TESTIMONY

of the

American Medical Association

Health Subcommittee
House Committee on Energy and Commerce

RE: Examining the Pharmaceutical Supply Chain

Presented by: Gerald Harmon, MD

December 13, 2017

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The American Medical Association (AMA) applauds the Health Subcommittee of the U.S. House of Representatives Committee on Energy and Commerce for convening key stakeholders to examine the pharmaceutical supply chain and consider well-crafted and effective public policy solutions that would alleviate the high cost of prescription drugs.[1] It is our goal to ensure that 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 prescriptions or physician-administered drug treatments. Below we briefly outline what the escalating cost and complexity of obtaining these treatments mean for patient adherence, timely access, and health outcomes. The AMA has a large body of policies that address the rising cost of prescription drugs and we look forward to continuing dialogue to seek solutions to improve access, lower costs, and reduce the administrative burdens without stifling innovation.

The cost to patients, physician practices, and the health system

Patients are facing mounting costs and administrative barriers to obtaining prescription drugs from a pharmacy or through physician-administered treatments. Patients and physicians often must navigate complex and resource intensive requirements. These are consequential problems that may negatively impact the ability of patients to obtain needed medications in a timely manner and to maintain treatment.

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 due to those higher costs as well. Patients may take greater clinical risks when treatments are cost prohibitive. If patients delay, forgo, or ration their pharmaceutical treatment, their health status may deteriorate. This means patients who cannot afford their medication will

[1] Throughout this document the term pharmaceuticals and prescription drugs are referenced—both encompass biologicals and biosimilars as well.

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 typically 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 continues 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 management utilization 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.

Two broad pathways: pharmacy-dispensed or physician-administered pharmaceuticals

While physician practices are varied and patient coverage and preferences differ markedly, there are generally two different ways in which patients receive their prescription drug treatments: pharmacy-dispensed or physician-administered.

First, a physician or other duly licensed clinician prepares a prescription and it is either transmitted electronically, or in some instances, provided to the patient who then takes it to a pharmacy. The physician is not involved in the acquisition or dispensing of the medication, but, as detailed below, this does not insulate physicians and their practices from administrative and other resources costs. The patient then must obtain the medication from a pharmacy. The dispensing pharmacy is responsible for obtaining any applicable payments from the patient and health insurer. For patients who receive a prescription from a clinician, many of the policies, processes, and challenges to ensure they receive and take their medicine are similar across Medicare and commercial insurers. For Medicare beneficiaries this may be a benefit under the Medicare Part D prescription drug benefit. Alternatively, Medicare Part D benefits may be bundled together with inpatient and outpatient covered services in a single private plan (referred to as Medicare Advantage/Part C).

Alternatively, a physician may administer a pharmaceutical treatment to the patient. In this scenario, the physician must obtain, store, prepare, and administer the pharmaceutical. The physician is responsible for seeking reimbursement from any applicable insurer in addition to any applicable patient co-payment or deductible. Patients who have health insurance may have coverage for outpatient care that includes physician-administered pharmaceutical treatments, which, by way of example, for Medicare beneficiaries are covered and paid under the Part B benefit and are often referred to as Part B drugs. Part B drugs are a subset of pharmaceuticals that treat chronic and/or severe illnesses, such as cancer and rheumatoid arthritis, which require much greater physician involvement than a normal prescription that patients obtain from a pharmacy. Part B drugs typically must be injected or infused in a physician's office or outpatient facility, and often require clinical monitoring. Based on a recent U.S. Government Accountability Office (GAO) report, the general payment methodologies for physician-administered drugs vary across public insurers and commercial insurers.

There are different reimbursement systems for the Medicare Part B physician-administered drugs and those covered under Medicare Part D, and these differences are mirrored in the commercial market. The challenges that patients and physicians face are mounting under both pathways, as discussed below. The methods used by commercial and public insurers to cover and calculate payment for medication varies based on whether it is a pharmacy-dispensed or a physician-administered drug. This has implications for the requirements, tasks, and resources that physicians and their staff must expend to ensure that a patient has timely access to treatments.

Pharmacy-dispensed pharmaceuticals

With increasing frequency over the past decade, physicians no longer are able to prepare a clinically appropriate prescription for their patient and be reasonably assured that the patient will be able to receive the medication and take it on a consistent basis as prescribed. In 2016, 89 percent of prescriptions dispensed were for generic pharmaceuticals;[2] yet, the savings provided by generic use has been overshadowed by the increase in prices for brand drugs as well as for older, previously affordable, pharmaceutical treatments. These developments have led to a burgeoning number of more restrictive commercial and public insurer prescription drug plan designs and medication utilization management policies.

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, as discussed below, physicians rarely have readily accessible, accurate, up-to-date information on a patient's coverage and the insurer's utilization policies, along with clinical options and cost, at the point-of-prescribing. Both public and commercial insurers now have a large number of utilization management programs, such as medication step therapy, dosing limits, and prior authorization. The lack of uniformity or consistency places additional strain on a physician practice.

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. Typically, a physician and patient learn that prior authorization is required when the pharmacy staff notify them. 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, 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, delay, and paperwork.

Step therapy

Insurers have developed formularies of certain covered pharmaceuticals that require a patient to try a less expensive drug to ascertain whether it is effective before a more costly alternative will be covered. This step therapy requirement may not be known to the patient or physician in advance. The pharmacy staff will typically notify the patient and physician practice after the prescription is transmitted through e-prescribing or provided by the patient to the pharmacy. 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

[2] *Generic Pharmaceutical Access & Savings in the U.S.*, Association for Accessible Medicines (2017)

expensive alternative was not effective for the patient. Step therapy "shifts clinical decision-making away from physicians and toward centralized policies that define treatment steps for patient populations based on the potential for more cost-effective care."[3] Evidence is lacking that step therapy approaches improve patient outcomes. Rather, step therapy can "delay access to the most efficacious therapies, potentially trades prescription spending for time and hospital costs to patients and providers," and "fail-first policies, as their name suggests increase the risk of dangerous side effects."[4]

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 process for the patient, delaying necessary treatment and absorbing 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.

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

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 prescription drug 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.

Health plans and pharmacy benefit managers (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, 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. As a result, last year the AMA launched a grassroots campaign and website, TruthinRx.org, the goal of which was to expose the opaque process that pharmaceutical companies, PBMs and health plans 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.

Finally, 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

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[3] Does A 'One-Size-Fits-All' Formulary Policy Make Sense? Adrienne Chung, Joanna MacEwan, Dana Goldman. Health Affairs Blog.

[4] Id.

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.

The foregoing are just some of the onerous aspects of helping a patient obtain a prescription written by their physician or other duly authorized prescriber on the health team. The negative impact on physicians and patients of such policies that have been applied by insurers to pharmaceuticals (as well as devices and medical services and procedures) has prompted the AMA–along with a growing number of national medical specialty societies and state medical associations— along with the American Hospital Association, the American Pharmacists Association, and other stakeholders to call upon health plans, benefit managers, and any other party conducting utilization management, as well as accreditation organizations, to apply Prior Authorization and Utilization Management Reform Principles (Reform Principles) developed by these stakeholders. The Reform Principles include a number of recommended solutions.

Physicians are looking for the tools that would help their patients and their care teams to make the right clinical decision that meets patient clinical and coverage needs and personal preferences. There are promising examples that the AMA has committed to exploring and advancing. A recent publication on *The Impact of Information Technology on the Diffusion of New Pharmaceuticals*, which is part of a National Bureau of Economic Research Working Paper Series, found that physicians with information about generic drug availability and patient insurer formulary data at point-of-prescribing will prescribe more generics. The researchers combined data on prescriptions and use of a point-of-care electronic pharmaceutical reference database for over 125,000 individual U.S. physicians. They found that physicians who relied upon the reference database prescribed a significantly more diverse set of products, were faster to begin prescribing new generic drugs, and had a greater propensity to prescribe generics in general. Interestingly, the researchers found that physicians using the reference database were not faster to prescribe new branded drugs. The researchers concluded that the results suggested improvements to physician information access could have important implications for the costs and efficiency of medical care. It is clear that transparency among plans to aid global databases that are well-designed and clinically validated and updated could reduce administrative burdens and increase value.

Physician administered pharmaceutical treatments

The challenges associated with securing authorization or complying with applicable utilization policies of commercial and public health insurers discussed above concerning pharmacy dispensed drugs apply as well for physician-administered pharmaceuticals. In addition, physicians must comply with additional state and federal laws, regulations, and standards related to the professional licensing, acquisition, storage, preparation, administration, and disposal (when applicable) of physician-administered pharmaceuticals. In addition, physicians must have compliance and training programs for staff along with adequate staffing. All of the foregoing factors are relevant when considering the methodologies employed by Medicare and other public and commercial insurers to reimburse for physician-administered pharmaceuticals. Larger practices and hospital outpatient departments are able to leverage economies of scale for acquisition, overhead, and compliance savings that smaller, community-based physician practices with established relationships with patients often cannot.

In 2016, the GAO reported that compared to Medicare, other public insurers generally paid rates that were the same or lower than Medicare payment for physician-administered pharmaceuticals.[5] In the Veterans Choice Program the Veterans Health Administration reimburses providers at negotiated rates that, in

[5] *Physician-administered Pharmaceuticals: Comparison of Insurer Payment Methodologies* (GAO, August 1, 2016)

general, cannot exceed, and are, according to the GAO, usually equal to, Medicare's rate. State Medicaid plans under fee-for-service reimburse providers at their acquisition cost, as defined by the state. The GAO found that states often define acquisition costs at Medicare's rate. Finally, the GAO noted that, in contrast to Medicare, two commercial insurers often had higher than Medicare's rate. GAO found when interviewing the two commercial insurers that it could be the case that the Medicare payment rates are used as a benchmark for negotiation and the final commercial insurer rates are often above the Medicare rate. The GAO found that insurers' pharmaceutical utilization management and cost-containment approaches for physician-administered pharmaceuticals also varied. The GAO used as an example that certain insurers may be able to leverage purchasing power to negotiate lower payment rates.

As the Medicare program serves as a benchmark for other public and commercial insurers, the following summarizes the current responsibilities and challenges that physician practices face under the Medicare Part B program for physician-administered pharmaceuticals. Currently, Part B drugs are set at the Average Sales Price (ASP) +6 percent. The ASP is defined as the volume weighted average manufacturer sales price net of all rebates, discounts, and other price concessions. Pharmaceutical manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) are required to submit ASP sales prices and volume to CMS quarterly for each pharmaceutical. CMS then uses this data to calibrate the ASP rates in a subsequent quarter, with a two-quarter lag (i.e., first quarter sales are the basis for third quarter ASP payment rates). Under budget sequestration, however, Medicare is required to make a two percent reduction in its 80 percent share of covered charges, so that the actual rates are ASP+4.3 percent today.

Pharmaceuticals paid under Medicare Part B generally fall into three categories: (1) pharmaceuticals furnished incident to a physician's service in the office or HOPD; (2) pharmaceuticals administered via a covered item of durable medical equipment; and (3) other categories of pharmaceuticals explicitly identified in the law. Physicians purchase the pharmaceuticals directly from manufacturers and distributors, and Medicare reimburses physicians for the cost of the pharmaceuticals. A separate payment is made for administration of the pharmaceutical.

The ASP is an average, so nearly half pay more than average and nearly half pay less. Physicians who pay more than average, often small practices or rural providers, start at a disadvantage with this methodology. The rebates and discounts that ASP incorporates typically are only secured by hospitals and other large purchasers, which has over time reduced the ASP and created tremendous financial pressure on physician practices (small and mid-size) because they are not able to negotiate such discounts, nor do they have the financial reserves to benefit from prompt pay discounts. In addition, some beneficiaries may not be able to meet their 20 percent copayment, which then falls to the practice as debt. Another pressure is the two quarter lag time for ASP payment rates to reflect current prices—the fluctuation in price may be significant enough that physicians face losses. Furthermore, physicians can also be reimbursed inaccurately due to prompt-pay discounting programs where discounts negotiated between the manufacturer and the distributor are included in the calculation of the ASP, but not passed through to physicians decreasing their margins for reimbursement. In contrast, hospital outpatient departments (which are more expensive sites of service for Medicare) are often able to obtain pharmaceuticals below the existing reimbursement rate.

It is already the case that many smaller practices have had to refer cancer and other patients who need chemotherapy and other expensive life-saving drugs to hospital outpatient departments, thereby undermining continuity of care and creating burdens for frail and medically compromised patients. A study by the Moran Company puts the shift in chemotherapy services for Medicare patients at 30 percent between 2005 and 2011. Data from the Medicare Payment Advisory Commission came to a similar conclusion, specifically noting that Medicare Part B drug expenditures in hospital outpatient departments grew at 20 percent a year between 2009 and 2012 compared to five percent a year in physician offices. Studies by Moran, Milliman, and Avalere all have found that this shift increases costs to both the insurers

and patients. A 2012 study by Avalere concluded that after adjusting for patient risk the average total cost of care for chemotherapy patients was about 24 percent higher in the hospital outpatient department than in a physician office. It found that the cost of chemotherapy in the hospital outpatient department exceeds costs in the office by 42 percent to 67 percent, with the cost of the drug itself coming in at 25 percent to 47 percent higher in the hospital outpatient department.

For small physician practices, opportunities to select between pharmaceutical treatments can be limited. Physicians often have little flexibility to choose between different pharmaceuticals, either because the patient's condition will dictate use a particular drug treatment, or because eventually they are going to have to use each of the options. As noted by MedPAC, in oncology, the appropriate medication regimen for a particular patient depends not just on the type of cancer but on the stage and other variants. Some of the pharmaceuticals are given together. Some are given sequentially; as the efficacy of the first choice drug wanes, a second and then potentially a third one will be used. Cancer drugs in particular are toxic, requiring special inventory management and safe handling by specially trained personnel which is another cost.

When physicians are not able to offer physician-administered pharmaceuticals, the gains that could be realized from the various innovation initiatives for breakthrough drugs will be undermined by payment methods that forces physicians to refer to practices that do not have an established relationship with the patient, so the most appropriate targeted treatment can be received. Fragmentation of care for patients faced with serious health challenges can contribute to poor outcomes.

Conclusion

The AMA thanks the Subcommittee for this hearing and for careful consideration of the cost and administrative burdens associated with rising pharmaceutical costs. We welcome the opportunity to work closely with the Subcommittee moving forward.