Medicare Drug Pricing: Strategies for Managing Costs

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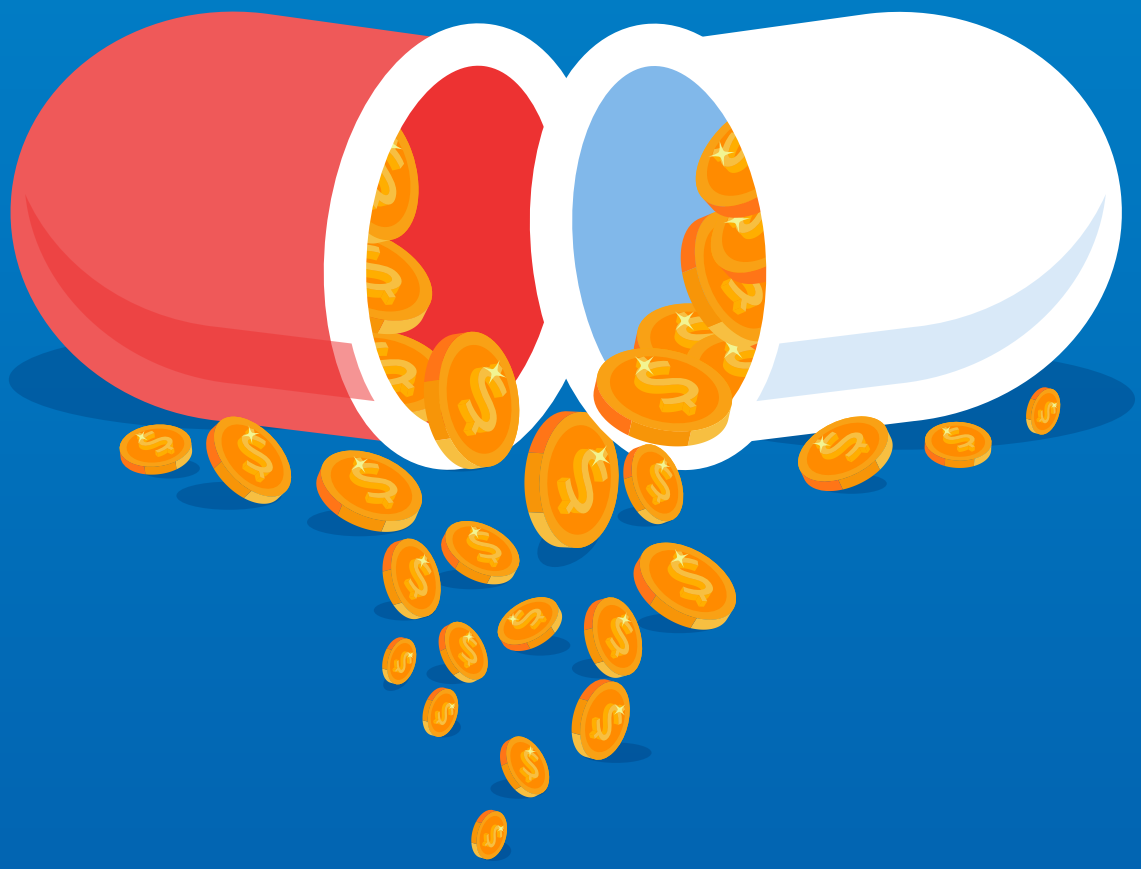

U.S. drug spending has increased dramatically in the last 20 years. Americans pay the highest drug prices in the world, which leads to higher direct spending for patients and payers—both in the private and government sectors. Meanwhile, health plans are forced to raise premiums or make benefits less generous as prices continue to skyrocket. Novel drugs, such as immunotherapy and gene therapy for cancer or anticoagulants for blood clots, are among the most expensive and account for a large share of Medicare drug spending.[1] The federal government, as the largest purchaser of prescription drugs for Medicare seniors and some disabled individuals eligible for Medicare or Medicaid, lacks the power of direct price negotiations with manufacturers which some argue contribute to our nation's inability to curb the dramatic rise in prescription drug spending.

Research suggests that lack of affordable access to prescription drugs and other health care services greatly burden more vulnerable populations, who often skip or underutilize their recommended drug doses, which leads to poor medication adherence and ultimately worse health outcomes.[2]A look at federal efforts to lower drug prices and overall drug spending, especially through the Medicare program, might suggest a way forward.

1 Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending | KFF
2 Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age | KFF

Drug Flow and Contracting: A Complex Story

A broad array of players is involved in dispensing drugs to patients through a complex supply chain. Manufacturers produce pharmaceuticals or prescription drugs, physicians prescribe those pharmaceuticals to their patients, and patients in turn purchase them from pharmacies. Most often, patients pay some portion of the cost through out-of-pocket cost sharing (e.g., copays or coinsurance) required by their health plans. Wholesalers often distribute drugs between manufacturers and pharmacies, while health insurers, Pharmacy Benefit Managers (PBMs), and other intermediaries arrange and finance coverage through drug formularies or other preferred drug lists. A small number of companies acting as intermediaries between these manufacturers and payers—and ultimately providers and their patients—often dominate certain markets, particularly among the larger PBMs. This ***lack of robust competition among these intermediaries, otherwise known as the "middleman," offers little to no incentive to reduce drug costs for the patient,*** and in turn are major factors that drive increases in overall drug spending.[3]

Medicare prescription drug spending among seniors and some disabled individuals is substantial, both in absolute terms and as a proportion of total Medicare spending, and is growing rapidly. Medicaid, a health insurance program jointly administered and financed by the federal government and state governments, usually provides eligible low-income groups with prescription drug coverage at little to no out-of-pocket cost for eligible beneficiaries but the overall cost burden on states in recent years has similarly increased in a substantial way. In most cases, private health plans in the commercial sector are mandated to cover prescription drugs. These individuals access drug coverage through employer-sponsored health benefit plans or purchase an individual health insurance plan through the Affordable Care Act (ACA) Marketplace, sometimes at a lower or subsidized cost. In recent years, both employer-sponsored plans and ACA marketplace plans have experienced rapidly increasing premiums or cost-sharing arrangements due largely to the rise in cost for pharmaceuticals.[4]

> Medicare is the largest payer in the U.S., accounting for roughly a third of all drug spending in 2020.

Because Medicare is the largest payer in the United States—accounting for roughly a third of all drug spending in 2020 when Part B and Part D are combined—Medicare payment policy can play a large role and should be considered as a major influencer to impact prescription drug prices and overall drug spending across all payers in the country.

The Medicare program provides coverage for both inpatient and outpatient drugs prescribed to Medicare beneficiaries through Parts B and D.

Medicare Part B covers drugs that are typically administered or overseen by the order of a physician, such as intravenous infusions or other injectables.

Medicare Part D provides coverage for prescription drugs typically dispensed by retail or specialty pharmacies as oral medications.

Each Medicare Part component uses distinct mechanisms to pay for drugs covered under their respective benefit structures and face different spending and affordability challenges.

Drug benefit design in Medicare Parts B and Part D

Medicare Parts B and D both offer prescription drug coverage under different federal guidelines. Medicare Part B mostly covers drugs administered by a health professional, such as intravenous infusions or other

3 Follow the Pill: Understanding the Prescription Drug Supply Chain | Avalere Health
4 Tracking the rise in premium contributions and cost-sharing for families with large employer coverage - Peterson-KFF Health System Tracker

injectables. Drugs provided through the Part B drug benefit are reimbursed based on the average sale price (ASP) of the drug among nearly all U.S. purchasers (with some limited exceptions) plus a 6 percent add-on payment to cover drug administration fees.

Some drug manufacturers reduce the sale price of a Part B drug if a purchaser (e.g., large provider system or group physician practice) agrees to use it exclusively rather than a competitor's alternative. Manufacturers may also reduce the price of a more common drug if a purchaser agrees to also buy the manufacturer's specialty drugs to treat conditions like cancer or HIV/AIDS. Often these arrangements can "box in" practitioners, forcing them to prescribe a manufacturer's drug even when higher-value or cheaper alternatives are available. In some cases, these package deals and pricing schemes can result in providers even paying more to buy a generic drug than its brand name equivalent.[5]

Medicare Part D covers most outpatient prescription drugs. Benefits are offered through private plans—either stand-alone prescription drug plans (PDPs) for traditional fee for service enrollees or Medicare Advantage prescription drug (MA-PD) plans for people with Medicare Advantage Plan. Plans are offered by private insurance companies that typically provide other health insurance products beyond Medicare Part D plans, and there are often many choices based on location of residence and income level. These plans offer an array of coverage generosity (e.g., zero premium plans in exchange for higher cost-sharing of certain Part A or Part B services). The Medicare Modernization Act (MMA) of 2003 prohibits the government from interfering with negotiating lower drug prices between individual private plans and drug manufacturers.

In concept, insurers use their purchasing power or large volume of enrollees to negotiate lower prices for their pharmaceuticals, which in theory should drive the cost of drugs down for all Medicare beneficiaries enrolled in Part D. Cost sharing under Part D often is in the form of coinsurance, which is calculated as a percentage of the list prices. This could incentivize manufacturers to set a higher initial launch price for drugs, recognizing that other nations invoke stronger price controls while the U.S. government may not. The current structure of the Part D benefit may create financial incentives for plans to not manage costs for beneficiaries as closely as they may do for other insurance products, especially those Medicare Part D enrollees with high drug costs. For example, there is no cap on out-of-pocket spending so the financial burden for the catastrophic coverage costs is on Medicare not the plans. The Part D benefit structure may also discourage any efforts among manufacturers to limit year-to-year inflationary increases among drugs if there's little or no competition in their class.

A small number of medications are responsible for a large majority of money spent on Medicare Part B drug costs and often covers some very expensive medications, such as[6]:

Immunosuppressants
(e.g., brand name: **Orencia**; generic name: **Abatacept**)

Osteoporosis injections
(e.g., brand name: **Prolia**; generic name: **Denosumab**)

Cancer immunotherapy
(e.g., brand name: **Keytruda**; generic name: **Pembrolizumab**)

Macular degeneration
(e.g., brand name: **Eylea**; generic name: **Aflibercept**)

[5] Evaluation of the Oncology Care Model – Participants' Perspectives (cms.gov) (see p.60).
[6] Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending | KFF

Financing Challenges/Drivers of Increased Spending:

The growth of specialty drugs and the role of PBM rebates and discounts

While the prescription drug supply chain is intricate and many factors are known to contribute to high drug prices, a recent surge of often highly priced specialty drugs is increasingly accounting for a significant portion of spending growth.[7] This phenomenon has led to more competition through new and breakthrough developments in higher-value or cheaper biosimilars and generic drugs. Payers, in turn, are looking to improve access to these less costly drugs by adding them to their formularies or finding other means of value-based purchasing programs to encourage providers to prescribe these cheaper alternatives when efficacy and safety are otherwise the same as the costlier originator's or brand-name equivalent's. Value-based models such as Medicare's Oncology Care Model (OCM) and Medicare Advantage Value-Based Insurance Design Model (VBID) have goals to incentivize providers to reduce total spending and select higher-value therapy options, when available, on these newer specialty drugs.[8] [9]

> Pharmacy Benefit Managers (PBMs) negotiate drug prices with manufacturers but could also create perverse incentives that keep drug prices artificially high.

PBMs often act as a middleman in negotiating drug prices with manufacturers on behalf of insurers. Normally, PBMs use rebates to drive lower prices - the higher the purchased drugs are priced, the larger the rebates they could successfully negotiate. As a middleman, PBMs retain some portion of the rebate savings achieved. This role and their handling of how rebate savings can be achieved has been controversial. For example, when using the list price to calculate rebates, PBMs could create a perverse incentive for manufacturers to raise prices or keep them artificially high. Also, a practice known as "spread pricing" could drive up prices for generic drugs,[10] whereby the PBM charges an insurer more than it pays the manufacturers for a drug (mostly a generic drug). The spread between the two prices has grown in the recent years. Policy discussions have emerged to improve transparency on this practice of rebates, and how it gets passed on as savings to insurers or patients.

Medicare Models Offer Insight

Oncology Care Model (OCM) Evaluation: Abt is currently in its sixth year of conducting an evaluation of OCM, which is a chemotherapy-based episode payment model focused on providing higher quality and more coordinated

7 AARP Report: Average Specialty Drug Price Reached $84,442 in 2020, Rising More Than Three Times Faster Than the Prices of Other Goods and Services - September 28, 2021

8 Evaluation of the Oncology Care Model: Performance Periods 1-6 - OCM Impacts on Payments (cms.gov)

9 Evaluation Report of the First Three Years (2017–2019) of the Medicare Advantage Value-Based Insurance Design Model Test (cms.gov)

10 The Secret Drug Pricing System Middlemen Use to Rake in Millions (bloomberg.com)

oncology care. By the fourth year of the Model, Medicare experienced net losses in any cost savings when factoring in monthly enhanced payments and performance-based incentive payments participants received to increase care coordination and quality. However, OCM practices had achieved a small relative reduction of total episode payments of about 1 percent relative to comparisons. This small impact was largely driven by reductions in Part B non-chemotherapy (supportive care) drugs, and not in chemotherapy Part B or Part D payments.

Thus, there is encouraging evidence that OCM led to more value-based or cost-conscious use of supportive care drugs. Case studies from the evaluation revealed that any single value-based program in oncology care is not enough of a motivator to offset the very powerful fee-for-service payment incentives of the current ASP plus 6 percent reimbursement for Part B chemotherapy drugs. And that Part D plan sponsors are in a better position to manage or incentivize greater use of higher-value drug treatments through drug formularies, drug rebates, medication therapy management programs, or any cost-sharing requirements for Part D (oral) chemotherapies among Medicare beneficiaries.

Accountable Care Organizations (ACOs)

Abt's evaluation of Medicare's ACO Investment Model (AIM) found substantial savings to Medicare after three years, primarily driven by decreases in hospital, skilled nursing facility, and outpatient facility care services. ACOs might increase prescription drug spending directly through efforts to improve performance on quality measures such as chronic disease control. Alternatively, ACOs may indirectly reduce wasteful prescribing as part of related initiatives to reduce unnecessary Part A and B spending. Abt used a difference-in-difference framework with weighting and regression adjustment and found that, in the first performance year, AIM ACOs were able to reduce Part D expenditures. In subsequent years, AIM ACOs did not result in increased prescription drug spending.[11]

Looking Ahead: Models that Might Show a Way Forward

Beginning in 2021, CMS implemented a new voluntary model for Part D plan sponsors to offer diabetic beneficiaries dependent on insulin affordable copayments (capped at $35) for a broad set of formulary insulins. This Senior Savings Model could be scaled to include additional drug classes with high out-of-pocket costs or utilization for beneficiaries. If successful, these enhanced alternative Part D could greatly help beneficiaries with certain medications.

CMS could integrate value-based approaches to reduce drug spending within current shared savings programs or episode-based (bundled) payment models:

Shared savings: The CMS Innovation Center could consider models in Medicare Part D that target greater use of biosimilars, generics, or other high-value products. Such models aim to achieve potentially meaningful savings that can be shared between prescribing providers, their patients, and the government. Such a model could build on other value-based programs like Accountable Care Organizations (ACOs). Currently ACOs do not include Part D spending in calculating spending targets, but a new innovation center model could test holding prescribers accountable for a reduction in total cost of care over time, including drugs covered under Medicare Part D.

[11] The Effect of the Shared Savings Program on Medicare Part D Spending: Evidence from Rural and Underserved Areas - PubMed (nih.gov)

***Bundled payment for treatment episodes*:** These models could focus on episodes of care that include drugs and biologics accounting for a large proportion of Medicare Part B drug spending, along with the drug administration services, devices, and related services furnished to a beneficiary over a period of time. Conditions such as hepatitis C, HIV/AIDS, opioid use disorder, and diabetes are ones that could allow for treatments to occur and financial incentives to be aligned with cost reduction, while maintaining or enhancing quality, within a defined episode. Current or future iterations of existing models (e.g., Oncology Care Model) that test innovative bundled payments for a broad set of services could include financial incentives that promote greater use of biosimilars, generic drugs, and high-value single source products.

The Biden Administration faces formidable obstacles to addressing prescription drug spending. Given that, federal policy officials may find it worthwhile to test innovative drug pricing reform in more incremental stages, or find new ways to incentivize providers to use higher-value therapies through the Medicare or Medicaid programs—and perhaps the Affordable Care Act Marketplace, too, for those populations that rely on private health plans for coverage.

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