

Prescription Drug Spending in the U.S. Health Care System An Actuarial Perspective

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KEY POINTS

- Over the next decade, the Centers for Medicare and Medicaid Services projects that spending for retail prescription drugs will be the fastest-growing health care category and will consistently outpace that of other health care spending.
- Many strategies are being developed and tested, aiming at reducing prescription drug spend while maintaining or improving health outcomes.
- The important cost drivers of high prescription drug spending are increasing utilization, increasing average cost, and changes in drug mix.



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The focus of this issue brief is on prescription drug spending in the United States. The American Academy of Actuaries' Health Practice Council has undertaken a multiyear study of various components of the U.S. health financing system to help policymakers and the U.S. public better understand the challenges that are driving health spending growth and potential ways to address them.¹ Actuaries are uniquely qualified through rigorous education and experience to be experts in assessing the historical and future impact of factors and characteristics that impact levels of health care spending. The Academy's mission is to serve the American public and the U.S. actuarial profession.

Health care spending in the United States is high and continues to increase, as does the spending for prescription drugs in particular. In 2016, the U.S. spent \$3,337 billion, or 17.9 percent of the gross domestic product (GDP), on national health expenditures, of which \$329 billion was spent on prescription drugs.² In some years, prescription drug spending growth has far exceeded the growth in other medical spending, while in others it has fallen below other medical spending growth. Over the next decade, however, the Centers for Medicare and Medicaid Services (CMS) projects that spending for retail prescription drugs will be the fastest growth health category and will consistently outpace that of other health spending.³ As a result, policymakers, providers, pharmacy benefit managers, and insurers are considering options to slow prescription drug spending increases that affect health plans, consumers, and businesses. This issue brief will focus on retail prescription drugs, and not on drugs administered by physicians or in an outpatient hospital setting due to the unique characteristics associated with drugs administered in those settings.

¹ American Academy of Actuaries; "Controlling Health Care Spending Growth." Accessed at actuary.org/controlling-health-care-spending-growth/.

² Micah Hartman et al.; "National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions"; *Health Affairs* 37(1): 150-160; January 2018. Note that the "retail prescription drugs" category excludes drugs purchased directly from physicians or hospitals (e.g., infusion drugs).

³ Gigi Cuckler et al., "National Health Expenditure Projections, 2017-2016"; *Health Affairs* 37(3); March 2018.

There are enough unique features of prescription drug pricing and delivery that warrant examining prescription drugs separately from non-drug medical services. Both categories of care—drug and non-drug medical—have challenges related to utilization of unnecessary services, unit costs for certain services, and determination of the most appropriate treatment within a list of services (or drugs), but the specific details can vary substantially between them.

The American Academy of Actuaries' Prescription Drug Work Group developed this issue brief to highlight prescription drug issues present in our health care system, including cost drivers, the effect on various stakeholders, and possible approaches that might help address the health care cost growth associated with prescription drugs.

Drivers of Growth in Prescription Drug Expenses

Changes in utilization (including the introduction of new drugs) and increases in the unit cost or cost per dosage are the two primary drivers affecting prescription drugs expenditures. Additional factors include delays in introducing generics, higher cost inflation in the United States for pharmaceuticals relative to other nations, and the compensation of numerous stakeholders throughout the pharmacy supply chain.

Utilization

Increased utilization of drugs is a result of many factors including new approved guidance for prescribing a drug for additional indications or new categories of patients for particular drugs,

changes in disease prevalence, revisions in treatment regimen, and more effective disease identification, often as a result of improved access to preventive screening.

Overutilization leads directly to higher health care costs. There are many reasons overutilization occurs, including the way in which the U.S. health care pharmaceutical delivery system works. For example, in a fee-for-service system, many physicians are ultimately paid based on the number of services they provide; pharmacies are reimbursed by the number and day supply of prescriptions they fill, and pharmaceutical manufacturers receive income based on volume of pharmaceuticals that is driven off of formulary placement. Overutilization can also be driven by direct drug marketing that creates demand from patients who observe drug advertisements for a condition they may have and request their physicians prescribe drugs without adequate information on alternatives, contraindications, side effects, or efficacy.

At the same time, nonadherence can be an issue. Nonadherence occurs when patients do not follow appropriate drug treatment protocol, especially maintenance medications, such as those that treat diabetes and hypertension. In 2016, approximately one in seven adults in the United States did not fill a prescription due to cost; the number increases for individuals with two or more chronic conditions.⁴ Such nonadherence can lead to much higher medical costs for an individual patient if the patient incurs a stroke, heart attack, or some other occurrence as a direct result of failing to take the appropriate level of medicine.

⁴ Dana O. Sarnak et al.; "[Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?](#)" Commonwealth Fund issue brief; October 2017.

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Unit Costs

Another component of increases in prescription drug costs is cost per unit. Cost per unit generally increases over time. However, certain external factors may cause the cost per unit to increase materially. Brand drugs typically experience higher price increases as their exclusivity period ends. New brand drugs are often introduced at prices higher than the current drugs they are aiming to replace. Historically, switching to a generic form of a drug tended to result in lower prices, but recently some new generics have had very high unit costs, while some other generics have had substantial price increases as a result of acquisition or repricing. Furthermore, new therapies are often introduced at high unit costs.

Drug Mix

The underlying mix of drugs directly impacts the total prescription drug spend. If utilization shifts to the more costly drugs, the increase in unit cost is greater than the average cost inflation due to the change in the underlying drug mix. Formularies are often used to mitigate cost increases due to changes in the underlying drug mix.

Health plans and pharmacy benefit managers (PBMs) develop their own formularies—lists of drugs covered by prescription drug plans—unless precluded, as is the case with some Medicaid state rules. Formularies seek to balance the need to manage costs and provide comprehensive therapeutic coverage, while remaining an attractive option for purchasers, recognizing that patients/consumers may seek out plans with formularies that include drugs they use regularly.

Formulary construction takes into account the review of a pharmacy and therapeutics committee focused on efficacy, safety, and availability of coverage; a separate review may determine the most cost-effective therapies that accounts for impacts of rebates, administration fees, price protection, purchasing discounts and average wholesale price (AWP) discounts. Most formularies incent members to use clinically appropriate and cost-effective medications through lower cost-sharing. Regulatory bodies often oversee the administration of formulary lists, and some may designate which therapeutic classes must be covered and act to ensure that consumers have choices.

Specialty Pharmaceuticals

Specialty drugs are one of the fastest growing cost areas of pharmaceutical spending. This term generally applies to pharmaceuticals that are classified as high cost and/or high complexity. Biologics, which are drugs derived from living cells, are often classified as specialty drugs. They typically have higher prices than traditional brand and generic medications.

Gilead Sciences' Sovaldi is one example of a specialty drug that is not a biologic medication (however complex to administer) but represents a significant clinical advancement in the treatment of hepatitis C. It first became available in the U.S. market in December 2013 at a price of \$84,000 for the most common treatment duration of 12 weeks. At that price, in terms of cost versus outcome, the Institute for Clinical and Economic Review (ICER) found that Sovaldi met the threshold of high care value given the treatment is curative.⁵ Other clinically advanced medications for hepatitis C became available a year later, and competition led to significant reported net price reductions to about \$30,000 for a course of therapy. However, even with this competition, these drugs still cost tens of thousands of dollars through the course of therapy.

⁵ ICER examines the cost-effectiveness of prescription drugs compared to the clinical effectiveness. It defines high care value as meeting a threshold of less than \$50,000 to \$100,000 per quality-adjusted life year (QALY), meaning year of life gained; low care value is defined as \$101,000 to more than \$150,000 per QALY.

Benefits vs. Costs for New Treatments

Pharmaceutical and biotech industries are experiencing significant growth because many new treatments recently have been launched, and others are working their way through the U.S. Food and Drug Administration (FDA) approval pipeline. These new therapies come with a financial cost. Some examples include:

- Luxturna, a new gene therapy, treats children and adult patients with an inherited form of vision loss† that may result in blindness. Luxturna's cost is \$850,000 for the treatment of both eyes.
- CAR T-cell therapy is a form of immunotherapy aimed at certain cancer treatments. CAR T-cell therapy approved drugs range from \$475,000 to \$1,500,000 per patient.
- Specialty drugs for autoimmune conditions such as rheumatoid arthritis, MS, and Crohn's disease can cost thousands of dollars per month.
- New therapies for high cholesterol and dermatological diseases have led to increases in costs for patients and health insurers.

A key question becomes whether a new prescription treatment merits a substantially higher cost. Several organizations globally are attempting to address this question. For example:

- The Institute for Clinical and Economic Review (ICER) is a nonprofit organization that evaluates clinical evidence for alternative therapies, including pharmaceuticals, to treat specific conditions.
- New Zealand's Pharmaceutical Management Agency (PHARMAC) has published The Prescription for Pharmacoeconomic Analysis, which provides documentation of the organization's cost-utility analysis approach, one of nine decision criteria used to support PHARMAC's allocation of allowed funding for health care expenses for the people of New Zealand.
- The National Institute for Health and Care Excellence (NICE) establishes guidelines in England, quality standards, and performance metrics to the National Health Service as a means of determining efficacy of covering a specific prescription drug.

† Biallelic RPE65 mutation-associated retinal dystrophy

While Sovaldi was a breakthrough in treatment protocols for a deadly disease, other specialty drugs are often used to treat symptoms that aren't necessarily curative, but still have a high cost. Some examples include disease-modifying therapies (DMTs) for multiple sclerosis (MS). These drugs do not cure MS; however, they are intended to reduce relapses and progressive disability. In a 2017 report, ICER found that, with one exception, all of the DMTs studied exceeded the threshold of \$150,000 per quality-adjusted life year (QALY).⁶

The introduction of more of these specialty pharmacy medications is contributing significantly to unit cost inflation.⁷ At the same time, many specialty drugs may help avoid more expensive procedures in the future. For example, unchecked hepatitis C can result in a liver transplant or liver cancer. A transplant is generally more expensive than the new drugs, and may result in greater overall trauma to the patient and larger chances of future complications and health risks. Even so, not all individuals with untreated hepatitis C will require transplants, so the likelihood of requiring more expensive treatments must be considered when considering overall health care costs.

Additional Drivers of Prescription Drug Cost Increases *Delays in Introduction of Generics*

Generic drugs, which are copies of brand drugs whose patents have expired, are generally less expensive than their brand counterparts and can lower health care costs. However, some brand manufacturers have found ways to extend the life of patents. One strategy, called "pay for delay," is when a pharmaceutical company with a brand-name drug pays generic manufacturers not to enter its market. These extensions delay pricing reductions from generics and cause pharmaceutical prices to remain higher overall. Other strategies that delay generics include changes to formulations, strength in dosing, and increases in FDA-approved indications that could be treated by the drug. Each of these changes results in the generic product having to go back to the drawing board to redesign the product and get FDA approval.

6 *Disease-Modifying Therapies for Relapsing Remitting and Primary-Progressive Multiple Sclerosis: Effectiveness and Value*; Institute for Clinical and Economic Review; March 6, 2017.

7 Rabah Kamal and Cynthia Cox; "[What are the recent and forecasted trend in prescription drug spending?](#)"; Kaiser Family Foundation; Dec. 20, 2017.

U.S. Paying More Than Other Nations for Pharmaceuticals

A large disparity exists between the prices of drugs in the United States compared with other countries. Assigning an index value representing the cost of a basket of prescription drugs to compare prices across countries showed the index values ranged from 95 in Germany to 46 in the United Kingdom, reflecting that U.S. retail prices for commonly prescribed drugs were 5 percent to 117 percent higher than prices in the other six countries included in the study. Prices for patented brand-name drugs are about 18 percent lower in Japan, and cancer drug prices are 20 percent to 40 percent lower in Europe.⁸ Several causes have been identified as contributing to higher U.S. prices.

- *Lack of a central negotiating authority.* In Canada and many European countries, it is common for the government to take responsibility for transactions with pharmaceutical companies. However, others believe these savings may be difficult to realize in the United States, especially because there is a ban on a federally required formulary.⁹ The federal government cannot negotiate prices for any populations other than Medicaid beneficiaries and military veterans. The commercial populations are subsidizing the low cost in these negotiated areas.
- *Access to all approved drugs.* The U.S. public and its health care system prioritizes accessibility and opportunities for coverage to all FDA-approved drugs to treat a condition. The U.S. health system uses tools such as cost-sharing and formulary to try to drive utilization to lower-cost alternatives but rarely completely eliminates coverage for a high-cost drug with no alternative. In contrast, other countries limit access to drugs where value is not, in their estimation, demonstrated to be significantly better than alternatives. Some state Medicaid programs are moving in this direction, creating state

mandated preferred and non-preferred drug lists, where sometimes less than half the drugs in a particular therapeutic category are available without prior authorization.

- *Greater ability to pay.* Prices may be higher due to the ability of U.S. health insurers to absorb those prices. Some patients are largely shielded from the high cost of these drugs due to mandated limits in insurance out-of-pocket costs. In addition, a large portion of the drug development and research processes are absorbed by the American payer as a result of their ability to pay.
- *Regulatory environment.* The FDA must review all of the clinical trials and determine if the drug is safe, effective, and its benefits to users outweigh its risks, which can take longer and cost more than reviews by other nations. Furthermore, the United States has requirements for patent and exclusivity periods. The general term for a new patent, which the FDA requires to be submitted for new drugs, can be up to 20 years. Similarly, the FDA can grant exclusive marketing rights for drugs that meet certain statutory requirements for varying periods (e.g., seven years for orphan drugs) that may or may not run concurrently with the patent period.¹⁰ An example of this is the seven-year exclusive marketing rights granted to orphan drugs (drugs for treatment of rare diseases).

Numerous Links in the Pharmacy Supply Chain

In addition to drug manufacturers, the pharmacy supply chain can include wholesalers, PBMs, physicians and hospitals, and retail and mail order pharmacies. Historically, prices along this pipeline have been determined as a percentage of a benchmark, such as average wholesale price (AWP), average sales price (ASP), or wholesaler acquisition cost (WAC), which is usually directly related to the list price set by the manufacturer.

The list price does not account for the additional areas that are acquired and negotiated by the PBMs.

⁸ Sarnak; op. cit.

⁹ Chuck Shih, Jordan Schwartz, and Allan Coukell; “[How Would Government Negotiation of Medicare Part D drug Prices Work?](#)”; *Health Affairs* blog; Feb. 1, 2016.

¹⁰ “[Patents and Exclusivity](#)”; FDA/CDER SBIA Chronicles; May 19, 2015.

These amounts can influence coverage decision and may or may not be retained by the PBMs. These amounts include rebates, formulary administration fees, price protection, purchasing discounts, and group purchasing organization fees. This practice can exacerbate the lack of transparency and the potential for cost increases that outpace the incremental value added of the downstream supply chain. This may not be apparent to the end payer (i.e., Medicare, employer, etc.)

Research and Development

While the process of bringing a drug to market can be long, expensive, and risky, the degree to which spending on research and development contributes to the high prices paid by consumers is less than clear and continues to be studied. There is no good source for the exact cost of bringing a new drug to market, but there is widespread recognition that the costs run into at least many hundreds of millions of dollars per new drug product.¹¹

Impact of High and Increasing Prescription Drug Costs on Payers

In many situations, use of prescription drugs may lead to better overall health outcomes and even lower overall health care costs. However, increased prescription drug use without an accompanying increase in quality of care or life, or lower overall health care costs, may have a negative effect. Rapidly increasing prescription drug costs can have a significant effect on the various stakeholders in the health care system:

- *Insurers, Government, and Other Payers*—Prescription drug costs represent a significant issue for payers as they try to maintain a balance between revenue and costs. Increases in costs due to utilization increases, unit cost increases, and changes in the mix of drugs increase the burden on budgets, as well as making prescribed drug costs difficult to predict. Copay coupons can influence the mix and often make the brand less expensive than or comparable in cost to the generic to the patient, but at the expense of the insurer and patient over time.

- *Insured Members*—As plan costs for prescription drugs increase, insured member costs will likely increase through higher cost sharing and premium contributions. The Affordable Care Act (ACA) does provide for a maximum out of pocket (MOOP) limit for drug and medical costs combined for the commercial market. The MOOP for 2018 is \$7,350 per person per year, which can represent a substantial percentage of income for most individuals. Cost increases to employers and other plan sponsors over the past several decades have resulted in increased cost sharing, increased member contributions to premiums, and even elimination of some employer or other sponsored health plans. Pharmacy claims are subject to the deductible in high-deductible health plans, exposing members to more cost sharing.
- *Government Programs*—Increasing plan costs for government health care programs will likely cause issues for individuals enrolled in these programs and for the public as a whole. Individuals enrolled in government programs may be forced to pay higher premium contributions and/or cost sharing, or incur more rigid plan eligibility requirements. Government programs also may consider not covering or restricting the use of some of the highest-cost drugs for fiscal reasons.
- *Uninsured Population*—Drug prices are usually higher for uninsured individuals than for insured members because some payers can negotiate lower prices due to their contracting efforts, so price increases can be more of a challenge for this population. Costs and subsequent increases in costs may be offset partially by a discount drug card, copay coupons, or subsidies provided by patient assistance programs. Discount drug cards have also been used in commercial populations. While these cards can help reduce out-of-pocket spending, especially for the uninsured and low-income population, they can cause increased prescription drug spending as costs shift to higher-cost drugs. This, in turn, can lead to higher premium increases.

¹¹ [Prescription Drugs: Innovation, Spending, and Patient Access](#); Office of the Assistant Secretary for Planning and Evaluation; Dec. 7, 2016.

Options to Address Spending

Pharmaceutical treatments may enable patients to achieve a quality of life inaccessible without pharmaceutical management of their conditions when used appropriately. Expensive treatments may mean a person who is disabled can continue to live an active, productive life.

To that end, there are many possible steps that can be taken to address the rising costs of pharmaceuticals both by policymakers and by payers of health care costs. At the federal level, a few of the potential changes that have been suggested by stakeholders include:

- **Streamlining the drug approval process.** The FDA approval process is different for brand and generic drugs. While the multi-phase process for a brand drug approval can take several years, the generic approval process, while still lengthy, can be more abbreviated. Expediting the brand and generic approval process would lower costs through reduced research costs and administrative fees, offering these new prescription drugs sooner to individuals that can prevent use of more expensive treatments, and for generic medications, introducing additional generic competition more quickly, which has been a recent major focus of the FDA.
- **Eliminating tactics that discourage generic utilization.** Shifting utilization to generic drugs has long been an effective means to lower prescription drug costs, but there are often obstacles put in place by brand manufacturers to preserve their market share. Laws or regulations are being discussed and could be enacted to prevent brand manufacturers from paying generic companies to delay manufacturing.

Additionally, manufacturers use copay coupons to offset cost-sharing barriers to continued use of brand medications.

- **Allowing prescription drug imports.** Purchasing prescription drugs outside the United States, where drug costs can be significantly lower, has been discussed as a way to lower costs for several years. However, allowing for the importation could introduce other risks, such as the government being unable to guarantee the safety and efficacy of these drugs. Many of these drugs are manufactured in countries with less stringent standards than those in the United States, and there is no guarantee these products would meet the FDA approval. Furthermore, savings realized by wholesalers, pharmacies, and other purchasers from importing prescription drugs may not necessarily be passed back to the consumer.
- **Negotiating or regulating drug prices.** Currently, under the Medicare Part D program, the federal government is not allowed to negotiate directly with drug manufacturers, in contrast to Medicaid and commercial payers. The Medicare Part D program is one of the largest users of medications, and taking advantage of its size by wringing out better pricing and higher rebates could help lower prescription drug costs. Broader regulations around price increase limits and transparency are being considered at the state and federal levels as a mechanism to limit pharmacy costs.

Health insurers, government agencies, and others that pay for health care services have several options to slow the growth of prescription drug costs.

Incorporating Value-Based Review Process

Several entities, such as ICER and DrugAbacus, are attempting to determine whether drug prices are reflective or consistent with their value.¹² These entities can provide purchasers, such as insurance companies, PBMs, and government agencies, with a more quantitative means of determining whether a price is commensurate with its value as well as whether a particular drug should be added to or removed from a formulary.

Similar studies have been required by many states over the years when considering newly proposed mandated health benefits to be included in insured benefit programs. These studies generally focused on three areas of analyses: medical efficacy, social impact/benefit, and financial impact.

These kinds of analyses are appropriate for existing drugs as well as new drugs. Before retaining a particular drug in a formulary, the drug company would need to demonstrate that its inclusion met the medical efficacy and increased social and financial impact criteria. There are many ways of negotiating, including using the values ICER defines for certain drugs to negotiate discounts and rebates.

Outcomes-Based Contracting

To date, there has been limited success creating risk-based contracting for drugs. Some of the barriers include data collection and availability and outcomes measurement, as well as a number of legal and regulatory concerns (e.g., FDA regulations, anti-kickback statutes, and Medicare/Medicaid price reporting requirements).¹³

However, there have been some value-based initiatives where the price of the drug is dependent on the patient's outcome.

Express Scripts SafeGuardRx has launched programs aimed at diabetes, hepatitis, cholesterol, and oncology.¹⁴ For example, for its Diabetes Care Value Program, Express Scripts guaranteed per-patient spending caps will result in participating plans experiencing an average increase in diabetes drug-spend in 2017 that is approximately half of what the industry is currently forecasting for U.S. commercial payers.

In 2017, Harvard Pilgrim Health Care signed a three-year value-based care contract with drug maker AstraZeneca for two therapies used to treat acute coronary disease and type 2 diabetes.¹⁵ The arrangements will use patient outcomes as a measure of the effectiveness of each treatment, which will be incorporated into reimbursement rates for the drug manufacturer. For example, AstraZeneca's Brilanta, a medication that treats acute coronary disease by lowering a patient's chance of having a repeat heart attack or suffering a fatality from one, is part of the arrangement. Harvard Pilgrim will monitor the number of return hospitalizations for patients treated with Brilanta after they are discharged from the hospital. Any reduction in return visits achieved for acute coronary syndrome will be measured against patients receiving an oral antiplatelet therapy. If a reduction in visits is recorded, that will factor into the price paid for the drug.

Benefit Plan Modifications

Health insurers and self-funded employers have already begun to address the rapid increase in pharmacy costs via benefit plan modifications. These modifications are generally of two types—those focused on financial factors and those focused on member behavior.

12 Petre B. Bach and Steven D. Pearson; "Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs"; *JAMA*; Dec. 15, 2015.

13 Alison Sexton Ward, Mark Linthicum, Michelle Drozd, Alison R. Silverstein, Joe Vandigo; "Regulatory, Legal Uncertainties Are Barriers to Value-Based Agreements for Drugs"; *Health Affairs Blog*; Nov. 4, 2016.

14 Lisa LaMotta; "Express Scripts puts pricing cap on diabetes drugs"; *BioPharma Dive*; Aug. 31, 2016.

15 Jess Migneault; "Harvard Pilgrim Enters Outcomes-Based Pharmaceutical Contracts"; *HealthPayer Intelligence*; June 2, 2017.

Partial fill or “split fill” programs

Some PBMs have suggested that health plans consider allowing for a less-than-30-day fill option for some drugs, especially the very-high-cost specialty drugs and particularly when a patient is just beginning treatment. This would eliminate “wasted” drugs if the patient could not tolerate the full dosage or if it became evident that the patient was not going to comply with the regimen. This could be coupled with outreach programs to support patients and to identify issues sooner.

Step therapy

These programs require patients to start with a preferred drug in a given therapeutic class and prove that the drug does not work for them (side effects, non-responsive, etc.) before being allowed to fill a non-preferred drug. Such programs are generally required for a specific list of therapeutic classes, such as hypertension, asthma, antidepressants, proton pump inhibitors, statins, etc.

Proponents say that these programs encourage safe, cost-effective medication use by allowing coverage when certain conditions are met.

Opponents assert these programs may encourage doctors to move away from more expensive—and from the patient’s perspective, possibly more effective—treatments, which are typically newer, toward less expensive, and possibly less effective alternatives, during which time the patient must prove that they either cannot tolerate the less expensive alternative and/or cannot achieve the desired results, which extends the recovery time.

Preferred pharmacy network

Some payers give consumers reduced cost-sharing as an incentive to use their preferred pharmacy network. The preferred pharmacy networks consist of pharmacies that have agreed to higher discounts in exchange for the potential increase in volume of prescriptions filled.

Prior authorization

Certain drugs may require prior authorization before a health plan will pay for them. The intent is to make sure that the therapy is medically necessary, appropriate for the patient, and follows clinical guidelines. Prior authorization programs seek to manage costs and better align care to best practices, usually by requiring justification for a therapy when a lower-cost option or preferred option is available. Prior authorization programs also seek to improve patient health by minimizing harmful drug interactions, side effects, unproven off-label uses, or overmedication.

Reference pricing

Reference pricing attempts to limit costs on the reimbursement of drugs by using equivalent drugs on the national market to set a reference price, where the portion of the price above the reference price would not be reimbursed for groups of drugs considered to be interchangeable. Proponents of reference pricing say that this practice provides patients with financial incentives to use the most cost-effective drug, because the patient has to self-fund the difference in costs. Opponents say that some patients experience side effects from the drugs that represent the reference price and should not be penalized financially. A potential option is to consider step therapy first, and then allow a higher price than the reference price if the patient passes the step therapy.

Deductibles, out-of-pocket limits, benefit designs

About 36 percent of employers reported having a prescription drug benefit deductible in 2015, compared with only 14 percent the year before.¹⁶ Coinsurance is also more common, and out-of-pocket limits are required by law under the ACA. Benefit designs are becoming more complex, with more employers using four-, five-, and even six-tier cost-sharing structures. All of these changes are directed at incentivizing the patient to use the lowest-cost drug possible.

¹⁶ Christine Huttin; *Drugs and Money. Prices, Affordability and Cost Containment*; 2003.

Specialty pharmaceuticals

The term “specialty pharmaceuticals” generally applies to pharmaceuticals that are classified as high-cost and/or high-complexity, including biologics. While specialty drugs are by definition high-cost, there is often an associated reduction in medical cost with appropriate use of the specialty drug. In building a specialty pharmaceutical management strategy, the cost of the specialty drug is considered after the expected medical cost offsets in addition to the expected clinical impact on the patient’s quality of life.

Part of the specialty pharmaceutical management strategy involves determining whether coverage should be through the medical benefit or pharmacy benefit. Historically, oral medications have been managed under the pharmacy benefits while medications that are injected are considered medical benefits. Because the costs and usage of specialty drugs are growing quickly, this determination becomes more important, and the determination of medical benefit or pharmacy benefit usually requires a drug-by-drug analysis.

Then, within both the medical benefit and the pharmacy benefit, there are multiple avenues for distribution that should also be optimized. Under the medical benefit, site of care optimization can occur between physician offices, hospitals, and infusion clinics. For the pharmacy benefit, the distribution can be handled by retail pharmacies, traditional mail pharmacies, and specialty pharmacies. Specialty pharmaceutical management programs focus on the value proposition of clinical support as a means to ensure the highest medical return on investment—medical cost offset relative to increased pharmacy spend—is achieved.

Increasing Pricing Transparency

In the U.S. health care system today, prescription drug costs per unit are often not known by the prescribing provider or the individual taking the

medicine. In situations where lower-cost drugs have efficacy at least as good as their higher-cost counterparts, better transparency can provide opportunities to lower both patient out-of-pocket payments and premiums.

Providers participating in gain- and loss-sharing programs would also benefit from pricing transparency by allowing them to more easily reach their goals while increasing quality of care, especially if done in conjunction with a comparative effectiveness approach.¹⁷ Provider access to unit cost data would be especially beneficial in situations where patients have reached their out-of-pocket maximums and have no incentive to use more-efficient drugs that maintain or increase quality of care.

CVS Caremark announced¹⁸ that it will begin providing real-time visibility to member-specific medication costs and available lower-cost therapeutic alternatives at the point of prescribing and at the pharmacy. This enhanced visibility to the patient’s benefit across all points of care could help eliminate potential dispensing delays, improve patient outcomes through increased medication adherence, and lower costs for members and payors.

Greater provider and patient ability to increase efficiency in drug usage and increase quality of care would lessen variability in trend increases from year to year, making it easier for actuaries to predict costs for future years and provide more financial certainty for individuals, employers, and governmental programs. Several web-based resources can help consumers find the lowest cost for drugs from local pharmacies.¹⁹ In addition, one of the best sources of drug prices may be the member’s own insurance carriers, most of which provide online tools to steer patients toward the lowest-cost prescriptions.

¹⁷ American Academy of Actuaries; *Comparative Effectiveness Research*; November 2017.

¹⁸ Evan Sweeney; “CVS Health adds real-time, member-specific drug pricing into e-prescribing”; *Fierce Healthcare*; Nov. 29, 2017.

¹⁹ Examples include: Drug Price Search [<https://www.rxpricequotes.com>], GoodRx [<http://www.goodrx.com>], LowestMed [<https://www.lowestmed.com>].

Conclusion

The U.S. health care system is extremely complex, and the prescription drug component is no exception. Most Americans are affected in one way or another by the U.S. health care financing system, whether through premium contributions, taxes, fees, out-of-pocket costs, access to care, and family income for those who work in various parts of the health care industry. Making significant changes to the system will be difficult because it affects so many people and makes up a substantial share of our economy.

The important cost drivers of high prescription drug spending are:

- **Increasing utilization** driven by factors including new indications for a drug, direct marketing to consumers, and the incentives in a fee-for-service system.
- **Increasing average cost** driven by factors including the exclusivity of the drug and higher prices of the newer versions of drugs.
- **Changes in drug mix** that are driven by the formulary, benefit design, and availability of alternative drugs.

Several ideas discussed in this issue brief may help lower prescription drug spending, such as outcome-based reimbursement, pricing transparency, reference pricing, and benefit plan modifications.

This paper discusses many important issues related to prescription drugs but is not designed to be an all-encompassing account. As with health care in general, there is no single issue that, once resolved, will make the health care financing system an efficient system with high quality of care. Rather, there are many issues, including those described in this issue brief, whose resolution will increase the effectiveness of our health care system either through increased efficiency, lower costs, increased quality of care, or an enhanced quality of life. In future work, we will examine some of these options in more detail.

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