



## **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 2019, 90 percent of prescriptions filled in the United States are low-cost generics which account for roughly 20 percent of total drug spending.<sup>1</sup> Most increases in prescription drug spending are driven by brand-name drugs, biologics, and specialty drugs.<sup>2</sup>

The Federal Government purchases prescription drugs through a wide range of programs. In 2018, the Federal Government spent about \$152 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 over 45 percent of the \$335 billion in total national expenditures on prescription drugs.<sup>3</sup>

From 2008 to 2018, federal prescription drug spending across the aforementioned federal programs increased 94 percent, but spending growth wasn't spread equally across the programs.<sup>4</sup> For example, Medicare drug spending increased 111 percent from 2008 to 2018, and the federal portion of Medicaid drug expenditures increased nearly 74 percent.<sup>5</sup> Over the same period, other federal prescription drug spending increased by only 31 percent.<sup>6</sup>

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.
- **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.<sup>7</sup> 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,<sup>8</sup> and national standardization contracts. On a drug-by-drug basis, the VHA selects the mechanism that offers the best value at the lowest price.<sup>9</sup>

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.”<sup>10</sup> 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.<sup>11</sup> Federal law also requires Medicare Part D plans to purchase six categories of drugs regardless of price or value.<sup>12</sup>

## 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. In 2019 and 2020, six states enacted laws to promote the importation of prescription drugs.<sup>13</sup>
- 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.<sup>14</sup>

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<sup>1</sup> Association for Affordable Medicine, *The Case for Competition: 2020 Generic Drug & Biosimilars Access & Savings in the U.S.* Report, <https://accessiblemeds.org/resources/reports/2020-generic-drug-biosimilars-access-and-savings-us-report>

<sup>2</sup> 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>.

<sup>3</sup> CMS, “National Health Expenditure Projections 2019-2028,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2019Tables.zip>.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* Notably, out-of-pocket prescription drug spending decreased nearly 6% from 2008-2018 while private health insurance spending increased 25%.

<sup>7</sup> 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/>.

<sup>8</sup> Pub. L. No. 102-585

<sup>9</sup> *See*, Kirchhoff, *supra*, note 2.

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<sup>10</sup> Pub. L. No. 108-173

<sup>11</sup> §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.”

<sup>12</sup> 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.

<sup>13</sup> Meredith Freed, Tricia Neuman, and Juliette Cubanski. *10 FAQs on Prescription Drug Importation.*, Kaiser Health News, July 28, 2021, <https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/>

<sup>14</sup> 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>.