

5 | Prescription Drug Financing

Overview

Prescription drug financing and pricing may be the most complicated issue in health care. There is substantial debate over the affordability of drugs for patients, private payers, and government programs in recent years. Many facets and actors impact the final cost and price of drugs to payers and patients, including: Research and development costs of – and the exclusivity afforded to – a new drug, manufacturing costs, and the impact of pharmacy benefit manager (PBM) negotiations on patient cost-sharing rebates and discounts. While [spending](#) on prescription drugs

constituted about 14% of overall national health expenditures in 2018, [one in four](#) Americans reported difficulty affording their medications. Additionally, as scientific advancement allows for more complex specialty drugs and potentially curative cell and gene therapies to enter the market, both the policy community and consumers are growing more concerned about how to pay for those drugs.

[Drug pricing](#), therefore, is an area ripe for [policy option](#) discussions. There are growing questions

about the tradeoffs between innovation and prices charged in the U.S. relative to other countries – and whether prices reflect the drugs’ value to health. [States](#) have moved faster than the federal government to establish boards to examine price increases and to regulate PBMs, among other actions. The policy community has also expressed increasing interest in learning from and incorporating international drug pricing approaches. These activities are likely to influence continued national debate and potential action building in the 117th Congress on legislation considered and passed in the last session.

Background

The term “**drug**” encompasses a wide range of **substances** used to diagnose, cure, mitigate, treat, or prevent disease. The term includes small molecule drugs and large molecule biological products, which can have distinct market characteristics and face different pricing and spending challenges. Chapter 4 of this Handbook defines different drugs and therapeutic biological products and describes their approval processes by the U.S. Food and Drug Administration (FDA), as well as the basics of patent terms and exclusivity periods.

Figure 5.1 summarizes the United States’ prescription drug distribution system, the major entities, and how funds and services flow between them.

Multiple federal laws have created and impacted the current prescription drug development pipeline, pharmaceutical marketplace, and drug coverage programs, including:

- **1983 Orphan Drug Act:** Provides incentives to develop drugs for rare diseases.
- **1984 Drug Price Competition and Patent Term Restoration Act ([Hatch-Waxman Act](#)):** Intended to streamline generic drug approval process. (Discussed in more detail in Chapter 4.)
- **1990 Omnibus Drug Reconciliation Act:** Authorized the [Medicaid Drug Rebate Program](#) (MRDP) which aims to expand prescription drug coverage for low-income patients.

- **2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA):** Authorized the Medicare Part D program which aims to expand prescription drug coverage for seniors.
- **2010 Affordable Care Act (ACA):** Changed the structure of [MRDP](#), established a [biosimilar](#) approval pathway, and closed the Part D [donut hole](#).
- **2016 21st Century Cures Act:** Aims to, among many other things, streamline the drug and device approval process.

The federal government covers prescription drugs for patients through two main health insurance programs – Medicare (through Parts B and D) and [Medicaid](#). Almost all [employer health plans](#) include prescription drug benefits, and individual marketplace plans must include drugs as one of the ten essential health benefits. (Note that private plans do not necessarily cover all drugs.) Similar to provider payment rate variation (as discussed in Chapter 3), [net prices](#), [spending](#), and ultimately patient out-of-pocket costs can vary significantly across different programs and payers. Many reasons drive this variation including the fact that these programs target different patient populations, use formularies differently, and are subject to different statutory requirements and regulations. For sake of brevity, we have focused on the Medicare drug benefit (Parts B and D) in this chapter.

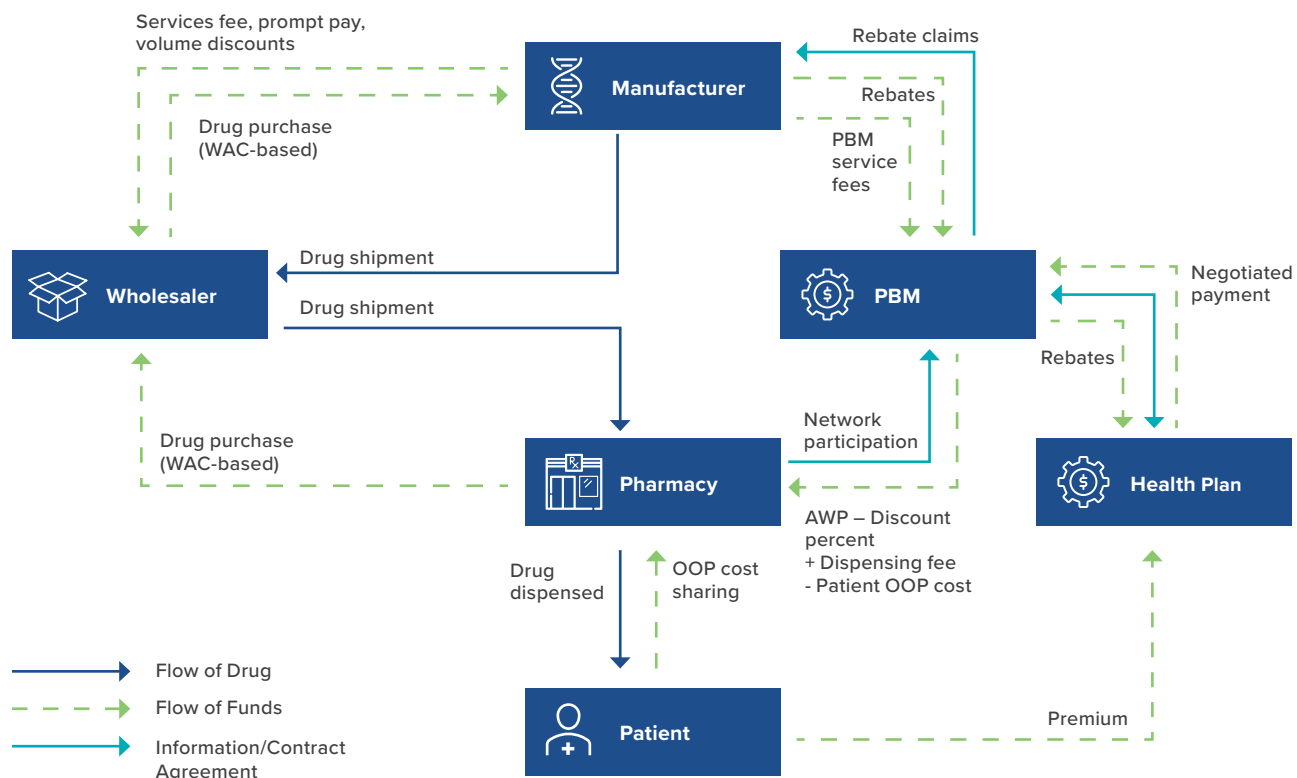
Drug Pricing Incentives in the Medicare Program

The Medicare program provides coverage for **out-patient drugs** prescribed to Medicare beneficiaries through Parts B and D. The Medicare Part B benefit covers drugs that are administered in a physician’s office setting. By contrast, the Part D program provides coverage for prescription drugs typically dispensed by retail pharmacies. Each program uses distinct mechanisms to pay for drugs covered under each benefit and face different spending and affordability challenges.

Drugs provided through the Part B drug benefit are reimbursed based on the average sale price (ASP) of the drug plus a 6% add-on payment to cover drug administration fees. Medicare Part B does not negotiate drug prices with brand-name manufacturers. Since the add-on payment increases as the ASP increases, there have been concerns that this creates incentives for physicians to administer higher-priced drugs. In the last several years, both CMS and Congress have proposed and considered changes to the ASP payment structure to address the arrangement’s potentially inflationary nature. They have also contemplated other approaches to contain Part B spending, including paying an amount derived from international prices, and penalties paid by manufacturers to Medicare if prices grow faster than inflation.

Medicare Part D, Medicare’s retail prescription drug benefit, was established in 2003 with the enactment of the Medicare Modernization Act (MMA). Funded with federal subsidies and beneficiary premiums, benefits are offered through private plans – either stand alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. The MMA included a “non-interference” provision that prohibits the government from interfering with negotiations between plans and drug manufacturers, or from requiring specific formularies or price structures for payment of the drugs. However, the law does include some drug coverage requirements on all Part D plans, including coverage of at least two drugs in each therapeutic class and nearly all drugs in six protected classes. In concept, insurers work to negotiate between manufacturers to drive the

Fig 5.1 Understanding the Prescription Drug Supply Chain



Source: “Follow the Pill: Understanding the Prescription Drug Supply Chain.” Olsen, M, Nam, D, Getachew, B. et al. Avalere. May 20, 2020. Available at <http://allh.us/BrTf>.

cost of drugs down for beneficiaries. Nevertheless, there has been a marked increase in the number of high-cost specialty drugs and drugs with prices rising faster than inflation. As a result, Part D beneficiary [premiums](#) and out-of-pocket costs are also [increasing](#). In 2017, [60%](#) of the drugs covered by Medicare Part D reported list price increases larger than inflation.

The Part D benefit structure may create incentives that lead to higher costs for Medicare. Primarily, the current structure of the Part D benefit may create financial incentives for plans to not manage costs for beneficiaries as closely, especially those with high drug costs. There are also concerns that the Part D benefit current structure could incentivize manufacturers to set a higher initial launch price for drugs. The benefit's structure may also discourage any efforts among manufacturers to limit year-to-year inflationary increases among drugs without any competition in their class. In response, policymakers are considering structural changes to the Part D benefit designed to address these issues, especially plan incentives, to encourage more efficient management and cost control.

Financing Challenges

In 2018, spending on drugs constituted 14% of overall national health expenditures. However, spending has increased in recent years, with retail prescription drug spending growing by [27%](#) between 2012 and 2016 – faster than other health expenditures categories. This growth [was attributed](#) to a surge in new specialty drugs coming to market in 2014. While spending slowed in 2016 and 2017, [CMS projects](#) that drug spending will increase by five to six percent between 2021 and 2028. Spending on prescription drugs is driven by brand-name drugs, which make up about [10%](#) of all prescriptions, but nearly [80% of spending](#). Policymakers should recognize that overall spending data may hide conflicting trends driven by the kind of drugs being studied, the conditions they treat, and consequently, their impact on individual patients' out-of-pocket costs. For example, recently a significant portion of spending growth has been [attributed](#) to a surge in new specialty drugs, with per

GLOSSARY OF TERMS

List Price: The price a manufacturer sets for a drug before discounts and rebates.

Net Price: The price of a drug after discounts and rebates are taken into account.

Rebate: A negotiated discount that payers are able to obtain from pharmaceutical companies due to purchasing volume and level of influence on drug product choice.

Average Sales Price (ASP): A manufacturer's reported average price for physicians, hospitals, and other purchasers of a drug. Inclusive of most discounts and rebates and only used for Medicare Part B drug payments.

Average Wholesale Price (AWP): A list price that does not reflect actual sales prices inclusive of discounts and rebates. Medicare payment for certain vaccines and blood products are based on a percent of AWP instead of ASP.

Wholesale Acquisition Cost (WAC): A price from a manufacturer to a wholesaler that is also related to the list price, but not the actual price of a drug. Used for new single-source drugs (brand-name drugs that do not have a generic) where average sales price data are not yet available. Usually lower than AWP.

capita growth in specialty drugs outpacing overall drug spending trends. Since 2014, prices for brand specialty drugs have increased by [57%](#), while generic drugs' prices fell by [35%](#).

As evidenced above in Fig 5.1, the prescription drug supply chain is complex and many interconnected factors drive spending and prices. We have chosen to focus on the costs of bringing new drugs to market and the role of rebates in this chapter as these drivers impact all federal programs and private drug benefit plans.

KEY DRUG COST ISSUES FOR THE 117TH CONGRESS

- Growing affordability issues for Medicare beneficiaries for Part B and Part D drugs.
- Financing for very high-cost drugs that may be curative or very effective.
- Role of PBMs in managing drug formularies and how rebates affect list prices for drugs.

Cost of Innovation and Bringing Drugs to Market

The question of how much biomedical innovation costs is often brought up in discussions over how drugs are priced and their impact on federal, state, and household budgets. Unfortunately, estimates of the cost to bring drugs to market vary widely depending on the study, companies examined, and data used. For instance, a [2016 study](#) of multinational biopharmaceutical companies estimated that research and development (R&D) costs were \$2.6 billion per approved drug. In contrast, a [2020 study](#) on research and development costs for drugs approved by the FDA estimated that the median cost to bring a new drug to market was \$985 million. The methodologies and sources of data can vary widely from one study to another resulting in wide ranges of estimates.

The path from discovering a new potentially medicinal compound to FDA approval can be [long](#), taking an average of 10-15 years, with the final five years or so accounting for human clinical trials. It can also be much shorter than that, particularly for highly effective new therapies and precision medicines. After discovery, sponsors must successfully navigate preclinical and clinical research consisting of three trial phases. Of the drugs that enter the clinical research phase, only

[25-30%](#) advance from Phase 3 trials. After completing clinical research, *New Drug Applications* (NDAs) or *Biologics License Applications* (BLAs) are submitted to the FDA for approval. Timelines for reviewing applications range from six months for priority reviews to 10 months for standard reviews. Pharmaceutical manufacturers are [required](#) to conduct post-market surveillance with Phase 4 studies that assess drugs' effectiveness and their long-term effects.

The [National Institutes of Health](#) (NIH), is one of the eleven operating divisions of the U.S. Department of Health and Human Services, and, with an annual budget of [\\$41.7 billion](#), is a major funder of basic and translational science, including drug innovation. In addition to funding basic science that supports drug development, a recent study found that an estimated [25%](#) of newly approved drugs had late-stage development links to NIH funding or academic medical centers. Discussion around research and development costs also raises the question of which taxpayer-funded programs contributed to any given drug's discovery process, and how that contribution should factor into its future market pricing.

Role of Pharmacy Benefit Managers' Rebates and Discounts

[PBMs](#) came to prominence in the 1980s, playing a role in negotiating drug prices with manufacturers on behalf of insurers. PBMs manage prescription drug benefits for insurers by developing formularies, negotiating rebates and discounts from manufacturers, and contracting with pharmacies which are reimbursed for drugs dispensed to beneficiaries (See Fig 5.2). Patient [benefits](#) can include home delivery of medications, adherence programs, and managing high-cost specialty medications.

PBMs use rebates to drive lower prices, with the volume of drugs purchased used as a lever to encourage larger

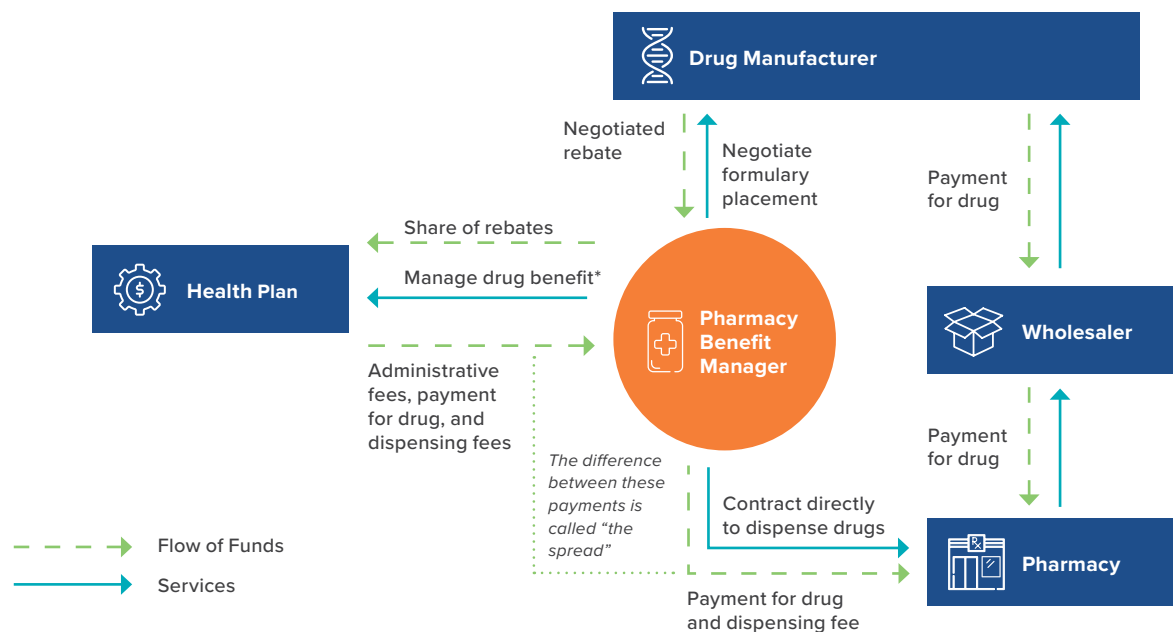
rebates. In exchange for their efforts, PBMs typically retain some portion of the savings achieved. Positioned between manufacturers and insurers, they are in the “middle” of the transaction chain.

One of the side effects of using rebates is that it can lead to higher overall health spending, potentially by increasing list prices, which are paid for by the uninsured and those with insurance that base cost-sharing on list prices. PBMs receive rebates that are often calculated as a percentage of list price (the price of a drug that is set by the manufacturer). Some critics say this creates a perverse incentive for PBMs to favor more expensive drugs or drugs with larger rebates. This has also raised questions of whether these rebates contribute to manufacturers raising their list prices to offset larger rebates to PBMs. Unfortunately, data can support both arguments (and furthermore, data is somewhat hard to come by as many entities consider it proprietary information). A Pew study found that manufacturer rebates grew from \$39.7 billion in 2012 to

\$89.5 billion in 2016. However, a survey of insurers and PBMs found that PBMs passed a greater percentage of rebates back to insurers – increasing from 78 to 91% over the same period.

PBMs have also been at the center of controversies related to generic drug pricing. In negotiating prices for drugs, PBMs can use a model called “spread” pricing, in which a PBM charges an insurer *more* than it pays the pharmacy for a drug and then retains the difference. While these are voluntary agreements between PBMs and payers, there are increasing concerns about how this spread pricing practice may be driving up prices for generic drugs – which are usually far less expensive than brand-name drugs – and in turn may be driving up costs for insurers, premiums, and government programs. In 2019, CMS restricted the practice within the Medicaid program, but spread pricing is still used in the commercial market. Calls for greater transparency on rates and requirements to pass on rebates to insurers or patients are likely to continue.

Fig 5.2 Role of Pharmacy Benefit Managers in the Prescription Drug Supply Chain



Source: “Pharmacy Benefit Managers and Their Role in Drug Spending.” The Commonwealth Fund. April 2019. Available at <http://allh.us/nj4h>.

International Approaches to Drug Financing

The U.S. paying more for prescription drugs relative to counterparts in other developed countries is not new. Calls for prescription drug reimportation to reduce costs for Americans date back decades. However, the current drug pricing debate has renewed interest in how other developed countries approach drug pricing and financing. These countries use a range of tools to support their drug pricing and

financing approaches, including health technology assessments that examine the clinical benefits of a drug, negotiating drug prices, setting limits on post-approval price increases, and using reference pricing. Some of these tools are described in more detail in Table 5.1, below. These or similar options are being discussed for potential adoption in the U.S. Note that many countries employ multiple options or approaches for drug pricing depending on the type of drug and its level of competition in the market.

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Table 5.1 Overview of International Approaches to Drug Financing

Pricing/Financing Approach	Description
External Reference Pricing	Setting prices for drugs by taking into account what other countries pay , which can lower the price of drugs depending on the countries used in the analysis
Internal Reference Pricing	Setting prices based on payments for clinically comparable products , however, cannot be used for drugs without any comparable alternatives
Value-Based Pricing	Setting prices based on an assessment of the value , including clinical benefits of a drug
Negotiation	Setting prices with manufacturers using reference prices or value assessments

Source: "Payment Policies to Manage Pharmaceutical Costs." Docteur, E., Lopert, R. The Pew Charitable Trusts. March 2017. Available at <http://allh.us/Bpnr>.

RESOURCES

Chapter 5: Prescription Drug Financing

Listed by the order in which they appear in Chapter 5.

OVERVIEW

Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. <http://allh.us/UbxC>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

Frequently Asked Questions About Prescription Drug Pricing and Policy. <http://allh.us/uw6d>

Prescription Drug Pricing. <http://allh.us/rRXN>

2021 State Legislative Action to Lower Pharmaceutical Costs. <http://allh.us/JNCY>

BACKGROUND

Drugs@FDA Glossary of Terms. <http://allh.us/eF9D>

Orphan Drug Act: Background and Proposed Legislation in the 107th Congress. <http://allh.us/jXvG>

The Hatch-Waxman Act: A Primer. <http://allh.us/Ew7u>

Medicaid Prescription Drug Pricing and Policy. <http://allh.us/TqbD>

Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. <http://allh.us/qVkd>

What Happens to Medicaid Drug Policy if the ACA is Overturned? <http://allh.us/uehW>

Health Policy Brief: Biosimilars. <http://allh.us/Byhw>

Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead. <http://allh.us/rCx9>

The 21st Century Cures Act (Division A of P.L. 114-255). <http://allh.us/URcY>

Medicaid's Prescription Drug Benefit: Key Facts. <http://allh.us/jpRa>

2020 Employer Health Benefits Survey. <http://allh.us/Bnfb>

A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. <http://allh.us/NkB8>

How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid? <http://allh.us/UJTc>

DRUG PRICING INCENTIVES IN THE MEDICARE PROGRAM

Part B Drugs Payment Systems. <http://allh.us/MpTE>

Medicare Part D Prescription Drug Benefit. <http://allh.us/QDCA>

Negotiation of Drug Prices in Medicare Part D. <http://allh.us/j4xb>

General Drug Categories. <http://allh.us/np8c>

An Overview of the Medicare Part D Prescription Drug Benefit. <http://allh.us/9t4h>

Assessing Drug Price Increases in Medicare Part D and the Implications of Inflation Limits. <http://allh.us/hBdt>

The Prescription Drug Landscape, Explored.

<http://allh.us/VRTf>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

National Health Expenditure Projections 2019–28. <http://allh.us/XUhg>

Why Are Prescription Drug Prices Rising and How Do They Affect the U.S. Fiscal Outlook? <http://allh.us/Exhd>

Medicine Spending and Affordability in the United States. <http://allh.us/hpJ3>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

COST OF INNOVATION AND BRINGING DRUGS TO MARKET

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. <http://allh.us/dwtb>

Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. <http://allh.us/XVQU>

The Pharmaceutical Drug Development Process. <http://allh.us/J3BD>

National Institutes of Health: About NIH.

<http://allh.us/AGuR>

National Institutes of Health: Budget. <http://allh.us/hX3K>

Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study. <http://allh.us/j63p>

ROLE OF PHARMACY BENEFIT MANAGERS' REBATES AND DISCOUNTS

Pharmacy Benefit Managers. <http://allh.us/vngQ>

The Value of PBMs. <http://allh.us/3EfK>

Pharmacy Benefit Managers and Their Role in Drug Spending. <http://allh.us/nj4h>

The Prescription Drug Landscape, Explored. <http://allh.us/VRTf>

Pharmacy Benefit Managers and Their Role in Drug Spending. <http://allh.us/nj4h>

CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers. <http://allh.us/wCuV>

Box: Glossary of Terms

Medicare Part B Drug Average Sales Price. <http://allh.us/dpuN>

Medicare Part D Prescription Drug Benefit. <http://allh.us/QDCA>

Use of Average Sales Price Payment Methodology. <http://allh.us/WGbJ>