

REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following four reports were presented by W. Alan Harmon, MD, Chair:

1. ESTABLISHED PATIENT RELATIONSHIPS AND TELEMEDICINE (RESOLUTION 215-I-18)

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 215-I-18 REMAINDER OF REPORT FILED

See Policies H-480.946, H-480.969, D-480.964 and D-480.969

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

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

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

Interstate Medical Licensure Compact

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

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

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

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

AMA POLICY AND RESOURCES

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

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

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

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

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

- Application to situations where there is a telemedical transmission of individual patient data from the patient's state that results in either; (i) provision of a written or otherwise documented medical opinion used for diagnosis or treatment or; (ii) rendering of treatment to a patient within the board's state;
- Exemption from such a licensure requirement for traditional informal physician-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](#).

DISCUSSION

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

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

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

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

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

Finally, the Council believes that state-based exceptions and carve-outs of not only AMA telemedicine policy, but also state licensure laws, will further complicate oversight and regulation and could potentially diminish the standards and patient safeguards that are centerpieces of AMA policy. Accordingly, the Council also recommends reaffirming Policies H-480.946 and H-480.969.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) work with state medical associations to encourage states that are not part of the Interstate Medical Licensure Compact to consider joining the Compact as a means of enhancing patient access to and proper regulation of telemedicine services.
2. That our AMA reaffirm Policy H-480.946, which delineates standards and safeguards that should be met for the coverage and payment of telemedicine, including that physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services.
3. That our AMA reaffirm Policy H-480.969, which maintains that state medical boards should require a full and unrestricted license in that state for the practice of telemedicine, with no differentiation by specialty, unless there are other appropriate state-based licensing methods, and with exemptions for emergent or urgent circumstances and “curbside consultations.”
4. That our AMA advocate to the Interstate Medical Licensure Compact Commission and Federation of State Medical Boards for reduced application fees and secondary state licensure(s) fees processed through the Interstate Medical Licensure Compact.
5. That our AMA work with interested state medical associations to encourage states to pass legislation enhancing patient access to and proper regulation of telemedicine services, in accordance with AMA Policy H-480.946, Coverage of and Payment for Telemedicine.
6. That our AMA reaffirm Policy D-480.969, which supports coverage for telemedicine-provided services comparable to coverage for in-person services.

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2. ADDRESSING FINANCIAL INCENTIVES TO SHOP FOR LOWER-COST HEALTH CARE

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policy H-185.920

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

BACKGROUND

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

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

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

POTENTIAL BENEFITS AND RISKS OF FIPs

Potential Benefits

FIPs could benefit patients, payers, and the health care system in several ways. Both underinsurance and cost-related non-adherence pose significant challenges to patients and providers. Even when a service is covered by a health plan, patients may incur significant costs in the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo necessary care.⁶ Similarly, cost-related non-adherence refers to a state in which patients are unable to pursue recommended medical care due to financial barriers.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 trade-offs 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 incentivizes patients to choose one of these lower-cost regimens by offering these regimens with no patient cost-sharing, plus the prepaid debit card rewards.

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

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

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

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

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

DISCUSSION

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

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

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

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

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

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

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

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

RECOMMENDATIONS

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.
2. That our AMA support the following quality and cost principles for any FIP:
 - a) Remind patients that they can receive care from the physician or facility of their choice consistent with their health plan benefits.
 - b) Provide publicly available information regarding the metrics used to identify, and quality scores associated with, lower and higher-cost health care items, services, physicians and facilities.
 - c) Provide patients and physicians with the quality scores associated with both lower and higher-cost physicians and facilities, as well as information regarding the methods used to determine quality scores. Differences in cost due to specialty or subspecialty focus should be explicitly stated and clearly explained if data is made public.
 - d) Respond within a reasonable timeframe to inquiries of whether the physician is among the preferred lower-cost physicians; the physician's quality scores and those of lower-cost physicians; and directions for how to appeal exclusion from lists of preferred lower-cost physicians.

- e) Provide a process through which patients and physicians can report unsatisfactory care experiences when referred to lower-cost physicians or facilities. The reporting process should be easily accessible by patients and physicians participating in the program.
 - f) Provide meaningful transparency of prices and vendors.
 - g) Inform patients of the health plan cost-sharing and any financial incentives associated with receiving care from FIP-preferred, other in-network, and out-of-network physicians and facilities.
 - h) Inform patients that pursuing lower-cost and/or incentivized care, including FIP incentives, may require them to undertake some burden, such as traveling to a lower-cost site of service or complying with a more complex dosing regimen for lower-cost prescription drugs.
 - i) Methods of cost attribution to a physician or facility must be transparent, and the assumptions underlying cost attributions must be publicly available if cost is a factor used to stratify physicians or facilities.
3. That our AMA support requiring health insurers to indemnify patients for any additional medical expenses resulting from needed services following inadequate FIP-recommended services.
 4. That our AMA oppose FIPs that effectively limit patient choice by making alternatives other than the FIP-preferred choice so expensive, onerous and inconvenient that patients effectively must choose the FIP choice.
 5. That our AMA encourage state medical associations and national medical specialty societies to apply these principles in seeking opportunities to collaborate in the design and implementation of FIPs, with the goal of empowering physicians and patients to make high-value referral choices.
 6. That our AMA encourage objective studies of the impact of FIPs that include data collection on dimensions such as:
 - a) Patient outcomes/the quality of care provided with shopped services;
 - b) Patient utilization of shopped services;
 - c) Patient satisfaction with care for shopped services;
 - d) Patient choice of health care provider;
 - e) Impact on physician administrative burden; and
 - f) Overall/systemic impact on health care costs and care fragmentation.

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3. IMPROVING RISK ADJUSTMENT IN ALTERNATIVE PAYMENT MODELS

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policies H-385.907, H-385.908 and D-478.995

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

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

It is important to note that risk adjustment is distinct from both the assumption of financial risk and risk associated with professional liability. In an APM with downside financial risk, APM providers may be accountable for providing care within a capped payment amount and need to either absorb or repay spending in excess of that amount. Risk adjustment, the focus of this report, is a mechanism for adjusting payment rates, budgets, or both, based on the health status and expected spending on a patient population. Improved risk adjustment models will have positive spillover effects in other areas of payment policy, importantly in the Merit-based Incentive Payment System (MIPS), which adjusts FFS payments up or down according to performance in four categories. Similar to APMs, MIPS scores should

be risk adjusted to account for variations in patient complexity, sociodemographic factors, and costs outside of the physician's control. As many small and specialty practices will stay in MIPS, better risk adjustment is needed to avoid unfairly penalizing those who care for the sickest and most vulnerable.

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

BACKGROUND

Risk is the process of modifying payments and benchmarks and allowing payers to estimate future spending. Risk adjustment systems assign patients a risk score based on demographic factors and health status. Demographic factors may include age, gender, dual eligibility for Medicare and Medicaid (a proxy for socioeconomic status or disability), and whether the patient resides in the community or in a health care facility. Patient health status is usually based on the diagnosis codes submitted on claims in a calendar year. The importance of accurate risk adjustment is increasing as organizations such as Accountable Care Organizations (ACOs) and other APMs bear financial risk for managing a patient population as well as understanding the needs of individual patients and tailoring care delivery to each patient.

Despite the rising importance of risk adjustment, there are fundamental problems with current risk adjustment methodologies. Most risk adjustment systems only predict about 20-30 percent of the variation in services and spending across patients and are designed to predict spending on a large insured patient population, not adjust for differences in patient needs.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 patients that may have particular care needs. Consequently, the usefulness of stratification models relies on data availability, which should encompass the patient's own assessment of his or her health including SDOH. To date, most risk stratification models use a diagnosis-based formula and do not include many SDOH that materially affect patient's health and ability to follow a particular treatment plan.

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

Outlier Payments or Individual Stop Loss Insurance

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

Risk Corridors or Aggregate Stop Loss Insurance

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

Payment Adjustment for External Price Changes

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

AMA POLICY

AMA policy promotes physician-led payment reform programs that serve as models for others working to improve patient care and lower costs (Policy D-385.963). Policy H-390.844 emphasizes the importance of physician leadership and accountability to deliver high quality and value to patients. The AMA advocates for providing opportunities for physicians to determine payment models that work best for their patients, their practices, and their regions (Policy H-390.844). Policy D-390.953 directs the AMA to advocate with the Centers for Medicare & Medicaid Services (CMS) and Congress for APMs developed with specialty and state medical societies.

With respect to risk adjustment, Policy H-165.842 states that health insurance coverage of high-risk individuals should be subsidized through mechanisms such as risk adjustment. Policy H-395.908 states that the AMA will work with CMS and interested organizations to design systems that identify new 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 SDOH factors. It also calls to account for differences in patient needs, such as functional limitations, changes in medical conditions compared to historical data, and ability to access health care services. Policy H-395.908 further calls for the AMA to explore an approach in which physicians managing patient care can contribute additional information, such as disease severity, that may not be available in existing risk adjustment methods to more accurately determine the appropriate risk stratification. Policy H-390.849 calls for adequate risk adjustment methodologies and

encourages attribution processes that emphasize voluntary agreements between patients and physicians. The policy also states that reformed payment rates must be sufficient to maintain a sustainable medical practice and that payment reform implementation should be undertaken within a reasonable timeframe and with adequate assistance.

AMA ACTIVITY

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

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

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

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

DISCUSSION

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

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

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

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.
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.
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.
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.
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.

6. That our AMA support risk adjustment systems that use fair and accurate payments for external price changes beyond the physician's control.
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.
8. That our AMA support risk adjustment mechanisms that allow for flexibility to account for changes in science and practice as to not discourage or punish early adopters of effective therapy.

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4. ADDITIONAL MECHANISMS TO ADDRESS HIGH AND ESCALATING PHARMACEUTICAL PRICES

Reference committee hearing: see report of Reference Committee J.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTIONS 802 AND 805
REMAINDER OF REPORT FILED
TITLE CHANGED**

See Policies H-110.980, H-110.983, H-110.986, H-460.909 and d-330.954

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

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

THE IMPACTS OF HIGH AND ESCALATING PRESCRIPTION DRUG PRICES AND COSTS

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

Approximately 5.8 billion prescriptions were dispensed in the US in 2018, 90 percent of which were dispensed as generics. The retail price differentials between specialty, brand-name and generic drugs are noteworthy. Examining the retail prices of drugs widely used by older Americans, in 2017 the average annual retail price of therapy for specialty drugs was \$78,781, dropping to \$6,798 for brand-name drugs, and \$365 for generics.⁵ Overall, the list price of the average brand drug was \$657.08 for a 30-day prescription in 2018, a noteworthy increase from \$364.92 in 2014. The average prices of brand-name drugs at pharmacies before coupons and discounts are applied were \$229 lower than list prices in 2018 for a 30-day prescription.⁶ Average generic pharmacy prices for a 30-day prescription were relatively stable from 2014 to 2018, increasing to \$19.10 from \$18.50.⁷

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

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

Employer-sponsored health plans as well as health plans sold in the individual market have also had to absorb the higher costs of prescription drugs, which often translate to higher premiums, higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the higher costs of specialty and certain generic drugs. In 2018, 88 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.¹² This year, almost all standalone Medicare Part D plans have a benefit design with five tiers for generic and brand-

name drugs and cost-sharing that deviates from the standard 25 percent coinsurance for all covered drugs between the deductible and the initial coverage limit.¹³

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

In 2018, overall out-of-pocket costs for prescription drugs reached \$61 billion, an increase from \$56 billion in 2014. Across Medicare, Medicaid and commercial health plans, 8.8 percent of patients pay more than \$500 per year out-of-pocket for prescriptions. Medicare beneficiaries have a notably higher incidence rate of high out-of-pocket expenses for prescription drugs, with almost 20 percent paying more than \$500 out-of-pocket.¹⁴ Nonpreferred generic tiers in many cases have higher copayments than patients have become accustomed to for generic medications. In addition, plans with specialty drug cost-sharing tiers often require coinsurance amounts of 25 to 50 percent, versus requiring a fixed copayment. Considering the costs of many specialty medications, patients could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of specialty drugs in Medicare could cause the number of Part D enrollees who reach the catastrophic coverage threshold to grow substantially, resulting in increases in Medicare spending to plans for reinsurance.

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

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

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

EMERGING APPROACHES TO ADDRESS HIGH AND ESCALATING DRUG PRICES

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

Utilizing Binding Arbitration

An emerging policy option that has been put forward to address high and escalating drug prices is using binding arbitration in the event of failed drug price negotiations in order to settle on the final price of the drug. Supporters argue that binding arbitration has the potential to build upon the negotiations that currently take place along the pharmaceutical supply chain that determine coverage of and payment for prescription drugs. In the US, binding arbitration is currently used in public-sector labor-management negotiations, and Major League Baseball uses the approach in the event of failed negotiations for baseball players' salaries. While negotiated prices between the

pharmaceutical company and the payer/government entity in question would remain the preferred solution, arbitration has the potential to help equalize the bargaining power of both parties of the negotiation, while incentivizing negotiating parties to negotiate in good faith. If negotiations fail to conclude with a price agreeable to both parties, they could submit to final offer arbitration or conventional arbitration.

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.

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

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

Legislation has also been introduced in Congress that would use international drug prices to determine whether a drug’s price is excessive, trigger additional interventions, and serve as an upper limit in drug price negotiations. Senator Bernie Sanders (I-VT) and Representative Ro Khanna (D-CA) have introduced S 102/HR 465, the Prescription Drug Price Relief Act of 2019. Notably, under the bill, the price of a prescription drug would be considered “excessive” if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan. Even if a drug’s price does not meet this criterion, or if pricing information is unavailable in at least three of the five countries, a drug’s price could still be considered excessive if it is higher than reasonable in light of factors outlined in the legislation, including cost, revenue, and the size of the affected patient population. If brand-name drugs are found to be excessively priced, the drug would be included on a public excessive price database. Open, nonexclusive licenses would be issued for the drug; and review of

corresponding applications for generic drugs and biosimilar biological products would be expedited to facilitate competition as well as the entry of lower-cost options into the marketplace.^{22,23}

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

Relevant AMA Policy and Advocacy

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

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

Tying Pharmaceutical Pricing to Market Exclusivity

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

Exclusivity periods for pharmaceuticals are not tied to the list price at which they enter the market, nor to the rate at which they increase in price from year to year. The Council notes that two potential options have been proposed to

more closely tie drug market exclusivity to pricing behavior. First, a policy strategy has been put forward to implement contingent exclusivity periods for new brand drugs. Under this policy option, drug manufacturers with a newly approved drug would be able to set their list price at whatever they wish, but the length of the exclusivity period would depend on whether their list price is reasonable, ie, if it aligns with the drug's value. Multiple options could be utilized to assess a drug's value, including cost per quality-adjusted life year (QALY), or a value-based price benchmark. Contingent exclusivity periods, therefore, could potentially lengthen the exclusivity period for drugs with lower cost per QALY, and reduce the exclusivity period for drugs priced too highly to align with their value. For example, in the case of an innovator biologic, a biologic with a low cost per QALY could see its exclusivity period extended to 15 years from 12 years, whereas a biologic priced too high relative to its value could have its exclusivity period set to 7 years.²⁵

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

Relevant AMA Policy

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

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

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

DISCUSSION

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

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

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

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

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

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

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

The Council believes that the recommendations of this report add to the already large body of AMA policies that address the high cost of prescription medications, which guide AMA advocacy efforts to improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. Pursuant to these

policies, the AMA supports: (1) requiring manufacturer and pharmaceutical supply chain transparency; (2) increasing competition and curtailing anti-competitive practices; (3) ensuring prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow including in the electronic health record; and (4) streamlining and modernizing the utilization control methods used by health insurers in response to higher prescription drug costs.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
 - a. The arbitration process should be overseen by objective, independent entities;
 - b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;
 - 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 for the drug in question to inform the arbitrator's decision;
 - f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer;
 - g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
 - h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
 - i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
2. That our AMA advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
 - a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
 - b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
 - c. The use of any international drug price index or average should preserve patient access to necessary medications;
 - d. The use of any international drug price index or average should limit burdens on physician practices; and
 - e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.
3. That our AMA support the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction.
4. That our AMA reaffirm Policy H-110.983, which advocates that any revised Medicare Part B Competitive Acquisition Program meet certain outlined standards to improve the value of the program by lowering the cost of drugs without undermining quality of care.
5. That our AMA reaffirm Policy H-110.986, which outlines principles for value-based pricing programs, initiatives and mechanisms for pharmaceuticals, and supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.

6. That our AMA reaffirm Policy H-460.909, which outlines principles for creating a centralized comparative effectiveness research entity.
7. That our AMA reaffirm Policy D-330.954, which states that our AMA will work toward eliminating Medicare prohibition on drug price negotiation.

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