicable
16 specialty clinical oversight when determining which specialty drugs to give preference on their
17 formularies. (Directive to Take Action)

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

Received: 10/17/19

RELEVANT AMA POLICY

Incorporating Value into Pharmaceutical Pricing H-110.986

1. Our AMA supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.

3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

Citation: CMS Rep. 05, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS-CSAPH Rep. 01, A-17; Reaffirmed: CMS Rep. 07, A-18

Value-Based Insurance Design H-185.939

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.

b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.

⁸ American Society of Clinical Oncology. ASCO Position Statement on the Affordability of Cancer Drugs.

- c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
 - d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
 - e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
 - f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
 - g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
 - h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
 - i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).
- Citation: CMS Rep. 2, A-13; Reaffirmed in lieu of Res. 122, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed: CMS Rep. 05, I-16; Reaffirmation I-16; Reaffirmed: Joint CMS/CSAPH Rep. 01, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: Joint CMS CSAPH Rep. 01, I-18; Reaffirmed: CMS Rep. 06, A-19

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987

- 1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
 - 2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
 - 3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
 - 4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
 - 5. Our AMA supports improved transparency of PBM operations, including disclosing:
 - Utilization information;
 - Rebate and discount information;
 - Financial incentive information;
 - Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
 - Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
 - Methodology and sources utilized to determine drug classification and multiple source generic pricing;and
 - Percentage of sole source contracts awarded annually.
 - 6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.
- Citation: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815
(I-19)

Introduced by: American Society of Clinical Oncology, American College of Rheumatology, American College of Gastroenterology, American Association of Clinical Endocrinologists, American Gastroenterological Association, American Academy of Ophthalmology

Subject: Step Therapy

Referred to: Reference Committee J

1 Whereas, In 2017 our AMA along with 17 other medical specialty and healthcare organizations
2 established the Prior Authorization and Utilization Management Reform Principles urging health
3 plans, pharmacy benefit managers and third-party administrators to reform utilization
4 management protocols including step therapy;¹ and
5

6 Whereas, Our AMA, at its June 2019 House of Delegates Annual Meeting, resolved to continue
7 to advocate against the use of step therapy protocols in Medicare Advantage plans with the
8 additional patient protections laid out in Policy D-320.981, “Medicare Advantage Step Therapy”;
9 and
10

11 Whereas, On April 16, 2019 Representative Raul Ruiz (D-CA) and Representative Brad
12 Wenstrup (R-OH) filed H.R. 2279 “The Safe Step Act”, bipartisan legislation that mirrors patient
13 protections against step therapy protocols that have been enacted legislatively in more than 20
14 states across the country²; and on September 25, 2019 Senator Lisa Murkowski (R-AK),
15 Senator Doug Jones (D-AL), and Senator Bill Cassidy (R-LA) introduced S. 2546, the Senate
16 version of this legislation; and
17

18 Whereas, Legislators in Colorado (2018 HB 1148), Connecticut (2017 HB 7023), Georgia (2016
19 HB 975), and Maryland (2017 HB74/SB919) have all gone above and beyond the general
20 protections against step therapy protocols by enacting “Jimmy Carter” legislation- allowing more
21 cancer patients to receive the same lifesaving treatment that the former president received by
22 preventing health plans from limiting coverage of drugs for stage IV cancer patients; and
23

24 Whereas, Health plans’ use of step therapy frequently reduces access to innovative and
25 complex drugs including biologics and chemotherapy, which have been a lifeline for patients
26 with chronic and life-threatening conditions including but not limited to cancer, rheumatoid arthritis,
27 Crohn’s disease, ulcerative colitis, macular degeneration, multiple sclerosis, osteoporosis,
28 primary immunodeficiency diseases, and others; and
29

30 Whereas, Health plans also apply often step therapy to antiemetics in cancer care, negatively
31 impacting patient quality of life, adherence to treatments, and in some cases leading to
32 increased emergency room visits or hospitalizations; therefore be it

¹American Medical Association. Prior Authorization Reform Principles. 2017. Date Accessed: September 26, 2019. URL: <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>

² National Psoriasis Foundation. Press Release: Patient Advocates Applaud Filing of the Safe Step Act’ in the US House of Representatives. April 16, 2019. Date Accessed: September 30, 2019. URL: <https://www.prnewswire.com/news-releases/patient-advocates-applaud-filing-of-the-safe-step-act-in-us-house-of-representatives-300832818.html>

1 RESOLVED, That our American Medical Association extend its advocacy for the patient
 2 protections against step therapy protocols outlined in D-320.981, "Medicare Advantage Step
 3 Therapy," to all health plans (Directive to Take Action); and be it further

4
 5 RESOLVED, That our AMA actively support state and federal legislation that would allow timely
 6 clinician-initiated exceptions to, and place reasonable limits on, step therapy protocols imposed
 7 by health care plans. (Directive to Take Action)

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

Received: 10/17/19

RELEVANT AMA POLICY

Medicare Advantage Step Therapy D-320.981

1. Our AMA believes that step therapy programs create barriers to patient care and encourage health plans to instead focus utilization management protocol on review of statistical outliers.
2. Our AMA will advocate that the Medicare Advantage step therapy protocol, if not repealed, should feature the following patient protections:
 - a. Enable the treating physician, rather than another entity such as the insurance company, to determine if a patient "fails" a treatment;
 - b. Exempt patients from the step therapy protocol when the physician believes the required step therapy treatments would be ineffective, harmful, or otherwise against the patients' best interests;
 - c. Permit a physician to override the step therapy process when patients are stable on a prescribed medication;
 - d. Permit a physician to override the step therapy if the physician expects the treatment to be ineffective based on the known relevant medical characteristics of the patient and the known characteristics of the drug regimen; if patient comorbidities will cause, or will likely cause, an adverse reaction or physical harm to the patient; or is not in the best interest of the patient, based on medical necessity;
 - e. Include an exemption from step therapy for emergency care;
 - f. Require health insurance plans to process step therapy approval and override request processes electronically;
 - g. Not require a person changing health insurance plans to repeat step therapy that was completed under a prior plan; and
 - h. Consider a patient with recurrence of the same systematic disease or condition to be considered an established patient and therefore not subject to duplicative step therapy policies for that disease or condition.

Citation: Res. 714, A-19

Medicare Advantage Step Therapy D-320.984

Our AMA will continue strong advocacy for the rejection of step therapy in Medicare Advantage plans and impede the implementation of the practice before it takes effect on January 1, 2019.

Citation: Res. 810, I-18

Medicare Part B Competitive Acquisition Program (CAP) H-110.983

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- (1) it must be genuinely voluntary and not penalize practices that choose not to participate;
- (2) it should provide supplemental payments to reimburse for costs associated with special

handling and storage for Part B drugs;

(3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;

(4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;

(5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;

(6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;

(7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and

(8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Citation: Res. 216, I-18

Eliminate Fail First Policy in Addiction Treatment H-320.941

Our AMA will advocate for the elimination of the "fail first" policy implemented at times by some insurance companies and managed care organizations for addiction treatment.

Citation: Res. 802, I-16