

Prescription Drug Pricing: Striking the Right Balance

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KEY TAKEAWAYS

There is growing public concern that prescription drug costs are too high and provide insufficient value, so policy makers are right to focus on reform in this area.

Policy changes under consideration can generally be grouped in one of three categories: intellectual property, product regulation, and coverage and reimbursement.

Policymakers should understand the broad implications of these initiatives and ensure policies strike the right balance to reduce costs and protect patient access.

Both federal and state policymakers are focused on prescription drug costs, responding to perceptions by many Americans that costs are too high and do not provide sufficient value for their price.¹ In May 2018, the Trump Administration unveiled its American Patients First Blueprint on prescription drug pricing. Since then, there has been a flurry of activity in the Administration, Congress, and the states related to drug pricing. Tackling this public policy issue is a sizable undertaking and complex.

The issue and the various policy recommendations can generally be grouped into one of three categories: intellectual property issues, product regulation issues, and coverage and reimbursement issues. Policymakers should evaluate these initiatives through these categories, understand their broader implications, and ensure that policies strike the right balance to reduce costs and protect patient access.

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Administrative Action

On May 11, 2018, the Trump Administration released its American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.² This Blueprint identifies four policy challenges and outlines a series of policy reforms to increase competition, to better negotiation, to put in place incentives for lower list prices, and to lower out-of-pocket costs. The Administration has focused primarily on leveraging its administrative authority to advance its agenda.

For example, the Administration took steps to speed up the availability of generics and biosimilar drugs, approved state experimentation with new payment models for prescription drugs in Medicaid, and revised tools to provide information on prescription drug spending trends and price increases in the Medicare and Medicaid programs.³ The Administration has also solicited input on several other policy changes, including changes to rebate rules in Medicare,⁴ and finalized a rule requiring the inclusion of list prices in direct-to-consumer advertising.⁵

Congressional Action

Congress has also been active on the topic of drug pricing. The Senate and the House of Representatives have held a number of hearings with testimony from key stakeholders. For example, in the Senate, the Health, Education, Labor, and Pensions Committee held a hearing on the Administration's prescription drug blueprint with U.S. Department of Health and Human Services Secretary Alex Azar, the Finance Committee held a series of hearings on drug pricing, and the Judiciary Committee held a hearing on intellectual property and prescription drugs. In the House of Representatives, hearings on prescription drugs were held in the Ways and Means Committee, the Energy and Commerce Committee, and the Oversight and Reform Committee.

Legislatively, Congress passed and President Trump signed into law two bills banning insurers from preventing pharmacists from sharing pricing information with patients.⁶ The House has recently taken action on advancing the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, a bill that would stop the gaming used by brand-name manufacturers to delay generic competition, as well as several other drug-related bills.⁷ In the Senate, committee leaders have indicated they will put forward drug-pricing legislation early this summer.⁸

State Action

The states, too, have been active on the topic of drug pricing. States have considered a wide range of prescription drug legislation that impacts both private and public coverage, including policies related to benefits and access, pricing and payment, cost sharing, and transparency to name a few.⁹

Industry Action

From the industry side, both pharmaceutical manufacturers and prescription-benefit managers have testified before Congress and offered recommendations that likewise cover a broad range of policy areas.¹⁰ In addition, there has been a rise in private-sector initiatives aimed at assisting consumers navigating these complex pricing arrangements.¹¹

Understanding the Key Policy Issues

While seemingly complex and sometimes disparate, the issues surrounding prescription drug pricing can generally be grouped into three basic categories: intellectual property issues, product regulation issues, and coverage and reimbursement issues.

Intellectual Property. This category consists of pricing issues that result from laws designed to recognize and protect intellectual property through mechanisms such as patents, copyrights, and trademarks. Central to intellectual property law is the concept of “exclusivity,” meaning the legal recognition that, at least for some period of time, only the owner has the right to use or commercialize the property.

For pharmaceuticals, the two most important forms of intellectual property protections are patents and marketing approvals. It is important to keep in mind that, despite some interactions and functional similarities, drug patents and drug marketing approvals are actually separate processes, governed by different statutes, and administered by different agencies—the Patent and Trademark Office and the Food and Drug Administration (FDA), respectively—and that the exclusivity granted by each operate in parallel, not sequentially.¹²

However, the public policy purpose behind both is the same. It is to encourage the development and diffusion of socially beneficial innovations. For lawmakers, the objective should be to strike a balance between providing sufficient incentives to encourage robust innovation and providing opportunities for others to eventually spread the benefits of innovation more widely through competitive production and pricing.

That was the balance that the Hatch–Waxman Act of 1984 sought to achieve.¹³ On the one hand, to encourage investment in developing new treatments, the legislation included provisions that enabled innovators to project with greater certainty the expected period of market exclusivity for a novel drug if it obtained FDA approval. On the other hand, to diffuse the benefits of innovation more quickly, the legislation also included provisions that made it possible for competing producers to enter the market with generic versions as soon as the exclusivity attached to an innovative product expired.

Today, policymakers should reject proposals that would stifle innovation by making intellectual property protections less certain—such as compulsory licensing laws that force owners to accept payments limited to amounts determined by a government entity, either by law or arbitration. However, policymakers should also guard against the law inadvertently permitting the unwarranted creation or extension of exclusivity.

For instance, in 2006 the FDA launched an initiative to apply current standards to drugs approved prior to the 1962 amendments to the Food, Drug and Cosmetic Act. The result was that a number of older, cheaper generic drugs suddenly became much more expensive.¹⁴ This occurred because the FDA’s initiative treated them as “new” drugs, which meant that first applicant to demonstrate to the FDA that the drug was safe and effective automatically received a period of market exclusivity, during which the FDA could not approve any competing generic versions. The far better approach would have been for Congress to instead appropriate funding for studies of the drugs. That would have gotten the FDA the data it wanted without triggering shortages and price hikes.

Similar issues have arisen around the appropriateness of some industry practices that have the effect of extending exclusivity—thus delaying generic competition. Policymakers should therefore ensure that the system does not permit companies from getting unwarranted additional exclusivity.¹⁵

Product Regulation. The second category consists of drug-pricing issues that arise as a byproduct of the laws and regulations governing the manufacture, marketing, distribution, and sale of the pharmaceutical products themselves. To preserve public health and safety, prescription drugs are subject to a range of detailed regulations. Indeed, the FDA’s authority to decide whether a drug is sufficiently safe and effective to be marketed as a treatment for one or more specific conditions is just the best known of a number of regulatory responsibilities that Congress has given the agency.

The FDA also regulates the ingredients, factories, production lines, and processes used to make drugs to ensure that drugs are free of any harmful

ingredients or contaminants and that they work as intended. Furthermore, the FDA regulates the drug supply chain so as to ensure, among other things, that drugs are not counterfeit, have not been altered or tampered with since leaving the factory, and have not lost potency through improper handling or storage.

However, some FDA regulatory actions can have the side effect of limiting the supply of a drug—resulting in price increases. Key examples include abruptly changing manufacturing standards, or inaction, such as delays in approving applications for new generic versions of a drug or applications to modify a drug already in production.

Lawmakers addressing issues in this category should first determine the extent to which regulatory or internal process changes at the FDA can solve the identified problem versus where it is necessary for Congress to change the statute. For instance, in the 2012 and 2017 legislation reauthorizing FDA user fees, Congress included provisions designed to increase the availability of cheaper generic drugs.¹⁶ Yet just as important was that FDA leadership also prioritized that goal and implemented regulatory and process changes to achieve it.¹⁷

Coverage and Reimbursement. This category includes issues related to how drugs are covered and reimbursed by public programs and private health plans. For this category, in most cases, the issue is less with the price charged by the drug manufacturer and more about what the patient is charged when he or she picks up the prescription. That distinction is relevant to identifying both problems and potential solutions.

For instance, sometimes the price of a generic drug is less than the applicable plan's co-pay. Plans have been criticized for collecting the higher co-pay and contractually preventing pharmacists from telling enrollees that they can pay less if they purchase the drugs without using their insurance. Here the issue is not the price of the drug itself but what the *patient* is being charged, which is a function of plan design. Specifically, this issue occurs in plans that use fixed-dollar co-pays but not in plans that apply only deductibles or co-insurance. As previously noted, Congress and the Administration took action earlier this year, but further review of contract rules in the private and public sector might be necessary.

In general, both public and private plans exhibit fewer enrollee cost-sharing issues when their coverage designs treat drugs much the same as other medical services. In the private sector, coverage designs have evolved, and continue to evolve, in response to changing conditions. Indeed, private plans began integrating drug coverage with other benefits years ago as doctors used more new drugs as first-line therapies for more medical conditions.

Government-administered coverage lacks such flexibility because significant changes can only be made through formal legislative or regulatory processes. However, by organizing public programs around the concept of premium support, lawmakers can leverage the private sector's processes of continuous improvement and adaptation for the benefit of public program enrollees. For instance, enrollees in Medicare Advantage plans, in which drug coverage is integrated with other plan benefits, are more protected from incurring high out-of-pocket drug costs than enrollees in standalone Medicare Part D plans.

When it comes to this set of drug cost issues, lawmakers should focus on addressing the underlying problems in public programs rather than layering additional administrative and regulatory schemes (such as international reference pricing) on to the programs. A better place to start would be to provide greater flexibility in plan designs for Medicare Part D and Medicare Advantage and to consolidate Medicare's fragmented design into a more integrated benefit model that uses private-sector negotiation to determine market prices—rather than government price-setting.¹⁸

Policymakers should also identify if there are any statutory or regulatory barriers that block private industry from responding to changing consumer demand and adapting to new market conditions.

Striking the Right Balance

Activity on prescription drug pricing has gained momentum at the Administration level, the Congressional level, and the state level. Policymakers should consider reform proposals not only through the lens of prescription drug policy but also in the context of the larger policy issues and their broader implications to ensure the policy decisions strike the right balance to bring down the cost—while preserving patient access to prescription drugs.

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