

REFORM FEDERAL PRESCRIPTION DRUG SPENDING

As a major direct and indirect purchaser of prescription drugs, Congress must analyze the current federal drug purchasing system, ensure that the drug marketplace is competitive, and protect taxpayers.

BACKGROUND

As of 2018, 90 percent of prescriptions filled in the United States are low-cost generics which account for roughly 22 percent of total drug spending.¹ Most increases in prescription drug spending are driven by brand-name drugs, biologics, and specialty drugs.²

The Federal Government purchases prescription drugs through a wide range of programs. In 2017, the Federal Government spent about \$133 billion on prescription drugs through Medicare, Medicaid, Children's Health Insurance Program (CHIP), the Department of Defense and the Department of Veterans Affairs (VA) alone. That amount represents almost 40 percent of the \$333 billion in total national expenditures on prescription drugs.³

From 2007 to 2017, federal prescription drug spending across the aforementioned federal programs increased 105 percent, but spending growth wasn't spread equally across the programs.⁴ For example, Medicare drug spending increased 120 percent from 2007 to 2017, and the federal portion of Medicaid drug expenditures increased 101 percent.⁵ Over the same period, VA prescription drug spending increased by only 35 percent.⁶

Many variables contribute to the discrepancy in prescription drug spending across different federal programs, but, ultimately, the Federal Government pays different prices for many of the same prescription drugs depending on the federal program:

- **Medicare Part D** is a voluntary drug benefit offered through private health care plans that contract with the Department of Health and Human Services (HHS). The Part D program relies on market competition to limit spending. Plan sponsors, which compete for enrollees, negotiate rebates, discounts, and other price concessions with manufacturers. The Affordable Care Act (ACA) amended Part D to require additional price discounts from manufacturers.
- **Medicare Part B** covers, among other services, injectable or intravenous drugs administered as part of a service in a doctor's office or hospital outpatient department. Part B also covers specific drugs, such as immunosuppressant products, vaccines, transplant drugs, and oral end stage renal disease medications. Under Part B, physicians who purchase prescription drugs for administration are reimbursed by Medicare for the average sales price of a drug, plus an additional 6 percent.

Quick Take

The Federal Government spends billions of taxpayer dollars on prescription drugs across a patchwork system of federal programs.

Congress must create transparency for federal drug purchasing programs to reduce drug costs imposed on taxpayers.

- **Medicaid** prescription drug coverage is an optional benefit covered by all states. Manufacturers that choose to sell their drugs to state Medicaid agencies must enter into a national rebate agreement with the HHS Secretary and provide information on their lowest or “best” drug prices.⁷ Manufacturer rebates vary depending on the specific product. States may limit formularies and require use of generic drugs when possible. Drug manufacturers that participate in Medicaid must sell their products at a discounted price to health providers covered by the 340B program.
- **The Veterans Health Administration (VHA)** reduces variability in access to pharmaceuticals by using a national formulary process. The VA uses multiple contracting mechanisms to acquire pharmaceutical supplies including the federal supply schedule (FSS), performance-based incentive agreements, or blanket purchase agreements (BPAs), temporary price reductions, pricing under the Veterans Health Care Act of 1992,⁸ and national standardization contracts. On a drug-by-drug basis, the VHA selects the mechanism that offers the best value at the lowest price.⁹

Medicare prescription drug purchasing is notably distinct in that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which created Medicare Part D, contains a “noninterference provision.”¹⁰ This provision prohibits the HHS Secretary from intervening in negotiations between Part D plan sponsors, drug manufacturers, and pharmacies or from requiring a specific Part D formulary.¹¹ Federal law also requires Medicare Part D plans to purchase six categories of drugs regardless of price or value.¹²

CONSTITUTIONAL AUTHORITY AND REPUBLICAN PRINCIPLES

The Constitution authorizes Congress to tax and spend in a manner that promotes the general welfare of the United States.¹³ Congress must protect a competitive drug marketplace and ensure that federal programs secure the best prices possible with federal purchasing power.

POLICY SOLUTIONS

All prescriptions are not created equally. Some have been around for decades, are effective treatments, and are quite affordable in generic form. Others represent cutting-edge biotechnology, treat relatively small populations, and are exceptionally expensive branded drugs and biologics. Congress may consider the following options to address drug prices:

- Require cost transparency for prescription drugs and biologics purchased by the Federal Government. Because of various rebates and discounts, determining the actual cost of a given unit of a specific therapy often proves difficult. The Federal Government should standardize this formula for federal purchases and provide a price-per-unit cost under each federal program that purchases prescription drugs.
- Allow reimportation of drugs that meet FDA standards. Significant price differences for the same drugs and biologics sold inside and outside of the United States are well documented. Allowing the safe reimportation of drugs purchased from foreign countries should result in cost savings for consumers. Currently, four states enacted laws to promote federal importation of prescription drugs in 2019.¹⁴
- Permit the HHS Secretary to negotiate drug prices with drug manufacturers. In May 2019, the Congressional Budget Office (CBO) released a letter to Chairman Grassley asking for an update to a 2007 letter on Medicare Part D price negotiations. CBO’s 2019 letter upheld the 2007 findings which suggested that cost savings would not occur unless the government possessed an additional “stick” to

leverage drug companies in price negotiations.¹⁵ Enabling negotiations provides Congress a reference point for further action.

- Address practices that unnecessarily delay generic alternatives coming to market. Whether it's limiting frivolous petitions against generic drug approvals, ensuring generic manufacturers' access to drug samples, or curbing reverse-payment settlements which delay generics coming to market, Congress has many options to make lower-cost generic drugs and biologics available as soon as patents expire.¹⁶

Please contact Cameron Smith or Kelsey Wall with the Republican Policy Committee at (202) 225-4921 with any questions.

¹ Association for Affordable Medicine, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S.* Report 4 (2019), <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>.

² Suzanne M. Kirchhoff, Judith A. Johnson, and Susan Thaul, Cong. Research Serv., R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy* 9 (2018), <https://fas.org/sgp/crs/misc/R44832.pdf>.

³ CMS, "National Health Expenditure Projections 2018-2027," at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2018Tables.zip>.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* Notably, out-of-pocket prescription drug spending decreased 10% from 2007-2017 while private health insurance spending increased 31%.

⁷ Rachel Dolan and Marina Tran, *Pricing and Payment for Medicaid Prescription Drugs*, Kaiser Family Foundation, Jan. 23, 2020, <https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/>.

⁸ Pub. L. No. 102-585

⁹ *See*, Kirchhoff, *supra*, note 2.

¹⁰ Pub. L. No. 108-173

¹¹ §1860D-11(i) of the Social Security Act states, "In order to promote competition under this part and in carrying out this part, the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

¹² The categories are antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretroviral drugs (such as those used to treat HIV), and anti-cancer drugs.

¹³ U.S. Const. art. 1, § 8.

¹⁴ Steven Findlay, *States Pass Record Number of Laws To Reel In Drug Prices*, Kaiser Health News, Sept. 9, 2019, <https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/>.

¹⁵ Letter from Cong. Budget Office Director Keith Hall to Sen. Chuck Grassley, *RE: Negotiation Over Drug Prices in Medicare* (May 17, 2019), <https://www.cbo.gov/publication/55270>.

¹⁶ *See generally*, Aaron S. Kesselheim, *Strategies That Delay Market Entry of Generic Drugs*, The Commonwealth Fund, Sept. 18, 2017, <https://www.commonwealthfund.org/publications/journal-article/2017/sep/strategies-delay-market-entry-generic-drugs>.