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The Honorable Michael F. Bennet
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The Honorable Todd Young
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Dear Senators:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in response to your letter to stakeholders dated February 28, 2018, seeking comments and recommendations to address price transparency. The AMA appreciates the opportunity to provide feedback on Congressional efforts to increase health care price and information transparency to empower patients, improve the quality of health care, and lower health care costs.

The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients increasingly are becoming active consumers of health care services. Achieving meaningful price transparency can help lower health care costs and empower patients to make informed care decisions. The AMA supports price transparency and recognizes that achieving meaningful price transparency may help control health care costs by helping patients to choose low-cost, high-quality care.

The AMA supports the following specific measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility:

- Patient confusion and health literacy should be addressed by developing resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
- All health care professionals and entities should be required to make information about prices for common procedures or services readily available to consumers.

- Physicians should communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status of the patient (e.g., self-pay, in-network insured, out-of-network insured) where possible.
- Health plans should provide plan enrollees or their designees with complete information regarding plan benefits and real-time, cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
- Health plans, public and private entities, and other stakeholder groups should work together to facilitate price and quality transparency for patients and physicians.
- Entities promoting price transparency tools should have processes in place to ensure the accuracy and relevance of the information they provide.
- All-payer claims databases should be supported and strengthened.
- Electronic health records (EHR) vendors should include features that assist in facilitating price transparency for physicians and patients.

The lack of transparency in health care pricing and costs is primarily the result of a health care financing system that depends largely on the complex arrangements between and among employers, third-party payers, providers, and patients. These arrangements can make it difficult to identify accurate and relevant information regarding costs associated with specific medical services and procedures. For example, contracts offered by payers to providers frequently delineate contracted rates as proprietary information. Insurer payment policies, coverage rules, and cost-sharing requirements are difficult to communicate in a common manner. Moreover, determining whether a provider is in-network may be difficult because of outdated provider directories or confusion associated with multiple plan contracts. Price also varies depending on where the service is performed, which impacts cost and a patient's cost-sharing. The cumulative effects of each of these factors often make it difficult to provide accurate pricing information for an individual patient in the absence of an actual service claim.

Because the vast majority of health care is compensated through insurance companies at individually contracted rates, many practices or facilities do not maintain standard fee schedules that reflect the amounts that patients would be reasonably expected to pay if directly billed by the provider. In some cases, providers may be concerned that developing and publicizing a cash-pay fee schedule could negatively affect contract negotiations with third-party payers. Physicians should be able to freely negotiate payment rates with insurers. However, providers and insurers may also be reluctant to make certain pricing information available because of concerns about antitrust laws.

Even if basic pricing information were widely available, there are additional barriers to achieving meaningful price transparency in health care. For example, an ideal price transparency system would allow patients to access relevant and accurate information prior to receiving care. This would enable patients to anticipate their potential costs in advance, and to choose among providers to seek the best value care. Yet, anticipating the need for health care services is often difficult. The urgent nature of some medical care, the inability to predict the particular course of treatment that might be indicated or identified subsequent to the initial complaint, and the intensity and scope of service required often leave patients without time or ability to evaluate their options prior to receiving care.

Another key component of price and information transparency involves prescription drug pricing. Greater transparency among pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and health plans will shed light on the rationale for drug price increases and why patients pay what they do for their medications. Pharmaceutical manufacturers have not offered the transparency that allows physicians or their patients to get to the reasoning behind price increases, and neither have they explained the increases. Physicians and patients need to be fully informed to appropriately evaluate treatment options and make the best decisions for a patient's course of treatment. Health insurers and PBMs need to become more transparent so that patients and physician prescribers are fully informed about formularies, prescription drug cost-sharing, and the use of utilization management techniques (e.g., prior authorization and step therapy).

For feedback on your specific questions, please see below.

1. What information is currently available to consumers on prices, out-of-pocket costs, and quality?

The AMA recognizes that accurate cost information for consumers is tied to consumers' insurance, or lack thereof. Consumers who are insured, whether through private insurance, Medicare, or Medicaid, may face different costs for the same health care item or service (prescription drugs, physician services, hospital services, medical testing, etc.), depending upon their specific insurance plan although that is not always a guarantee of what the patient's plan will cover. Generally, insured consumers can best learn about cost by contacting their insurance provider. The AMA notes that consumers, regardless of insurance status, sometimes also turn to their respective health care provider for information on prices and out-of-pocket costs. Physicians and other providers can communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible. Uninsured consumers are especially reliant on information provided to them by hospitals, physicians, pharmacies, and other stakeholders.

Consumers who are privately insured must contact their insurance provider to obtain information about the cost-sharing they should expect for a given item or service, as the price they will pay depends on their specific plan, how much of their deductible has been met, the level of coinsurance and/or co-payment that may be required, and the setting where services are delivered, as payment rates are usually different for different types of facilities. Health plan members can call the customer service number on the back of their insurance cards to inquire about estimated costs of items and services performed by identified providers, and a number of health insurance plans will provide some of this information, along with some quality data, online. Most major health insurers offer some kind of cost estimator tool to help enrollees research and predict their out-of-pocket costs for certain health care services. In addition, some large employers have a cost and quality tool available for their employees. It is not clear, however, whether these calculators are always reflective of the actual costs incurred by patients.

For consumers enrolled in original Medicare (Part A and Part B) or Medicare Advantage (MA), the costs such as deductibles, co-payments, coinsurance, out-of-network rates, and any out-of-pocket maximums Medicare beneficiaries incur vary based on their particular plan, and also for consumers with original Medicare, whether they are enrolled in Medicare prescription drug coverage or a Medicare supplemental

plan (and which level of supplemental plan). Medicare has a website that provides pricing information on services covered by the Medicare Physician Fee Schedule. It provides more than 10,000 physician services, the associated relative value units, and a fee schedule status indicator. The pricing amounts are adjusted to reflect the variation in practice costs based off of geographic area. While available, the information itself is difficult to obtain and interpret. Medicare.gov also allows beneficiaries to obtain coverage information regarding some tests, items, and services, but this information is limited, with patients ultimately having to coordinate with both their health care and health insurance providers to learn about the costs they may incur.

Consumers enrolled in state Medicaid programs receive information on their respective cost-sharing obligations, which can vary by state and eligibility group, through enrollment materials as well as at the time of service. Medicaid beneficiaries can also contact their state Medicaid agency or respective Medicaid managed care organization to inquire about cost-sharing obligations.

Medicare provides additional data on quality and cost. The Centers for Medicare & Medicaid Services (CMS) publishes the Part C and D Star Ratings each year to measure quality in MA and Prescription Drug Plans (PDPs or Part D plans), assist beneficiaries in selecting their plans, and determine MA Quality Bonus Payments. Medicare also publishes quality and cost information on the Physician Compare website. Medicare publishes physician quality data through Star Ratings on Physician Compare based on consumer testing if high reliability and validity standards are met. CMS also makes raw physician quality data available to the public through the Physician Compare downloadable database. The downloadable database also includes cost information. Researchers and other public entities can use the downloadable database information to make their own comparisons about physicians. However, this data is not always transparent, accurate, or easy to interpret. For example, the methodologies used by health plans to assess a physicians quality and cost often vary and conflict with the methodologies used to calculate star ratings in public reporting programs. In addition, the AMA has repeatedly expressed our concerns regarding how risk adjustment is incorporated into quality and cost scoring and public reporting methodologies, and believes further testing of publicly reported data is needed.

Initiatives led by nonprofit entities also have information available that can be used to help consumers obtain general price estimates of medical care. For example, on the FAIR Health website, consumers can search for in- and out-of-network prices for specific medical services or episodes of care within their geographic region.

2. What information is not currently available, but should be made available to empower consumers, reduce costs, increase quality, and improve the system?

The AMA believes that health plans should provide plan enrollees with complete information regarding plan benefits and real-time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect a patient's out-of-pocket costs. A significant obstacle to price transparency and cost containment is complexity. Determining the exact services needed and comparing prices among providers is a challenge for many consumers and physicians, especially in light of significant price variation across site of service and within and across markets. It is difficult for consumers to identify relevant pricing information due to a wide variety of insurance benefit structures and cost-sharing requirements. This challenge is exacerbated when a patient needs multiple services

where it is difficult to ensure that every provider involved in the care is in-network and that every service is covered and determine at what cost. Though pricing tools may help identify in-network providers and estimate costs, they often lack consistency and should be standardized through uniform formatting. Providing consumers with meaningful, accurate, and readily-available price information will reduce costs and improve the health care system.

In addition to relying on health plans for pricing information, patients also rely on their physicians. To the extent price and quality information is available, physicians should engage in shared decision-making with their patients to communicate information about the cost of their professional services to individual patients taking into consideration the insurance status of the patient. The AMA believes that EHR vendors can support the availability of this information by including features that assist in facilitating price transparency for physicians and patients.

It also should be stated that the adequacy and accuracy of provider networks are essential to patients' informed decision-making. Patients need to be able to access all needed primary and specialty care within their insurance plan's provider network, and efforts by state and federal regulators to require insurers to meet objective network adequacy standards should continue. Moreover, provider directories are the tools with which patients may choose their health insurance product and determine which physicians and other providers to see for care. Inaccuracies in provider directors can have significant financial implications for patients and therefore, the AMA strongly encourages policymakers to require that they are up-to-date, accurate, and transparent.

To make value-based health care choices, consumers need pricing information paired with quality information. Consumers must be able to understand and anticipate costs by knowing the price and quality of services before receiving them to be able to choose high quality lower-cost services and providers. However, integrating meaningful cost and quality information in a useable format in transparency efforts is challenging. Aggravating this challenge is the fact that many health care services still lack relevant quality metrics. Studies indicate that patients are willing and able to make choices based on value as long as the information is presented clearly.

The methodologies used by health plans, including Medicare, to assess a physician's quality and cost are not always transparent or easy to interpret, which makes it extremely difficult for physicians to improve quality and provide better value. Often the methodologies used to asses a physician's quality and/or cost conflict with the methodologies used for public reporting. Based on the AMA's analysis of available Medicare data, in several instances, physicians deemed to be of similar quality by one methodology were classified as having different levels of quality by other methodology. Additionally, some physicians classified in the highest (or lowest) level of quality by one methodology were not classified as such by the other methodology. The inconsistencies may result in physician frustration and dissatisfaction, and lead to a lack of confidence in the quality programs. Furthermore, it could lead to patients making incorrect assumptions about physician quality when deciding where to seek care.

Patient health literacy and confusion should be addressed to help patients understand the complexities of health care pricing, including the price variation across sites of service. The AMA believes that patients should be encouraged to seek information regarding the cost of health care services they receive or anticipate receiving based on accurate and consistent information.

3. What role should the cash price play in greater price transparency? How should this be defined?

Cash price may play a limited role in greater price transparency because the true out-of-pocket cost varies vastly from cash price because of the complexity of third-party payers including discounted fees, negotiated rates, use of in-network providers, deductibles, and co-payments. Even self-paying patients may have a different out-of-pocket cost from the cash price because the patient may receive charity care or prompt pay discounts.

The AMA recognizes that the term "cash price" typically refers to the price available to self-paying patients, outside of the scope of health insurance coverage. Discounted fees for insured patients originate from contracts that physicians, hospitals and other providers have with insurers. Prior to reaching an annual deductible, the majority of insured patients pay out-of-pocket for the full cost of their medical care, typically with access to the insurer's discounted fees. Upon reaching the deductible, most insured patients continue to be directly responsible for a portion of their medical bill—based again on discounted rates—in the form of co-payments or coinsurance.

Self-paying patients, however, pay directly for their medical services, and typically will not have access to the discounted fees of insurers for in-network physicians, hospitals and other providers. Alternatively, they pay the "cash price" for their respective medical service or prescription drug. Self-paying patients can seek the "cash prices" from their respective providers and pharmacies. Providers can communicate such information to individual patients, and hospitals can be encouraged to adopt, implement, monitor and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make access to those programs readily available to patients.

The AMA also notes that self-paying patients are often uninsured, and face cash prices that are commonly much higher than prices that insured patients pay for medical services and medications. However, there are instances in which cash prices can be lower than insurer discounted rates, to which patients are likely unaware. For example, a health plan's drug formulary can require patients to spend more on a prescription drug co-payment than they would be charged if they purchased the medication without insurance. In these situations, pharmacists may be aware of this price discrepancy, but can be prevented from informing patients of the "cash price" option due to certain provisions in their contracts with PBMs—commonly known as "gag clauses." The AMA would support efforts requiring pharmacies to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; and opposes provisions in pharmacies' contracts with PBMs that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price.

4. Different states have used different methods to work towards price transparency. What are the pros and cons of these different state approaches? What is the best quality and price information to collect for consumers and businesses?

States are experimenting in many different ways to promote price transparency in health care with the goal of providing patients and other stakeholders with important price information in an effort to lower costs. When it comes to providing patients with useful information for anticipating their health care costs and making decisions based on cost-effectiveness, payers and PBMs are in the best position to offer

information to aid in health care decisions, specifically the individual patient's financial responsibility for a service, procedure, device or medication. In 2017, there were nearly 200 individual pieces of state legislation across 34 states that attempted—in various ways—to increase transparency of drug costs, PBM practices, and health insurer actions.

While we cannot comment on every state law or regulation mentioned above, we are working with state medical associations to encourage states to adopt policies that would advance and promote meaningful price transparency without adding additional burdens or costs to the system. The AMA has model state legislation that would accomplish greater price and cost transparency for patients by requiring certain disclosures and other requirements by health insurance companies, pharmaceutical manufacturers, and PBM companies.

Selected state-level examples that promote price transparency include:

- Patients should have access to necessary information to determine what their financial responsibilities will be if they go outside of their provider network for care. Policy, such as that adopted in New York, requires health insurance companies to standardize the way in which they market and describe their out-of-network coverage, with comparisons to a realistic baseline derived from charge data from a source independent of insurance companies. That way, patients can have a clear idea of how much of the physician's bill the health insurer will pay and how much of that bill will remain the patient's financial responsibility.
- Patients should be able to discuss the cost of care, including pharmaceutical care, with physicians, hospitals, and pharmacists, without contract provisions that prevent these conversations. For example, several states have enacted legislation that prohibits gag clauses in payers' contracts with pharmacists (e.g., Connecticut, Georgia, Maine and North Carolina) that prevent pharmacists from discussing drug prices, payment options and other important cost information with patients. Arizona, Florida, Mississippi, Missouri, New Hampshire, New York, Pennsylvania, South Carolina, Virginia, Washington, and others are considering similar legislation.
- Vermont in 2016 became the first state to enact drug price transparency legislation, which includes provisions requiring a state regulatory board to identify medications that increased in price more than 50 percent over the most recent five-year period or 15 percent or more over the prior year. Vermont also authorized the state attorney general to further investigate price increases and seek damages from manufacturers.
- Louisiana enacted legislation last year that requires each drug manufacturer or pharmaceutical marketer doing business in the state to provide the current wholesale acquisition cost information for United States Food and Drug Administration approved drugs marketed in the state by that manufacturer, and the pharmacy board is required to publish the information online. The web portal is under development.
- Also in 2017, Nevada enacted legislation that requires the state Department of Health and Human Services to identify prescription drugs that are used to treat diabetes; requiring the manufacturer of those medications to provide information, including the costs of producing the drug; the total administrative expenditures relating to the drug, including marketing and advertising costs; the profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug; and additional information relating to rebates to PBM companies, coupons, and "any additional

information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription."

- Maryland enacted a "price gouging" bill that, if the price of an "essential or off-patent generic drug" increases beyond 50 percent, would require the manufacturer to provide certain justifications. For enforcement, the bill authorizes the attorney general to investigate and implement remedies, and it defines "price gouging" as "an unconscionable increase in the price of a prescription drug." It further defines "unconscionable increase" as "an increase in the price of a prescription drug that: (1) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and (2) results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of: (i) the importance of the drug to their health; and (ii) insufficient competition in the market for the drug."
- California in 2017 enacted wide-ranging drug price transparency legislation, which, among other things, would require disclosure of co-pays, cost-sharing, marketing costs and more. It also requires notice in a variety of areas, including having manufacturers to provide at least 60 days notice to the state of price increases above a certain threshold.

5. Who should be responsible for providing pricing information and who should share the information with consumers?

The AMA recognizes that stakeholders across the health care system have varying responsibilities and roles to play in providing pricing information to consumers. The responsibilities differ, however, based on whether patients are insured or uninsured.

For insured patients, health plans must provide plan enrollees or their designees with complete information regarding plan benefits and real-time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs. Such information must also be provided at the time of health plan enrollment to ensure patients have the information necessary to make informed health plan choices. Ultimately, health plans have the most accurate information necessary to share with their enrollees regarding the price they will pay, depending on their specific plan, how much of their deductible has been met, and the level of coinsurance and/or co-payment that may be required. For individuals with employer-sponsored coverage, employer human resources departments often augment the health benefits information provided to their employees. It is also imperative for third-party payers and purchasers to make such cost and pricing data available to physicians and other providers in a useable form at the point of service and decision-making, including the cost of each alternate intervention, and the insurance coverage and cost-sharing requirements of the respective patient. Specifically, PBMs, health insurers, and pharmacists should enable physicians to receive accurate, real-time formulary data at the point of prescribing.

For self-paying patients, physicians, hospitals, and other providers have a role to play in providing appropriate pricing information to patients. Physicians and other providers can communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible. The AMA believes that hospitals should adopt, implement, monitor, and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make

access to those programs readily available to eligible patients. Pharmacists must also inform patients of the cash prices of any medications they need.

6. What role should all-payer claims databases play in increasing price and quality transparency? What barriers currently exist to utilizing these tools?

The AMA believes that All Payer Claims Databases (APCDs) have potential to play an active and important role in increasing price and quality transparency. APCDs provide consumers with information that they and their health care providers can use to make informed decisions about the cost and the quality of care. Currently, about 22 states have APCDs or are in the process of establishing them. APCD files typically contain comprehensive datasets derived from medical claims, pharmacy claims, eligibility files, provider files, and dental claims from both private and public payers.[1] Access, release, and usage rules of these data depend on the state; however, this information is already being utilized for various purposes, including public health research, provider evaluation, and the creation of cost comparison tools.

It is essential that as APCD data are being used to inform patient decision-making, that the data are accurate and complete, and that proper safeguards are established for the programs using the data. For example:

- Physicians and other health care providers should be able to review, and correct any errors in, performance evaluations or the data upon which those evaluations are based;
- Posting of cost data, especially when used for comparison purposes, should never be done without the incorporation of quality data; and
- Any programs that use APCD data to evaluate the performance of physician and other health care providers should use accurate, meaningful, and statistically valid measures, methodologies and data, and those measures, methodologies, and data and any limitations associated with those measures, methodologies, and data should be completely transparent and fully disclosed to health care providers and the public.

Additionally, the AMA believes that state mandates on data submission to APCDs should apply to Employee Retirement Income Security Act of 1974 (ERISA)-regulated employee benefit plans, as such statutes do not typically "relate to" employee benefit plans, but instead are simply "general health care regulation," reserved to the states. Unfortunately, in 2016, the Supreme Court held in *Gobeille v. Liberty Mutual Insurance Co*. 136 S. Ct. 936 (2016) that ERISA preempts state APCD reporting requirements for such plans. The broad impact of this decision means that every state that has built an APCD or plans to do so does not have access to essential information on costs, utilization, and quality of health care services. Addressing this barrier is imperative to realizing the promise of these databases.

7. How do we advance greater awareness and usage of quality information paired with appropriate pricing information?

[1] All-Payer Claims Database Council, *available at* http://www.apcdcouncil.org/.

While the AMA supports the pairing of quality and cost data, we need to first ensure that the quality information is accurate, valid, and representative. The AMA continues to be very concerned that comparisons of physician performance using many of the current and future outcome and cost measures are likely to result in unfair and invalid assessments of the quality of care provided given the lack of insufficient risk adjustment and sample size. This concern is further exacerbated when the erroneous assumption is made that it is appropriate to attribute administrative claims measures across all specialties. The problem is worsened by applying a low minimum reliability score (0.4), which means that accountability for costs or quality will often be attributed inappropriately, particularly for practices that are just above the minimum case threshold.

The current risk adjustment methodologies do not adequately compensate for variations in patient mix, so physicians that treat patients with especially complex conditions or have large percentages of patients with social risk factors are at a disadvantage when compared to their peers. In many of the current programs, physician comparisons are made across sites of service such as a physician who treats frail and elderly patients in the nursing home compared to a primary care physician who treats patients in the traditional office setting. The severity of illness in the patient population and/or the intended outcome in these settings is often different. When these measures are attributed to a physician and posted to CMS' Physician Compare, it provides invalid assessments of quality and cost, and misinforms patients and families about the quality of care provided. We encourage Congress to explore modifications in the way CMS and private payers identify and adjust for differences in physicians' patient populations and to encourage the development and selection of measures that have been demonstrated to yield results that are more relevant and equitable and have strong reliability.

In addition, each payer has varying program requirements when it comes to measuring quality and most programs, including the Merit-based Incentive Payment System (MIPS), rely on and require reporting individual measures that often do not relate to one another. Instead, quality measurement programs should allow physicians to focus on activities that fit within their workflow and address their patient population needs to truly select and report the most meaningful measures to their patients and practice. In the future, it is our hope that composite measures that better reflect the quality of care delivered to patients will be available rather than individual measures. This allows for measurement around improving or managing a disease or condition.

8. How do we ensure that in making information available we do not place unnecessary or additional burdens on health care stakeholders?

The AMA appreciates Congressional concern surrounding unnecessary or additional burdens as it relates to price and information transparency. Successful implementation of any price transparency program will require cooperation and collaboration by all stakeholders, and there is risk of placing untenable and time-consuming requirements on entities and individuals who, ultimately, will not be able to offer a full or meaningful picture of patients' costs.

With approximately 87 percent of Americans covered by private or public health insurance, insurance companies control most of the information necessary to help patients understand the costs associated with the health care services they receive. Thus, health plans need to provide enrollees with complete information regarding plan benefits and cost-sharing information, such as the amount paid toward the

deductible and annual out-of-pocket maximum, patient cost-sharing responsibilities associated with specific in-network providers or services that are up-to-date, and specific amounts the insurance company would pay for out-of-network providers or services. At the same time, the AMA encourages physicians to provide patients with information about the cost of their professional services and empower patients with understandable information.

9. What current regulatory barriers exist within the health care system that should be eliminated in order to make it less burdensome and more cost-efficient for stakeholders to provide high-quality care to patients?

The AMA applauds the commitment from both Congress and the Administration in transforming the health care delivery system by focusing on patient-centered care and working with physicians to reduce administrative burdens. The AMA believes that by reducing physicians' administrative burden, the health care delivery system will improve quality of care, decrease costs, and be more effective, simple, and accessible.

The increasing amount of administrative responsibility forced upon physicians adds unnecessary costs not only to physicians but also to patients. Unnecessary administrative tasks undercut the patient-physician relationship. For example, studies have documented lower patient satisfaction when physicians spend more time looking at the computer and performing clerical tasks.[2] Moreover, for every hour of face-to-face time with patients, physicians spend nearly two additional hours on administrative tasks throughout the day.[3] The increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians.

The AMA is focused on working with Congress and the Administration to reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care. For example, the AMA has identified many regulatory barriers within the health care system that should be eliminated, shared these issues with the administration, and, on an ongoing basis, is working with the administration to address these concerns. The following represents some of the regulatory barriers that should be eliminated to reduce physicians' regulatory burden and allow them focus on providing high quality care to patients.

- Prior Authorization – Prior authorization and other utilization management programs can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. According to the attached 2017 AMA Prior Authorization Physician Survey, more than nine in 10 physicians (92 percent) said that the prior authorization process delays patient access to necessary care; and nearly four in five physicians (78 percent) report that prior authorization can sometimes, often or always lead to patients abandoning a

[2] Street RL et al., *Provider Interaction with the Electronic Health Record: The Effects on Patient-Centered Communication in Medical Encounters.* Patient Educ. Couns., 2014; Kazmi Z, *Effects of Exam Room EHR Use on Doctor-Patient Communication: A Systematic Literature Review.* Inform Prim Care, 2013; Farber NJ et al., *EHR Use and Patient Satisfaction: What We Learned*. J Fam Pract 2015.

[3] Sinsky C et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, Annals of Internal Medicine, 2016.

recommended course of treatment. Furthermore, more than nine in 10 physicians (92 percent) say that prior authorizations programs have a negative impact on patient clinical outcomes. Additionally, the very manual, time-consuming processes used in these programs burden physicians and other health care providers and divert valuable resources away from direct patient care. The AMA is advocating for numerous changes to reduce the prior authorization burden including restricting prior authorization requirements to outlier providers whose prescribing or ordering patterns differ significantly from their peers, not requiring prior authorization for drugs that are standard treatment for the patient's condition and/or have been previously approved unless there is evidence of widespread misuse, requiring all Medicare Advantage (where the majority of prior authorization in Medicare occurs) and Part D plans to publicly disclose to patients and physicians in searchable electronic format all drugs and medical services that are subject to coverage restrictions, and numerous other changes. Furthermore, the AMA believes that prior authorization requirements should not be expanded in Medicare Part A and Part B.

- Certification and Documentation – Documentation requirements are a major imposition that delay care with redundant requirements for verifying physician orders and voluminous medical records where the salient patient information is buried in reams of purposeless, formulaic language. These requirements are particularly hard on small primary care practices. Physicians are left with excessive administrative burdens that are aimed at stopping fraud and abuse by other providers and suppliers which takes time away from treating patients. The AMA is advocating for CMS to create a stakeholder workgroup to address CMS' program integrity needs while simplifying the bureaucratic certification and documentation requirements.
- MIPS Regulatory Changes – The MIPS program establishes a complex scoring system that requires physicians to understand numerous point systems, benchmarks, thresholds, case volumes and other calculations to determine their performance. This creates confusion and makes it harder for physicians to assess how their work was scored and improve their performance. The AMA is advocating for numerous regulatory changes to improve the MIPS program including:

    - Simplify and harmonize MIPS scoring across the four separate components of the program so that physicians can more easily calculate their progress toward achieving success;
    - Increase opportunities for physician reporting to be counted across multiple categories—such as receiving credit for Advancing Care Information (ACI), Improvement Activities, and Quality when reporting quality measures in a clinical data registry;
    - Quality performance category improvements such as maintaining the Quality Payment Program reporting threshold at 50 percent of patients, making outcome or high priority measures optional, allowing a reporting period option of a minimum of 90 days, and eliminating the all-cause hospital readmissions administrative claims measure;
    - ACI performance category changes such as eliminating prescriptive measures, change ACI reporting requirements to attestation alone, expanding the ACI facility-based exemption, improved alignment and flexibility when using EHRs across MIPS categories; and
    - Changes for alternative payment models (APMs) such as adopting physician-focused payment models. APMs for specialists, a nationwide medical home model, lowering financial risk requirements, and increased credit in the Improvement Activities performance category of MIPS.

- Health Information Technology (HIT) – The AMA is advocating for HIT changes including the implementation of a vendor data-blocking attestation requirement, increased transparency around

EHR costs, and improvements to the Office of the National Coordinator for HIT's (ONC) certification program.

- Stark and Anti-kickback Restrictions – Physicians are barred from participating in innovative and cost-saving care models due to outdated regulations, including Anti-kickback and complicated Stark prohibitions. The AMA is advocating for the creation of new statutory exceptions or safe harbors for Stark and Anti-kickback to facilitate APMs and the sharing of cybersecurity items and services.
- Program Integrity – Physicians are facing an increasing amount of pre-payment and post-payment scrutiny from a variety of government entities and contractors. The AMA is advocating for a single transparent, consistent, and fair audit process to reduce administrative burden. We also are advocating for a number of improvements including developing a uniform approach for reviewers in notifying physicians of review, requiring Recovery Audit Contractors (RACs) to reimburse for medical records, and implementing meaningful financial penalties for RACs who make errors. The AMA is also opposed to the recent push from the RACs to increase the number of claims they can audit.

By reducing administrative burden, Congress and the Administration can support the patient-physician relationship and let physicians focus on an individual patient's welfare and, more broadly, on protecting public health.

10. How can our health care system better utilize big data, including information from the Medicare, Medicaid, and other public health programs, to drive better quality outcomes at lower costs?

To better drive quality outcomes and lower costs, the health care system needs to better utilize clinical data. Many payers, including CMS, continue to rely on administrative claims data to assess physician's quality and cost because it does not require additional investments into new electronic systems or additional reporting on the part of a physician or practice. However, we disagree with the application at the individual physician or practice level of claims-based population-level measures, such as All-cause Hospital Readmissions, Medicare Spending per Beneficiary, and Total Cost of Care. Measuring cost and quality based on claims data does not provide physicians with real time information about their patients which they need to establish care coordination and disease management interventions.

Clinical data is a richer data source because it incorporates information that cannot be documented on a claim such as family history, patient allergies, functional status, and patient-generated health data. Clinical data is also needed to appropriately risk-adjust for differences in the stages of disease and other factors. In addition, claims data does not allow physicians to utilize predictive analytics to optimize their performance, know how they are performing compared to their peers, and implement improvement strategies. In the era of EHRs, registries, and other innovative digital health tools, continuing to rely on claims data to assess performance is a step backward and discourages physicians and the greater healthcare system from adopting electronic tools to improve care.

Maximizing big data and realizing its full potential requires a significant investment in the underlying infrastructure. The exchange or access to big data alone is not sufficient to enable physicians and their patients to achieve better quality at lower costs. There is a strong need to give physicians access to meaningful patient data across systems and platforms. Importantly, in order for information to support

patients and their care, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, interoperability can only provide knowledge when the data structure and meaning is consistent.

However, interoperability varies greatly in the health care system. Almost everyone agrees that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care. As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the greater the burden imposed on physicians and patients. To address this issue, the AMA has launched the Integrated Health Model Initiative (IHMI). The IHMI is a digital platform for stakeholder collaboration and clinical review to build a unified data model to organize data in an interoperable fashion. Utilizing the IHMI, different computer systems will be able to exchange data with unambiguous, shared meaning and be fully comprehensive across systems and clinical environments—enabling a true longitudinal patient health record independent of the data's originating source.

The IHMI will also support improvements in quality measurement. Currently, EHRs do not uniformly calculate electronic clinical quality measures (eCQMs) across different vendors and practices due to the lack of specificity within the ONC's Certified Electronic Health Record (CEHRT) program. Incorporation of data requires the development, maintenance, and refinement of administrative code sets such as the International Classification of Diseases (ICD), Current Procedural Terminology (CPT®) and clinical vocabulary standards such as SNOMED Clinical Terms® (SNOMED CT®), Logical Observation Names and Codes® (LOINC), and RxNorm. Creating standards and mapping tools will facilitate working across these different codes and ensure consistency when data is exchanged. The AMA, through its IHMI, is participating in activities to support ontological structures that will provide pathways for better data collection and analytics.

11. What other common-sense policies should be considered in order to empower patients and lower health care costs?

Prescription Drug Price and Cost Transparency

To empower patients and lower health care costs, the AMA strongly urges Congress to advance prescription drug price and cost transparency among pharmaceutical companies, PBMs, and health insurers. While the reasons for price increases are complicated and varied, rising costs may adversely affect patients' health when they cannot afford the medications prescribed to them. Pharmaceutical companies, PBMs, and health insurers contribute to the prescription drug cost equation, ultimately impacting patient cost-sharing, drug tiering decisions, prior authorization policies, and decisions whether to change formularies in the middle of a plan year. As a result, in 2016 the AMA launched a grassroots campaign and website, TruthinRx.org, the goal of which was to disclose the opaque process that pharmaceutical companies, PBMs and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency. To date, over 150,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency.

The AMA strongly urges Congress to advance drug price transparency measures that require pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic,

brand, or specialty) by ten percent or more each year or per course of treatment and provide justification for the price increase. In addition, patients can benefit if pharmaceutical manufacturers are required to publicly disclose a variety of information, to be easily accessible by consumers, which could include research and development costs, expenditures on clinical trials, total costs incurred in production, and marketing and advertising costs.

For patients and physician prescribers, it is a moving target throughout the year as to what prescription medication will be covered under the patient's insurance plan and what restrictions around coverage will be in place. The AMA supports improved transparency so that patients are fully informed about their specific formulary, prescription drug cost-sharing, and the use of utilization management techniques (e.g., prior authorization and step therapy) at the time of health plan enrollment. It is confusing and often disruptive for patients and physicians when health plans and PBMs change their formularies at any point during a patient's plan year to remove one pharmaceutical in favor of another, or add a new utilization management technique. This means that the patient may be forced to switch to a drug that is less effective, and it also is highly unlikely the patient receives a cost discount when the change is made. This switch may destabilize a patient or it will require additional resource expenditure by the physician and extended health care team to file an exceptions request and/or to file an appeal.

In addition, medication step-therapy protocols, and more broadly utilization management programs, can create significant barriers for patients by delaying the start or continuation of necessary medical treatment, which can negatively affect patient health outcomes. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances may necessitate an alternative treatment. Furthermore, if a patient switches plans at the end of a year, a new round of step therapy forces patients to abandon previously effective treatment and repeat a therapy that has been proven ineffective, delays care and may result in negative health outcomes. Recognizing these negative impacts, the AMA and other organizations have created the attached Prior Authorization and Utilization Management Reform Principles, which promote common-sense concepts to improve prior authorization, step-therapy, and other utilization management programs. More recently, the AMA, in collaboration with other national provider associations and insurer trade organizations, released the attached Consensus Statement on Improving the Prior Authorization Process. The consensus statement outlines key opportunities for prior authorization reform, including improving transparency for both patients and physicians regarding utilization management requirements, coverage restrictions, and drug costs by including this information at the point of prescribing in EHRs and creating protections for patient continuity of care when there is a health plan or mid-year formulary change.

The system of rebates and the lack of transparency that makes up the PBM business model lead to regular, disruptive changes in formularies, and have direct and consequential effects on patient care. To improve transparency in this space, the disclosure of rebate and discount information, financial incentive information and Pharmacy & Therapeutics committee information, would constitute critical steps forward. Other mechanisms that have been raised as potential solutions to spur increased PBM transparency include rebate pass-throughs, as well as allowing pharmacists to disclose the cash price of medications to patients at the point of sale.

Increasing Competition and Choice

To empower patients, promote high quality care, and lower health care costs, the AMA strongly supports and encourages competition between and among health care providers, facilities, and insurers. Providing patients with more choices for health care services and coverage stimulates innovation and incentivizes improved care, lower costs, and expanded access. Specifically, we recommend:

- Eliminating state certificate of need (CON) laws;
- Repealing the ban on physician-owned hospitals;
- Reducing the administrative burden to enable physicians to remain in independent practices that compete with hospitals; and
- Modernizing existing program integrity laws to allow for physician innovation.

Many hospital markets are highly concentrated and noncompetitive.[4] Moreover, embedded hospital market concentration is fast becoming an intractable problem for which antitrust provides no remedy.[5] Fortunately, regulators can take steps to encourage new entry.[6] Instead, CON has taken on particular importance as a way for community hospitals to claim territory and to restrict the entry of new competitors.[7] Consequently, CON laws lead to higher health care costs without improving health care quality.[8] By restricting the entry of competitors, especially physician-owned facilities, CON laws have weakened the markets' ability to contain health care costs, undercut consumer choice, and stifled innovation. Therefore, the AMA urges Congress to support the elimination of state CON laws. States should be urged either to repeal their CON laws or allow them to sunset, as recommended by the Brookings Competition Report.[9]

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[4] *See* Martin Gaynor and Robert Town, *The Impact of Hospital Consolidation-Update, the Synthesis Project*, Robert Wood Johnson Foundation (June 2012) ("Synthesis Project").

[5] *See, e.g.*, Thomas Greaney, *The Affordable Care Act and Competition Policy*, 89 OR. L. REV. 811 (2011) ("Antitrust does not break up legally acquired monopolies or oligopolies.").

[6] *Id.*

[7] *Id.;* Gaynor, Mostashari and Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care*, Carnegie Mellon University/Center for Health Policy, Brookings/USC Schaeffer Center for Health Policy and Economics (April, 2017) at 23 available at https://www.brookings.edu/research/making-health-care-markets-work-competition-policy-for healthcare/?utm_campaign=Economic%20Studies&utm_source=hs_email&utm_medium=email&utm_content=50778822 (hereinafter "Brookings Competition Report'); Tracy Yee et al., *Health Care Certificate-of-Need Laws: Policy or Politics*, Research Brief 4, National Institute for Health Care Reform (May 2011).

[8] Mitchell, M. & Koopman, C. (2016), *40 Years of Certificate-of-Need Laws Across America*, Mercatus Center, George Mason University, available at https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america; Stratmann, T., & David Wille, D. (2016), *Certificate-of-Need Laws and Hospital Quality*, Mercatus Center, George Mason University, available at https://www.mercatus.org/publications/certificate-needlaws-and-hospital-quality; Rivers, P. A., Fottler, M.D., & Frimpong, J.A., *The Effects of Certificate-of-Need Regulation on Hospital Costs*. Journal of Health Care Finance 36(4), 1–16 (2010); Ginsburg, P. B., *Wide Variation in Hospital and Physician Payment Rates Evidence of Provider Market Power*, Center for Studying Health System Change. HSC Research Brief No. 16. 94 (2010).

[9] Brookings Competition Report, *supra* note 7.

The federal ban on physician-owned hospitals reduces and restricts competition and choice in health care markets. The AMA believes physician-owned hospitals should be allowed to compete equally with other hospitals in the delivery system. Limiting the role of physician-owned hospitals only reduces access to high quality health care for patients. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. The inability of physician-owned hospitals to address the growing demand for high quality health care services in their community is bad for the entire health care market and does nothing but penalize patients who should have the right to receive care at the hospital of their choice. Thus, the federal ban on physician-owned hospitals should be repealed.

Mounting administrative burdens raise the fixed cost of practice, making it harder for smaller practices to compete.[10] As above, the AMA applauds the commitment to reducing physicians' administrative burden by focusing on patient-centered care and working with physicians to improve outcomes. Physicians are overburdened with paperwork, EHR documentation, and bureaucratic "administrivia," such as obtaining prior authorization and these administrative burdens are a major factor in why physicians are pushed to give up independence in exchange for health system employment where physicians are provided with administrative support to address these burdens.

The AMA believes that clarification of the Anti-kickback Statute, the Physician Self-Referral Law (also known as the Stark Law), and the Civil Monetary Penalties would help promote choice, competition, and innovative arrangements that pose little risk of fraud and abuse. We urge Congress to examine ways to modernize existing laws and requirements to reflect a more coordinated approach to delivering care while not limiting choice and competition. The AMA has continually advocated that the U.S. Department of Health and Human Resources set forth clear and commonsense fraud and abuse rules concerning the formation of innovative delivery models so that physicians can pursue integration options that are not hospital driven. Physicians should not have to become employed by a hospital or sell their practice to a hospital in order to participate in innovative delivery models. Ultimately, physicians should be able to maintain their independent practices while at the same time have access to the infrastructure and resources necessary to participate in APMs.

Thank you for the opportunity to offer our recommendations. We look forward to working with you and your colleagues to increase health care price and information transparency to empower patients, improve the quality of health care, and lower health care costs.

Sincerely,

James L. Madara, MD

Attachments

[10] Brookings Competition Report, *supra* note 7 at 23.