AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

Common-Sense Steps to Reduce the Cost of Health Care in the U.S.: Part II

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CONTENTS

INTRODUCTION

According to the Centers for Medicare and Medicaid Services ("CMS"), total U.S. health care spending topped $3.3 trillion in 2016,[1] representing almost 18 percent of the entire U.S. economy. This level of spending has strained the budgets of consumers and taxpayers.[2] Many Americans cannot afford health care services and treatments. The costs of medical care not covered by health insurance can lead to significant debt and bankruptcy.[3] For example, individuals with cancer are 2.6 times more likely to declare bankruptcy than individuals without cancer.[4] As such, all stakeholders, including the federal and state governments, insurers and pharmacy benefit managers, the pharmaceutical industry, pharmacies and pharmacists, health care practitioners, hospitals, and consumers, must do their part to reduce the costs of health care.

Aimed Alliance recommends that big-picture reforms be enacted nationally to improve the quality, and reduce the costs, of health care. Specifically, Aimed Alliance set forth principles for health care reform in Advancing Quality Health Care in the U.S.: A Roadmap for Consumer-Focused Reform. Aimed Alliance also provided state-level recommendations during its May 2016 legislative working group meeting, Closing Legal Loopholes to Improve Health Care.

In this three-part series, Aimed Alliance sets forth common-sense steps multiple stakeholders can take to help reduce the costs of health care for U.S. consumers and taxpayers under the current system. The proposals in this series are intended to address shortcomings in the current health care system. They are intended to be partial, interim fixes in the absence of system-wide reforms. Part one, published by Aimed Alliance in May 2018, focused on the federal government. This report is part two. It provides recommendations for the health insurance industry, pharmacy benefit managers, and pharmaceutical manufacturers. Part three will identify actions pharmacies, pharmacists, health care practitioners, hospitals, and consumers can take to reduce health care costs without sacrificing the quality of care.

The series accounts for the priorities of the Trump Administration and the political challenges the U.S. Congress has faced in 2018.

I. INSURERS

Insurers can modify several aspects of their business models to reduce health care costs. Possible actions include streamlining benefit utilization policies; providing coverage for services that can reduce long-term health care costs; providing timely, accurate information on health care policy benefits and their associated costs; and integrating pharmacy and medical benefits.

A. IMPROVE ADMINISTRATIVE EFFICIENCY OF BENEFIT UTILIZATION MANAGEMENT POLICIES

Health insurers should streamline administrative processes used to implement benefit utilization management policies to improve efficiency, reduce administrative burdens on providers and patients, and cut down on unnecessary spending. Benefit utilization management is "a set of techniques used by or on behalf of purchasers of health care benefits to manage health care costs by influencing patient care decision-making through case-by-case assessments of the appropriateness of care prior to its provision."[5] Examples of benefit utilization management policies include prior authorization, step therapy, nonmedical switching, and copay accumulator programs.

1. PRIOR AUTHORIZATION

The prior authorization process costs the United States health care system an estimated $23 to $31 billion each year.

Prior authorization policies require a practitioner or a plan enrollee to obtain an insurer's approval before the insurer will cover the cost of a treatment or medication.[6] Once a request for coverage is made, the insurer determines whether the treatment meets the insurer's medical necessity standards. While prior authorization policies are intended to save the health plan money, in their current form, they often result in administrative waste. The process can be time consuming and involve completing various forms using outdated modes of communication (e.g., paper copies submitted via fax) and lengthy follow-up calls.[7]

According to a 2018 survey conducted by Aimed Alliance, 63 percent of primary care physicians ("PCPs") reported that they needed to obtain 10 or more prior authorizations on behalf of their patients per week from insurers, and 84 percent of PCPs reported prior authorization requirements caused serious problems.[8] Practitioners spend an average of twenty hours per week completing paperwork to satisfy prior authorization requirements for treatments and tests, according to the American Medical Association.[9] According to a national survey conducted in 2009, the prior authorization process costs the United States health care system an estimated $23 to $31 billion each year.[10] Moreover, some insurers require

patients with chronic conditions to resubmit prior authorization requests every few months even though their condition has not, and may never, change, thereby creating significant administrative waste.[11] Others have cancelled or withdrawn previously approved prior authorization. Recurring prior authorization requirements or cancelled authorizations can delay care delivery, affect treatment adherence, cause poor health outcomes, and, as result, increase costs.[12]

Insurers can take several measures to improve administrative efficiency, save providers and patients time and resources, and reduce overall costs. Insurers should accept universal forms for prior authorization, which should be accepted electronically and tracked. Doing so will streamline the prior authorization process and cut down on administrative waste. For ongoing treatment plans, insurers should honor approved prior authorization requests for the duration of a patient's course of treatment.[13] For individuals with chronic conditions, prior authorization should be valid for the entirety of the plan year and inclusive of any renewal periods. Insurers should not revoke, limit, or condition coverage after approving prior authorization requests in order to avoid administrative burdens for providers and patients and delays in access to care.[14] Insurers also should provide accurate prior authorization information to electronic health record vendors to ensure that providers have up-to-date information at the point of care.[15]

2. STEP THERAPY

Step therapy policies, which are also referred to as "fail first," require individuals to try and fail on other treatments before an insurer will cover the treatment that was originally prescribed.[16] In theory, these policies are intended to steer patients into using safer, more established, and less expensive drugs over newer and more expensive medications.[17] In practice, step therapy policies can be unethical and inconsistent with standards of care, resulting in interference with the practitioner-patient relationship and significant delays in access to prescribed treatments.[18] Treatment delays can cause an individual's condition to worsen while they wait for approval of a prescribed treatment.[19] Additionally, individuals who switch plans may have to start the step therapy process over again, thereby failing on the same ineffective drugs more than once before accessing their prescribed treatment.[20] This process can delay access to effective care, affect stability, and lead to poor outcomes, which increases costs for patients and the health care system overall.

As a result of delays, individuals may experience increased health care utilization, thereby adding costs for the insurer as well.[21] For example, when Georgia's Medicaid program adopted a step therapy policy for schizophrenia medications, the program initially saved $20 per member per month.[22] However, the state

subsequently spent $32 per member per month on outpatient services because the medications used by patients were ineffective.[23]

To reduce administrative burdens and resulting delays in care, insurers should provide a fair and timely process for plan enrollees to request a step therapy override.[24] Step therapy protocols should be based on clinical guidelines and scientific evidence. Moreover, the override process should allow for automatic exceptions to step therapy requirements if 1) a required drug could result in an adverse reaction; 2) a required drug may be ineffective for the particular patient; 3) the prescriber deems the drug medically inappropriate; 4) the patient previously tried and failed on the drug; or 5) the patient is stable on another medication.[25] If an automatic override is not feasible, then decisions on an override request should be made within 24 hours in urgent cases and 48 hours in non-urgent cases.

3. NONMEDICAL SWITCHING

Insurers sometimes make negative changes to their formularies after a plan year has begun, which can result in stable patients rationing their current, effective medication; switching from the current, effective medication to an alternative drug; or stopping treatment altogether. These negative formulary changes may include removing the medication from coverage, placing the drug in a higher tier, or increasing the out-of-pocket costs to the patient so that the treatment is no longer affordable. While such changes may save costs on the formulary side of the plan, they may increase costs on the medical side of the health plan.

A recent analysis of commercial health care claims found that potential cost-motivated changes to drug formularies resulted in higher medical services costs.[26] This trend was found for nine different chronic conditions, supporting a conclusion that continuity of care for patients with pre-existing prescriptions for chronic conditions could help control costs.[27] Similarly, a recent survey of a group of patients in Tennessee diagnosed with chronic or rare diseases found that when a health plan's formulary reduced coverage of a prescribed medication, 58 percent of plan enrollees who had to switch medications reported side effects from the new medication, including hospitalization.[28] As such, health plans should not limit or reduce coverage for any medication after the plan year has begun, including by 1) limiting or reducing the maximum coverage of prescription drug benefits; 2) increasing out-of-pocket costs for a covered medication; 3) moving a prescription medication to a more restrictive tier if the insurer uses a formulary with tiers; or 4) removing a medication from a formulary. Alternatively, they should allow stable patients to stay on their current, effective medication for the remainder of the plan year and subsequent years if patients reenroll in the same plan. Allowing stable patients to stay on their current medications can lower health care costs because maintaining the status quo may result in better health, fewer doctor visits, and fewer hospital stays.[29]

4. COPAY ACCUMULATOR PROGRAMS

Copay accumulator programs have also increased health care cost-sharing for consumers. Some consumers who are prescribed more expensive treatments are often able to obtain a finite amount of assistance for their copayments or coinsurance from drug manufacturers in the form of coupons. These coupons have traditionally counted toward consumers' deductibles and maximum out-of-pocket limits ("MOOP"). However, insurers have begun adopting copay accumulator programs, which prohibit coupons from accruing toward the health plan enrollee's deductible or MOOP. As a result, consumers who depend on copay assistance to offset high out-of-pocket costs for medication must pay their full health plan deductible once their copay assistance is exhausted.[30] This is especially burdensome for individuals in high deductible health plans.

Although the premise behind copay accumulator programs is to reduce drug spending by encouraging consumers to choose lower-cost medications, over 50 percent of the medications for which copay assistance is available have no generic substitute at all or only have another similarly priced, brand therapeutically equivalent drug, making these programs a poor cost-control tool.[31] Instead, consumers without alternative drug options are more likely to ration or stop taking their medications altogether once the financial assistance cap is reached,[32] or patients who are stable on their current medications may feel financial pressure to switch to alternatives that are not effective for them or that could result in adverse events. Individuals who do not adhere to their treatment program have higher medical expenses, including increased office visits and hospitalizations resulting from adverse events, relapses, and disease progression.[33] As such, any cost savings that insurers receive from forcing additional deductible costs onto consumers through copay accumulator programs will likely be outweighed by the increased medical spending.[34]

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Insurers should not adopt copay accumulator programs, and they should take special care not to have such programs in high deductible health plans. If they do adopt copay accumulator programs, they should allow exemption processes, especially if no generic medication exists for a particular treatment for which a plan enrollee is using copay assistance.

B. COVER PHARMACOGENIC TESTING TO OPTIMIZE TREATMENTS AND REDUCE ADVERSE DRUG REACTIONS

Insurers should cover preemptive pharmacogenetic testing ("PGx") so patients with certain genetic dispositions can avoid unnecessary, inefficient, and unsafe treatments. Pharmacogenetics is a relatively new field that studies how genes affect a person's response to a particular medication.[35] It combines the science of drugs (pharmacology) with the study of genes and their functions (genomics) to tailor medications and doses based on a person's genetic profile.[36] For example, genetic variability in certain drug metabolizing enzymes can alter the level of active metabolites in a patient's system, which may warrant the use of a different drug or dose for a particular patient.[37] Several well-replicated pharmacogenetic associations exist and, as such, the FDA now includes PGx biomarker information in more than 100 drug labels.[38]

When used appropriately, PGx can help practitioners optimize drug therapy and reduce the risk of adverse medication effects and drug interactions,[39] which are a major cause of morbidity and mortality, account for up to 30 percent of hospital admissions, and cost the U.S. approximately $170 billion annually.[40] It has been estimated that preemptive PGx—testing patients for a number of genetic biomarkers up front whether or not patients are currently prescribed medications associated with particular markers[41] —can save costs over the long term. A recent study evaluating the impact of preemptive PGx found that 99 percent of more than 1,000 study participants carried an actionable PGx variant in at least one gene, suggesting that "preemptive PGx genotyping may benefit most individuals, with particular value in individuals taking multiple medications."[42] Another recent study concluded that preemptive PGx at the age of 40 could prevent 17 percent of adverse drug reactions, which may result in a savings of $23 billion in health-related costs.[43] Similarly, another study estimated that an additional $12 billion could be saved if preemptive PGx is offered during infancy.[44] Given PGx's potential to reduce long-term costs, insurers should increasingly cover preemptive PGx, especially as evidence regarding cost effectiveness and clinical utility grows in this rapidly developing area of medicine.

C. INCREASE TRANSPARENCY OF BENEFITS AND COSTS

Insurers should increase the transparency of their benefit designs and the associated cost-sharing responsibilities. Doing so allows consumers to make informed decisions about their health care when selecting a plan and when starting new treatments or obtaining health care services.

As consumers continue to shoulder a larger portion of their health care costs, the availability of timely, accurate information on cost and quality could impact

consumers' choices, increase competition, and reduce costs for all stakeholders.[45] Yet, unlike nearly every other major sector of the U.S. economy, consumers generally lack such information. Surveys have shown that consumers want greater transparency and would compare health care prices if given the option,[46] and some evidence indicates that health insurer price transparency can reduce costs.[47]

Unlike nearly every other major sector of the U.S. economy, health care consumers generally lack information on service cost and quality.

While insurers are required to provide consumers with certain information about health plans, they do not always provide detailed information about out-of-pocket costs for treatments and services.[48] As such, health plans should provide information on the estimated costs for each medication covered in their formularies as well as the estimated costs for covered medical services, especially if such medications or services require coinsurance instead of copayments. Coinsurance, which requires a plan enrollee to pay a set percentage of a covered service, is far less transparent than copayments, which are flat fees, given that plan enrollees typically are unaware of the cost of a treatment or service at the point of care.[49]

Alternatively, insurers can choose not to impose coinsurance requirements at all and only require copayments. While many insurers currently provide price transparency tools for consumers, the effectiveness of such tools has been found to be limited due in part to low utilization rates and lack of consumer awareness.[50] As such, insurers should implement marketing strategies to improve consumers' awareness of the availability of price transparency tools. In addition, insurers should invest in measures aimed at improving price transparency at the point of care, as patients are more likely to act on pricing information when presented at the point of care.[51] Similarly, insurers should also work with electronic health record vendors to incorporate accurate formulary data and benefit utilization requirements to ensure that providers can discuss such information with patients at the point of care.[52]

By improving transparency, consumers can select a plan that meets their individualized needs in terms of covered health care treatments and services, as well as the costs they are willing to pay out of pocket for those treatments and services.

D. INTEGRATE PHARMACY BENEFITS AND MEDICAL BENEFITS

Health insurers should integrate pharmacy benefits and medical benefits within health plans to control health care utilization and spending.[53] Oftentimes, a

health plan's pharmacy and medical benefits[i] operate in silos. Silos are the result of a fragmented system whereby operational branches are focused on their own unique challenges and costs, data is not shared, and decisions are made without consideration of the impacts on the "big picture" objective of improving patient outcomes.[54] Silos can lead to suboptimal clinical and cost management.[55]

Managing the costs of prescription medications alone misaligns incentives to achieve both good clinical and financial outcomes for plan enrollees.[56] Rather, insurers must focus on managing total, long-term health care costs.[57] By integrating pharmacy and medical benefits, there is less of a conflict over silo management issues.[58] A 2017 study by Cigna found that plan enrollees whose medical and pharmacy benefits were both administered by Cigna were more engaged in managing their health conditions, resulting in a cost savings of approximately $253 per individual.[59] According to Cigna, gaining "a real-time view of … customers' health needs across both their pharmacy and medical benefits enables [Cigna] to more easily identify and support those who need help in managing their heath."[60] This improved health engagement can also result in cost savings for employers, especially with respect to plan enrollees with certain chronic conditions. For example, employers saved an average of $2,816 on annual medical costs for each plan enrollee with diabetes who had both pharmacy and medical benefits administered by Cigna.[61] Therefore, to improve health outcomes and reduce unnecessary health care spending, plans should consider integrating their medical and pharmaceutical benefits.

II. PHARMACY BENEFIT MANAGERS

Pharmacy Benefit Managers ("PBMs") are organizations that administer prescription drug plans on behalf of health insurers. They serve as intermediaries between health insurers, drug manufacturers, and pharmacies. One primary function of PBMs is to decrease drug costs for the insurer, and ultimately, the end user. Traditionally, PBMs have served this function by negotiating discounts and rebates with drug manufacturers on behalf of insurers, developing drug formularies[62] for pharmacy benefit plans, contracting with pharmacies, and processing and paying prescription claims.[63]

Recently, PBMs have received criticism for taking advantage of their strategic position as intermediaries between health insurers and other parties in the health system, allowing them to generate substantial profits at the expense of plan enrollees.[64] However, given their strategic position, PBMs have a significant opportunity to help lower the costs of health care in the U.S. Commonsense changes, such as passing rebates on to consumers, engaging in outcomes-based pricing arrangements, and ending clawback schemes and price spreading could result in significant cost-savings.

[i] "Pharmacy benefit" refers generally to the coverage of prescription drugs that are generally self-administered. "Medical benefit" refers generally to the coverage of medical, surgical, exploratory, therapeutic, or emergency care. In addition, drugs that are injected or infused in the office of a health care professional by a healthcare professional are covered under the medical benefit.

A. PASSING REBATE SAVINGS ON TO CUSTOMERS

PBMs should pass rebate savings negotiated with drug manufacturers on to insurers, who should then share them with consumers. PBMs negotiate lower medication prices with drug manufacturers in the form of rebates in exchange for listing the medications on the PBMs' formularies.[65] In theory, PBMs are supposed to pass the rebates on to insurers, which can then pass discounts on to plan enrollees. Yet, PBMs often keep a portion of the rebates as profit, which they reclassify as "administrative fees," rather than passing them on as savings—a concept referred to as "pass-through pricing."[66] In addition, the rebate system incentivizes PBMs to promote high-cost drugs to increase the profit they receive from rebates, referred to as "rebate pumping," instead of focusing on improving patient care and lowering prices.[67] As such, the rebate system in its current form creates an inherent conflict of interest for PBMs.[68]

Rather than reclassifying rebates as administrative fees, PBMs should follow the lead of UnitedHealthcare ("UHC") and pass the rebates on to insurers, who in turn should pass them on to plan enrollees in the form of lower drug prices. In response to growing consumer frustration over high drug prices, UHC recently announced that it would expand its direct-to-consumer pharmacy discount effective January 1, 2019.[69] Through a combined effort with its PBM, OptumRx, UHC will provide plan participants enrolled in fully-insured commercial group benefit plans with savings from pharmacy manufacturer rebates at the point of sale. UHC already gives employers who self-insure the option of passing rebates on to its employees. UHC predicts that the expanded discount program, which some have called a "step on the path to creating a more transparent pharmacy supply chain," will affect 7 million enrollees.[70] It has been estimated that PBMs generated a combined $130 billion in rebates in 2016.[71,ii] Such action can result in major cost-savings to both insurers and consumers, and other PBMs should follow suit.

PBMs generated a combined $130 billion in rebates in 2016, which could be passed directly to consumers, or to insurers to lower premiums.

B. PROMOTE OUTCOMES-BASED PRICING ARRANGEMENTS

PBMs should engage in outcomes-based pricing arrangements with drug manufacturers to reduce out-of-pocket costs for consumers, ensure medications are worth their price, and improve treatment adherence. Outcomes-based pricing is a payment arrangement between PBMs and drug makers that ties the price of a medication to how well it works. It requires drug manufacturers to provide PBMs with a rebate if the medication is ineffective for the consumer.[72] As such,

[ii]However, given that PBMs do not disclose rebates received from manufacturers, it is unclear what percentage they keep for themselves.

PBMs that adopt outcomes-based pricing contracts with pharmaceutical manufacturers can ensure that newer or more expensive modications are delivering value for their costs. Outcomes-based contract provsions can provde a check on increasingly expensive medication price and ensure new medications provide measurable clinical benefits for patients.[73]

Outcomes-based pricing can increase patient adherence to prescribed medications, which can help reduce overall medical costs.[74] Under some outcomes-based pricing arrangements, if a patient does not adhere to the treatment regimen, then the PBM does not qualify for the rebate.[75] To boost medication adherence rates, insurers and PBMs can adopt predictive analytics and artificial intelligence to identify patients that are more vulnerable to medication non-adherence and utilize intervention methods.[76] Such methods may include targeting patients through mobile apps, phone calls, letters, and other communication methods to check on their progress and remind them to take their medication.[77] Improving patient adherence can reduce avoidable health expenses. Patient non-adherence to prescribed medications results in an estimated $337 billion per year in additional medical and pharmaceutical expenses.[78]

Therefore, PBMs and drug makers should work together to adopt outcomes-based pricing strategies to tie coverage of new or more expensive drugs to improved patient outcomes, reduce unnecessary medical expenditures, and obtain rebates should a medication not work.[79]

C. END CLAWBACK PRACTICES

PBMs should end clawback practices in efforts to reduce drug costs for consumers. PBMs negotiate medication copayment rates with pharmacies. In some instances, the copayment rate that PBMs negotiate is so high that it exceeds the amount paid by uninsured patients and those who pay in cash without using their insurance benefit.[80] In such a case, PBMs will provide a percentage of the profit from that copayment to the pharmacy and keep the difference for themselves.[81] These overpayments that PBMs receive are referred to as clawbacks.

Compounding the problem, most patients do not realize that they could pay less for their medication if they do not use their insurance plan because of “gag clauses” in contracts between pharmacies and PBMs. These gag clauses bar pharmacists from informing consumers about less expensive options to pay for their medications.[82] Fortunately, on October 10, 2018, President Trump signed two laws into place that prohibit gag clauses. First, the Know the Lowest Price Act of 2018 prohibits the use of gag clauses in Medicare Part D and Medicare Advantage prescription drug plans effective January 1, 2020.[83] Specifically,

Medicare prescription drug plan sponsors and Medicare Advantage organizations cannot prevent pharmacies from, or penalize pharmacies for, informing plan enrollees that they may pay less out of pocket if they obtain a prescription medication from the pharmacy without the use of insurance coverage.[84] Second, the Patient Right to Know Drug Prices Act similarly prohibits insurers offering group or individual health coverage from using gag clauses, and also requires them to ensure that any PBMs they contract with do not implement gag clauses in pharmacy contracts.[85] Therefore, pharmacists largely will now be able to openly discuss medication prices and reduce out-of-pocket drug costs for many consumers.

PBMs should voluntarily remove gag clauses from their contracts even prior to these new laws going into effect in order to promote transparency and allow pharmacists to inform consumers that their medication is available at a lower price if they pay out of pocket rather than purchasing their medication through their insurance plan.[86]

PBMs should also end clawback practices, which can have a significant impact on the cost of health care. According to a 2013 study, clawbacks occurred on 28 percent of commercial pharmacy claims for generic drugs and six percent for brand drugs. PBMs received an estimated total overpayment of $135 million.[87] Therefore, this easy fix could have a significant impact at the pharmacy counter.

D. END SPREAD PRICING

PBMs should refrain from engaging in excessive spread pricing so that cost-savings can be passed on to insurers and, subsequently, consumers. Spread pricing refers to a practice in which the PBM charges the health plan more than it pays a pharmacy for dispensing a medication.[88] Similar to clawback practices, the PBM keeps the difference, or the "spread" between the two prices.[89] This practice inflates the cost of health care. PBMs typically earn anywhere from $5 to $200 per prescription without the pharmacy's or the health plan's knowledge.[90] Moreover, the PBM charges the insurer the spread price on top of any negotiated maintenance fee it collects to administer the insurer's prescription drug benefit program.[91]

In addition, when engaging in spread pricing, PBMs can reduce the prices on their "maximum allowable cost" (MAC) list for generic drugs. A MAC list includes a maximum amount that a plan or PBM will pay for generic drugs and for brand drugs that have generic versions available.[92] When PBMs reduce prices on their MAC lists to those below a pharmacy's costs, pharmacies are forced to take a financial loss to serve their customers.[93]

Rather than engaging in excessive spread pricing, PBMs should simply charge insurers a transparent maintenance fee and adopt pharmacy-friendly MAC pricing standards. As a result, cost savings can be passed on to the consumer.

III. THE PHARMACEUTICAL INDUSTRY

In 2016, American spending on retail prescription medications grew by 1.3 percent to a total of $328 billion. The spending growth was significantly low compared to 2014 and 2015 in which growth over the prior year was 12.4 and 8.9 percent, respectively.[94] Nevertheless, specialty drug spending has outpaced spending on other drugs, with growth rates reaching as high as 22.9 percent between 2013 and 2014.[95] Specialty drugs are generally used to treat complex conditions that require significant patient monitoring and specialized handling or administration, and they often have complicated manufacturing processes.[96]

Pharmaceutical companies attribute high drug prices in part to the high cost of research and development in the United States. The total cost to develop a new drug and bring it to market is estimated to range between $800 million to $2.6 billion.[97] Such estimates are impacted by several factors, including development time and likelihood of approval.[98]

Although the cost of research and development is high, pharmaceutical companies can reduce the cost of health care for Americans by ensuring that the value of medications match their prices and by improving competition in the marketplace.

A. UTILIZE OUTCOMES-BASED PRICING

The pharmaceutical industry should embrace outcomes-based pricing models for newer and more costly treatments, particularly in those markets where older, alternative treatments exist.

In exchange for placement on a drug formulary, pharmaceutical manufacturers may enter into outcomes-based contracts that require them to offer insurers or PBMs discounts if a medication turns out to be ineffective for individual plan beneficiaries.[99] As discussed above, outcomes-based pricing allows manufacturers to show the value of newly developed medications by tying the overall price to measurable clinical outcomes. This pricing method facilitates patient access to new treatments through insurance coverage and protects insurers and PBMs from paying increasingly high costs for new drugs

Outcomes-based pricing can protect insurers and PBMs from paying high costs for new drugs that offer marginal clinical benefits over older treatments.

that may not deliver significant health benefits over cheaper treatments. A 2017 survey of executives of PBMs, pharmacies, hospitals, and health insurers rated outcomes-based pricing strategies as the most promising way to lower medication prices, beating out exclusive contracts, government regulation, or using formulary exclusion lists.[100]

Pharmaceutical manufacturers should adopt outcomes-based pricing for drugs where new treatments offer significant and measurable clinical benefits. Whether a treatment offers significant clinical benefit should be measured by the patient given that patients may value treatment differently than industry. Sharing the risk and reward of bringing new medications to market can preserve coverage channels for both manufacturers and consumers, while ensuring that consumers are not overpaying for medications with little or no value.[101]

B. END PRICE GOUGING

Both brand and generic pharmaceutical manufacturers should keep medication price increases to justifiable levels. Price increases significantly above annual medical inflation levels should be paired with evidentiary support in efforts to avoid price gouging and prevent government-mandated price controls. Price gouging occurs when a drug maker raises the price of a drug to an unconscionable level. A price increase is considered unconscionable if it is "so egregiously unjust and so clearly tilted toward the party with superior bargaining power that no reasonable person would freely agree to [it]."[102]

Recently, bad actors in the pharmaceutical industry have significantly increased the price of existing medications without a legitimate reason. One of the best-known examples is Turing Pharmaceutical's 5,000 percent price increase of an antiparasitic medication shortly after acquiring the rights to the drug, which had been on the market for over 60 years.[103] The decision to increase the price from $13.50 per pill to $750 per pill in 2015 resulted in public outcry and calls to end price gouging.[104] Likewise, the maker of the epinephrine auto-injector raised that product's price by over 500 percent in less than a decade.[105] Such profit-driven price increases ultimately trickle down to consumers through higher out-of-pocket costs[106] and insurance premium hikes.[107]

Many generic medication prices are rising quickly, driving up consumers' out-of-pocket costs.[108] Over 400 generic medications saw price increases of 1,000 percent or more from 2008 to 2015.[109] Moreover, a recent congressional study observed price increases of over 300 percent for some generic medications from 2012 to 2014, while the price of several others increased well over 3,000 percent from 2013 to 2014.[110]

Recently, some manufacturers of naloxone, a medication that reverses the symptoms of an opioid overdose, have come under scrutiny for increasing their prices for the medication. The price of a branded injectable naloxone product increased from $575 in 2015 to $4,100 in 2018.[111] Likewise, the manufacturer of a generic injectable naloxone product more than tripled its price from approximately $3.75 per dose in 2012 to a current price of $11.87 per dose.[112]

Due to price gouging by a few manufacturers, the pharmaceutical industry has fallen under intense scrutiny regarding drug price increases. For example, some states have introduced legislation to improve pricing transparency and prevent price gouging.[113] At the federal level, there have been calls for the federal government to negotiate the pricing of how certain drugs. Specifically, the President's Commission on Combating Drug Addiction and the Opioid Crisis urged the President, upon declaring the opioid crisis a national emergency, to empower the HHS Secretary to negotiate reduced pricing of naloxone in order to improve access to the drug.[114] Moreover, in June, HHS Secretary Azar requested that the FDA establish a working group to determine how to safely import prescription medications from other countries in the event a single manufacturer dramatically increases the price of a drug.[115]

In response, many pharmaceutical companies have voluntarily opted to set a price increase threshold at less than 10 percent annually.[116] It should be noted, however, that price increases above the threshold could undoubtedly be justified for legitimate business reasons in certain cases, such as raw material shortages and production difficulties.[117] Moreover, drug manufacturers often raise prices to account for rebates offered to PBMs in order to get medications on formularies. Nevertheless, if the pharmaceutical industry self-imposes industry-wide good practices on price increases, such as limiting annual increases to a reasonable threshold and tying further increases to justifiable business rationales, then recently introduced state legislation and federal initiatives intended to prevent such practices may not be necessary, and cost savings may be realized by consumers.

C. END FILING OF IMPROPER CITIZEN PETITIONS

Pharmaceutical manufacturers should avoid filing frivolous citizen petitions to improperly delay generic medications from coming to market. A party may submit a citizen petition to the FDA to request the agency to take or refrain from taking a particular administrative action.[118] This includes petitions that ask the agency to take action against a pending abbreviated new drug application ("ANDA") (i.e., application for approval of a generic drug product).[119] Oftentimes, these petitions are based on claims that the generic drug pending approval does not meet required pharmacokinetic and bioequivalence standards.[120]

If the brand manufacturer submits a citizen petition early, such as when the FDA is making decisions about the bioequivalence requirements for a generic drug product, the petition may be a meaningful contribution towards the FDA's evaluation of an application.[121] However, when petitions are submitted late in the ANDA review process and do not raise valid scientific or legal issues, they may improperly delay the approval of an application.[122] As a result, Congress enacted Section 505(q) of the Food, Drug, and Cosmetic Act "to ensure that petitions are not used to improperly delay approval of abbreviated new drug applications."[123] This statute requires petitioners to certify the date they first discovered the information relied upon in the petition; specifies that the FDA cannot delay approval of an ANDA due to a request to take an action related to the ANDA, unless the request is in writing and the agency finds the delay is necessary to protect the public health; and requires the FDA to take final action within 150 days after a petition is submitted.[124]

Yet, some argue that brand manufacturers nevertheless use these petitions to delay generic market entry.[125] A recent analysis found that of the 124 section 505(q) petitions filed between 2011 and 2015, brand drug manufacturers submitted 92 percent.[126] Nearly 40 percent of the 124 petitions were filed late in the ANDA process—within six months of a patent expiration date, a data exclusivity date, or both.[127] The analysis also identified one case whereby a brand manufacturer filed a petition one day prior to the expiration of the only patent protecting the drug. As of the date the analysis was published, the FDA had not issued a substantive response for nearly one year—double the required 150-day response time.[128] In addition, one congressional report found that citizen petitions filed close to the patent expiration of a branded medication delayed approval of 10 generics, with delays ranging between 9 and 138 days.[129] Therefore, frivolous citizen petitions can significantly delay generic drugs from entering the market, thereby preventing competition and lower drug prices.

FDA Commissioner Scott Gottlieb recently stated that the agency is focused on stopping citizen petitions whose purpose is to "game" the citizen petition process and delay generic drug competition.[130] The FDA issued draft guidance on Oct. 2, 2018, which provides several factors that the agency may consider in determining whether a citizen petition's primary purpose was to delay the approval of an ANDA.[131] Among others, factors include submitting multiple petitions that raise an issue the FDA has already addressed, filing petitions at the end of a patented drug's patent exclusivity period, omitting supporting scientific data, and calling for other applicants to meet standards for testing, data, or labeling that are more rigorous than those applicable to the petitioner's product.[132] The draft guidance explains that the FDA intends to refer to the Federal Trade Commission petitions it determines have a primary purpose to delay an ANDA, raising the

The FDA intends to refer citizen petitions whose primary purpose is to delay generic drug competition to the Federal Trade Commission.

possibility of investigation and enforcement action for brand manufacturers who abuse the citizen petition process.

As such, brand manufacturers should avoid filing frivolous citizen petitions concerning their own medications in an attempt to delay generic entry. Doing so will allow consumers to have access to lower cost alternative medications sooner.

CONCLUSION

The health insurance industry, PBMs, and pharmaceutical manufacturers must proactively take part in efforts to reduce overall health care spending and the financial strain of health costs on consumers. The market-based solutions laid out herein will help achieve those goals by promoting efficient allocation of health care resources while preserving value for patients.

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