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Selected Issues in Pharmaceutical Drug Pricing

Many factors influence the prices consumers pay for prescription drugs. Congress has repeatedly attempted to address high drug prices through legislation, including bills that seek to increase generic competition, lower prices for certain health care entities that serve rural and vulnerable populations, and regulate drug price negotiations through the Medicare program. Congress has also proposed to cap out-of-pocket Medicare costs, increase drug price transparency, permit more drug importation, and regulate pharmacy benefit managers. This In Focus reviews several issues affecting drug prices of potential interest to the 118th Congress.

Economics of the Pharmaceutical Industry and the Life Cycle of Drugs

In 2020, U.S. expenditures on outpatient prescription drugs were \$348 billion, accounting for 8.4% of total healthcare expenditures. Over the last 20 years, this percentage has been as high as 10.5% in 2006 but has otherwise remained between 8 to 10%. The Congressional Budget Office found that from 2009 to 2018, the average net price of a prescription—the price of a prescription after subtracting the discounts and rebates that manufacturers provide to private insurers and federal programs—fell “in both the Medicare Part D and Medicaid program,” reflecting “the increased use of lower-cost generic drugs, which was partially offset by rising prices for brand-name drugs.” Despite these trends, concern about the price of prescription drugs has drawn much attention in Congress, partly due to the high price of sole-source (brand-name) drugs and biological products (biologics).

Researching, developing, obtaining approval for, and marketing pharmaceutical products has generally been a high-risk, high-reward endeavor. The discovery, development, and testing phases can be complex and lengthy, with a low success rate (~1 in 10,000 candidate molecules, according to some studies). However, pharmaceutical companies that succeed in bringing a new product to market benefit from exclusivity and, as sole-source providers, can set a higher price for their product in the absence of competition. As the market for a pharmaceutical product grows, sales and profits typically increase until competitors enter the market, either (1) as other products with similar functions and clinical applications receive their own separate approvals and are launched; (2) as exclusivity rights expire, permitting others to produce bioequivalent versions of the original product (i.e., generics or biosimilars); or (3) as the market matures and sales decline.

While pharmaceutical companies that produce sole-source drugs benefit from a lack of competition, the buyers’ market for drugs (purchasers) also lacks sufficient

competition to lower drug prices for patients through an efficient market. Health insurers, including private plans and public programs, typically contract with pharmacy benefit managers (PBMs) for drug benefit management services that include developing and maintaining formularies (lists of covered drugs), negotiating prices with drug companies including discounts and rebates, and reimbursing pharmacies for drugs dispensed to beneficiaries. Currently, the PBM market is dominated by three companies, raising questions about adequate competition and whether the negotiated discounts and rebates result in lower prescription drug prices for patients.

Policies to mitigate the high price of sole-source drugs include efforts to modify the timing and degree of competition through changes in the length and scope of exclusivity rights, and to impose certain restrictions on drug prices and price increases over time.

Patent Rights, Regulatory Exclusivities, and Generic Competition

Intellectual property (IP) rights play an important role in the development and pricing of prescription drugs and biologics. Two forms of IP are particularly important for pharmaceuticals. To encourage innovation, *patents* grant inventors the exclusive right to make and sell a novel invention (such as a new drug), potentially enabling the patent holder to charge higher-than-competitive prices during the patent term. Similarly, the Food and Drug Administration (FDA) grants *regulatory exclusivities* to pharmaceuticals meeting certain criteria. During a period of regulatory exclusivity, FDA will not accept and/or approve applications for a generic or biosimilar form of the drug.

IP rights are typically justified as necessary for pharmaceutical manufacturers to recoup their costs in research and development, including clinical trials and other tests necessary to obtain FDA approval and bring a drug to market. However, IP rights are sometimes criticized as contributing to high prices for pharmaceutical products in the United States by deterring or delaying competition from generic drug and biosimilar manufacturers. For example, some Members of Congress have criticized certain pharmaceutical patenting practices as unduly extending periods of exclusivity.

Studies show that generic competition lowers drug prices. Generic forms often cost a fraction of the price of a brand-name drug before generic entry. Whether and when generic or biosimilar competition is permitted, however, depends on the IP rights in the drug and, in many cases, litigation under the specialized patent dispute procedures of the Hatch-Waxman Act (P.L. 98-417) and the Biologics Price

Competition and Innovation Act (P.L. 111-148, §§ 7001-7003).

The 340B Drug Discount Program

Given the high cost of many drugs, Congress has proposed ways to make drugs more affordable for patients and providers who care for rural and underserved populations. One such program is the 340B Drug Discount Program (340B), which Congress created to enable healthcare providers that serve low-income and uninsured patients to purchase drugs at lower costs. The Health Resources and Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS), administers the Program. HRSA estimates that 340B sales constitute about 7.2% of the overall U.S. drug market; sales reached approximately \$44 billion in 2021.

The program requires the Secretary of HHS to enter into purchase price agreements (PPAs) with drug manufacturers that participate in the Medicaid program. PPAs require manufacturers to sell to qualifying “covered entities” certain outpatient drugs at a “ceiling price,” which is set via a statutory formula. Covered entities include Federally Qualified Health Centers, Tribal and Urban Indian organizations, Ryan White clinics, Critical Access Hospitals, and Disproportionate Share Hospitals (DSHs), which serve a disproportionate number of low-income patients. DSHs currently make about 75% of 340B sales.

Since its creation, Congress has significantly expanded the 340B Program to increase the number of eligible covered entities. The Government Accountability Office recommends that HRSA increase its oversight of covered entity eligibility requirements and its oversight to ensure that covered entities are not receiving duplicate discounts from Medicaid.

Drug manufacturers have recently challenged the Program’s expansion, particularly with respect to contract pharmacies, which provide 340B drugs to patients of covered entities outside of the provider setting. In 2020, several companies announced pricing restrictions on covered entities that use contract pharmacies, making it more difficult for covered entities to purchase drugs at or below ceiling prices. In 2021, HRSA issued violation letters to the manufacturers, notifying them that such restrictions violated the 340B statute. The manufacturers have since challenged HRSA’s authority to issue the letters in court.

Federal district courts have analyzed the 340B statute, legislative history, and HRSA’s guidance but have arrived at different legal conclusions. Two courts ruled that HHS acted within its statutory authority in issuing the violation letters, while two others disagreed. Three of the cases were appealed, and the appeals courts could release decisions at any time.

Medicare Drug Prices and the Inflation Reduction Act

Congress also included several provisions in P.L. 117-169, often referred to as the Inflation Reduction Act (IRA) of 2022, to lower prices for patients receiving prescription drugs covered and paid for under Medicare Parts B and D.

The IRA creates a new Drug Price Negotiation Program requiring the Secretary of HHS to negotiate prices for certain qualifying single-source drugs furnished to Medicare program beneficiaries, including those drugs and biologics with the highest expenditures in Medicare Parts B and D.

The first negotiated Maximum Fair Prices (MFPs) will take effect in 2026 for 10 eligible drugs or biologics. For 2027 and 2028, the HHS Secretary will select and publish a list each year of 15 negotiation-eligible drugs as selected drugs, rising to 20 for 2029 and subsequent years. A chemical drug will have to be FDA-approved for at least seven years before the Secretary can select it for negotiation. A biologic will have to be licensed for 11 years before it can be selected for negotiation. Certain types of drugs or biologics are exempt from negotiation. For example, single-source drugs manufactured by companies that meet the definition of a small biotechnology firm are exempt in years 2026 through 2028. For 2029 and 2030, there is a special MFP floor for qualifying single-source drugs of small biotech firms. Manufacturers are subject to an excise tax for non-compliance, including failure to enter into an agreement to negotiate an MFP.

Separately, the IRA also makes modifications to drug coverage and payment under Medicare Parts B and D to lower the cost to beneficiaries. Pharmaceutical companies are required to pay rebates to Medicare if they increase prices faster than consumer inflation. The IRA reconfigures the Medicare Part D retail prescription drug benefit to impose an annual enrollee out-of-pocket spending cap, expand subsidies for low-income enrollees, and cap annual premium increases, among other changes. Cost-sharing for certain Part D vaccines is eliminated, and the IRA sets a \$35 cap on enrollee cost-sharing for insulin covered through Medicare Parts B and D. The IRA also changes certain Part B drug payment formulas and delays implementation of a Centers for Medicare & Medicaid Services rule that would eliminate anti-kickback statute protections (safe harbors) for manufacturer rebates in Medicare Part D.

Considerations for Congress

Just as Congress authorized the programs discussed in this report, the 118th Congress could propose legislative changes to those programs or increase its oversight of them. As Congress considers additional action to address high-priced pharmaceuticals, it may also continue to weigh the balance between maintaining incentives for innovation and new drug discovery, while promoting access to pharmaceutical products at an affordable price.

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