STATEMENT

of the

American Medical Association

U.S. House of Representatives
Energy and Commerce Committee
Health Subcommittee

RE: Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain
Presented by: Jack Resneck, MD
Chair AMA Board of Trustees

May 9, 2019

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The American Medical Association (AMA) appreciates the opportunity to provide testimony to the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health as part of the hearing on Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain. The AMA strongly supports congressional efforts to identify the causes that have led to the high cost of prescription medication. We welcome the opportunity to support congressional efforts to develop well-crafted and effective public policy solutions that would alleviate these high costs and the rapidly multiplying burdens these high costs impose on patients, physicians, other health care providers, and the health care system.[1] Since the AMA last testified before the Energy and Commerce Committee costs have continued to rise for a number of prescription medications. In early 2019, it was reported that three dozen manufacturers of prescription medication had raised prices on 250 prescription medications with an average price increase of 6.3 percent, with some rising by 10 percent or more—well in excess of the rate of inflation over the corresponding period of time.[2] Physicians are focused on ensuring that our patients have access to and receive the right medical treatment at the right time, and we welcome the opportunity to share with the Subcommittee the steps that physicians take to help patients receive their medically necessary pharmacy-dispensed prescriptions or physician-administered drug and biological treatments. Below we briefly outline what the high cost and complexity of obtaining these treatments mean for patient adherence, timely access, and health outcomes.

The underlying causes contributing to the high cost of prescription medication, including rapid price hikes for certain medications, are exacerbated by industry non-disclosure and confidentiality agreements or policies. The AMA has a large body of policies that address the high cost of prescription medications and looks forward to continuing a dialogue that will improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. The solutions must also reduce the administrative burdens largely shouldered by patients and their health care teams. Among these policies, the AMA strongly recommends that policymakers prioritize legislation and regulatory action to: (1) require manufacturer and pharmaceutical supply chain transparency; (2) increase competition and curtail anti-competitive practices; (3) ensure prescribers have accurate point-of-care coverage and patient cost-

[1] Throughout this document the term pharmaceuticals and prescription drugs are referenced—both encompass innovator and follow-on biologicals as well.
[2] Drugmakers Celebrate the New Year by Raising Prices on Hundreds of Drug an Average of 6.3%, Forbes, January 2, 2019 citing RX Savings Solutions.

sharing information as part of their workflow including in the electronic health record (EHR); and (4) streamline and modernize the utilization control methods used by health insurers in response to higher prescription drug costs.

Manufacturer and Supply Chain Transparency

The AMA has launched a grassroots campaign and website, TruthinRx.org, the goal of which is to address the opaque process that pharmaceutical companies, pharmaceutical benefit managers (PBMs), and health insurers engage in when pricing prescription drugs. To date, more than 338,000 individuals have signed a petition in support of greater drug pricing transparency, with the campaign also generating more than one million messages sent to Congress demanding drug price transparency. This begins with shining a light on industry agreements and rebates. The AMA strongly supports federal legislation that would require manufacturers and insurers participating in federal health care programs to provide price and cost transparency so that physicians receive accurate, real-time formulary data at the point-of-prescribing as well as transparency for patients at the pharmacy point-of-sale. Also, the AMA 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; and legislation that authorizes the Attorney General (AG) and/or the Federal Trade Commission (FTC) to take legal action to address price gouging by pharmaceutical manufacturers and other measures to address anticompetitive behaviors.

The AMA applauds passage of legislation, now law, in the last Congress to curb gag clauses in both public health programs and commercial plans. Consistent with the AMA's long-standing efforts to increase transparency, we also support the Energy and Commerce Committee's efforts in passing H.R. 1781, the "Payment Commission Data Act of 2019. H.R. 1781 would provide access to essential data that the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) need to evaluate the practices of various entities within the pharmaceutical supply chain that are either not readily available or not available for independent analysis, including drug pricing and rebate data. It is essential that MedPAC and MACPAC have this information to provide data driven recommendations to Congress in order to improve the affordability of prescription medication while still providing adequate incentives to support innovation.

Combatting Anti-Competitive Practices

We applaud the Committee for taking steps to advance legislation to increase competition of less costly alternative medication and combat anti-competitive practices. The AMA strongly supports legislation considered by the Committee that expands the authority of the FTC and the U.S. Department of Justice to stop "pay-for-delay" arrangements between brand and generic manufacturers. We also strongly support legislation considered by the Committee that would stop brand manufacturer gaming of FDA requirements in order to inappropriately extend exclusivities including through "parking exclusivities," use of proprietary risk evaluation mitigation strategies, and preventing generic applicants from obtaining brand samples needed to establish bioequivalence. We also support the Committee's efforts to stop the misuse of patents and maneuverings that delay or prevent generic entry through misuse of risk evaluation mitigation strategies.

Workflow Integrated Point-of-Care Transparency

When prescribing a pharmaceutical for a patient, physicians must consider clinical factors, patient preferences, and other circumstances, as well as the cost to the patient based on variable insurance benefit designs, such as drug formularies. Yet physicians rarely have readily accessible, accurate, up-to-date information on a patient's coverage and the insurer's or PBM's utilization management policies, along with clinical options and cost, at the point-of-prescribing. This is compounded by time-consuming and

antiquated communication methods used by insurers to process utilization management and exceptions requests, including faxes, non-standardized forms, and understaffed telephone call lines. PBMs and public and commercial insurers now have a large number of utilization management programs, such as medication step therapy, dosing limits, and prior authorization, that the physician and patient must navigate.

Access to accurate patient coverage and cost-sharing information at the point-of-care would streamline the process, reduce burden for the physician and the patient, and speed delivery of the most appropriate care. In the larger context of health system costs, physicians do not have access to information about drug cost for the patient and the health care plan that they need to be good stewards and bring more value to the health care system.

The AMA urges Congress to consider what public policies are needed to ensure that manufacturers, PBMs, insurers, and electronic health record vendors move quickly to develop point-of-care software that provides patient coverage and cost-sharing information. There are several promising pilots underway by Surescripts, OptumRx, and others to deliver real-time pharmacy benefit data to physicians at the point-of-care. The AMA strongly advocates that this data should be available to all physicians, regardless of EHR vendor, and regardless of which PBM the patient has.

Insurer and PBM utilization control methods

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on their patients, on physician practices, and the broader health care system. The burden, however, is not solely caused by the escalating cost of pharmaceuticals, but the increase in medication utilization management policies as well, some of which are the result of increased pharmaceutical costs but also may be driven by other imbalances in the current drug supply chain. As a result, patients and physicians often must navigate complex and resource intensive requirements imposed by health insurers and PBMs. These are consequential problems that may negatively impact the ability of patients to obtain needed medications in a timely manner and to maintain treatment. If patients delay, forgo, or ration their pharmaceutical treatment, their health status may deteriorate and eventually require medical interventions in more costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease.

The time and expense that physicians and the extended care team, patients, and their caregivers spend complying with documentation requirements is another significant issue that needs to be addressed. Physicians and their staff will frequently undertake multiple steps before the patient is able to receive their prescription, including finding clinically appropriate but more affordable alternatives, identifying and applying for discounts or patient assistance programs, and filing appeals or exception requests. These time-consuming processes continue to divert the finite resources away from direct patient clinical care to a large volume of paperwork, emails, facsimiles, and phone calls. Administrative burdens have also led to increasing delays in medically necessary care. As outlined below, the high cost of pharmaceuticals not only negatively impacts the patient who requires them and cannot afford them. The cost is also passed on to other patients when physicians and the extended heath care team are consumed with repetitive administrative minutiae documenting, often repeatedly, medical need in order to comply with expanding insurer medication utilization management program policies. In addition, the two pincers that patients and physicians are squeezed between—high-priced pharmaceuticals and increasingly onerous documentation requirements—continue to erode the physician-patient relationship, as well as lower morale and fuel burn-out among the health care team members.

Prior authorization

Insurers outline in their coverage design that certain pharmaceuticals are subject to the insurer's review and approval before a prescription will be covered, even if it is on the formulary. Frequently, a physician and patient learn that prior authorization is required when the pharmacy staff notify them—that is, after the prescription has been received by the pharmacy and the medication claim has been rejected by the insurer or PBM. The physician and clinical staff will then need to provide documentation in the format required by the insurer and meet the insurer's criteria. This will often entail a significant amount of physician, pharmacist, and their extended teams' time. Every insurer has its own forms, criteria, and processes. This lack of standardization exacerbates delays and overall complexity. If an adverse decision is made by the insurer or PBM, the physician and staff will often need to assist the patient with filing an exceptions request or an appeal. Both an exceptions request and an appeal involve additional time and paperwork. But more importantly, the entire process results in significant delays in patient care or patients not receiving covered care that was determined by their physician to be medically necessary. In a 2018 AMA survey,[3] 91 percent of physicians reported that prior authorization is associated with delays in care and 91 percent also reported that prior authorization can have a negative impact on patient clinical outcomes. Significantly, 28 percent of physicians reported prior authorization led to a serious adverse event (e.g., hospitalization, disability, or even death) for a patient in their care. Moreover, 75 percent of surveyed physicians reported that prior authorization can lead to treatment abandonment, meaning the patient never received the care prescribed. This is a common occurrence with pharmacy-dispensed pharmaceuticals, as patients who arrive at the pharmacy to pick up their medication and learn that there is a delay due to prior authorization requirements may not return. Prior authorization is thus an important contributor to medication nonadherence.

Step therapy

Insurers and PBMs have developed formularies that require a patient for certain covered pharmaceuticals to try a preferred drug to ascertain whether it is effective before other alternatives will be covered. This step therapy requirement may not be known to the patient or physician in advance. The pharmacy staff will frequently notify the patient and physician practice after the patient submits the prescription to the pharmacy and the medication claim is rejected by the insurer or PBM. This, in turn, will require additional clinician and staff time (for both the physician practice and the pharmacy) to determine whether the alternative medication is appropriate based on the particular medical needs of the patient. If it is not, the physician will, after consulting with the patient, submit an exceptions request or appeal requiring the submission of additional documentation. In addition, it may require a subsequent patient visit and more time to assess the effectiveness of the treatment including submitting documentation to satisfy the insurer that the less expensive alternative was not effective for the patient. For patients who have had to complete a step therapy protocol, they may be required to re-do it again if they switch plans. These therapy interruptions can have devastating consequences for chronically ill patients, who may lose control of their disease until the original treatment can be reinitiated. Treatment disruptions for complex biological medications may result in long-term term loss of disease control if the therapy is no longer effective or causes adverse events when the drug is reintroduced.

Quantity and dosing limits

Increasingly, insurers are placing quantity and dosing limits on certain pharmaceuticals that are part of the covered formulary. Certain drugs may be limited to the amount that a patient may be prescribed per prescription for a certain time period. For example, one insurer limits patients to 30 tablets per prescription for levothyroxine per 30 days. Physicians may have to navigate the appeals or exceptions

[3] 2018 AMA Prior Authorization (PA) Physician Survey. Available at: https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.

process for the patient, delaying necessary treatment and expending additional time and resources. In addition, insurers may alter the dose that they will cover midway through treatment, which can cause confusion and potentially life-threatening consequences for patients.

Modifications to Formularies

Health plans and PBMs may also change their formularies at any point during a patient's plan year to remove one pharmaceutical in favor of another. This means that the patient may be forced to switch to a drug that is less effective or experience care disruptions during an exceptions process, 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. This is exacerbated by the continued restrictions of formularies by PBMs to remove previously covered medications.[4]

There is considerable variation between utilization review entities' prior authorization criteria and requirements and extensive use of proprietary forms. This lack of standardization is associated with significant administrative burdens for physicians and the extended health care team, who must identify and comply with each public and commercial insurer's unique requirements. Furthermore, any clinically based utilization management criteria should be similar—if not identical—across clinical utilization review entities.

Delays, costs, and administrative burden associated with helping a patient obtain a prescription written by their physician or other duly authorized prescriber on the health team has prompted the AMA—along with a growing number of national medical specialty societies and state medical associations—the American Hospital Association (AHA), the American Pharmacists Association (APhA), and other stakeholders to call upon health plans, benefit managers, and any other party conducting utilization management, as well as accreditation organizations, to follow Prior Authorization and Utilization Management Reform Principles (Reform Principles) developed by these stakeholders. The AMA strongly urges Congress to require health insurers participating in federal health care programs to adhere to these Reform Principles. We are also urging states to enact legislation requiring similar reforms. In addition, the AMA is directly working with commercial health plans to "right-size" prior authorization programs. Using the Reform Principles as a starting point for discussion, the AMA joined with the AHA, APhA, Medical Group Management Association, Blue Cross Blue Shield Association, and America's Health Insurance Plans to develop the Consensus Statement on Improving the Prior Authorization Process, which was released in early 2018. This document reflects agreement between providers and insurers on the need for prior authorization reforms that will reduce the overall volume of requirements, improve transparency, protect patient care continuity, and increase automation of the current manual process. Unfortunately, progress in implementing these reforms has been sluggish, as detailed in additional 2018 AMA survey results.[5] For example, 88 percent of physicians report that the number of prescription medications requiring prior authorization has increased, despite the agreement in the Consensus Statement to encourage overall reduction in these requirements. In addition, 85 percent of physicians report that prior authorization interferes with continuity of care.

<u>The Impact on Patients of Utilization Management Programs</u>

The foregoing can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affect patient health outcomes. The manual and time-consuming processes used in these insurer utilization management programs place excessive burdens on patients whose medically

[4] See https://www.statnews.com/pharmalot/2017/07/31/express-scripts-formulary-epipen/)
[5] Industry checkup: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/2019-03/prior-auth-survey.pdf

necessary treatment is delayed as well as physicians, the health care team, and pharmacies, and divert valuable resources away from direct patient care. Commercial and public health insurers tout the benefits of these programs to drive value. This comes, however, at the cost of delayed or denied patient care and wasted time and increased inefficiencies on the part of physicians and other clinical staff. As detailed in the 2018 AMA survey, practices report completing an average of 31 prior authorizations per physician per week, a workload that consumes 14.9 hours—nearly two business days—of physician and staff time every week.

The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the physician in consultation with his/her patient. While a particular pharmaceutical might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances, for example, may necessitate an alternative treatment. The failure to account for this can obstruct proper patient care. Too often, insurer utilization management programs do not allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials. Physicians and their patients do not have rapid, standard appeals processes for negative medication utilization management program decisions or other needed exceptions. Too many insurers still do not provide physicians with direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues.

The AMA's prior authorization grassroots advocacy reform campaign and associated online hub, FixPriorAuth.org, put a human face on the care delays and clinical harms associated with utilization management programs. Since July 2018, the website has captured over 500 patient and physician stories underscoring the troubling impact that prior authorization has on the delivery of timely, medically necessary care. The concerns raised in both the site's story gallery and patient and physician videos emphasize the importance of ensuring that patients generally, and Medicare beneficiaries in particular, are not subjected to the harmful prior authorization policies that have been inappropriately deployed in the commercial insurance market in order to prevent patients from obtaining medically appropriate and covered treatments. Notably, over 90,000 site visitors have signed a petition to Congress urging action on prior authorization reform.

Conclusion

The AMA thanks the Subcommittee for this hearing and for careful consideration of the patient harm, health system, cost and administrative burdens associated with high pharmaceutical costs. We welcome the opportunity to work with the Subcommittee and Congress to seek solutions moving forward.