

CHAPTER

2

**Assessing postsale rebates
for prescription drugs
in Medicare Part D**

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Chapter summary

The final amounts that Part D plans pay for the prescriptions that their enrollees fill are often lower than prices at the pharmacy. This is because the insurers that offer plans (plan sponsors) and their pharmacy benefit managers (PBMs) negotiate rebates and fees from drug manufacturers and pharmacies that take place after a prescription has been dispensed. Collectively, CMS refers to negotiated rebates and postsale fees as direct and indirect remuneration (DIR). Plan sponsors can use their portion of DIR to restrain growth in premiums or reduce cost sharing. Plan sponsors have long believed that Part D enrollees focus most on premiums when making their plan selection, and thus plan sponsors have strong incentives to use the DIR to keep premiums low. Because rebates and fees have become so large, the way in which sponsors apply DIR to constrain premiums or cost sharing has implications for the distribution of Part D costs among all enrollees, particularly those who use rebated drugs, and for the Medicare program at large. The Consolidated Appropriations Act, 2021, included a provision giving the Commission access to DIR data; this chapter provides insights from our analyses of the data.

DIR has grown rapidly: Between 2010 and 2021, it ballooned from \$8.6 billion to \$62.7 billion, expanding as a share of gross Part D spending from 11 percent to 29 percent. Most of that total was consistently made up of

In this chapter

- DIR constrains premium growth but can also lead to higher costs for some beneficiaries
- Rebates vary across drug classes based on therapeutic competition and formulary coverage policies
- Plan sponsors with vertically integrated PBMs have gained market share and negotiating leverage
- Looking ahead

manufacturer rebates, though the share declined over time as pharmacy DIR grew. In 2010, rebates accounted for 99 percent of DIR, but by 2021, rebates' share of total DIR declined to 80 percent. In 2021, the Medicare program kept about one-third of DIR to offset some of Part D's reinsurance subsidies.

Multiple factors have contributed to growth in manufacturer rebates.

- **Therapeutic competition and Medicare formulary policies.** Manufacturers negotiate rebates with PBMs for brand-name products that have therapeutic competitors in exchange for putting their drug on a plan's formulary and placing it in a position that helps the drugmaker win market share. For certain classes of drugs, such as medications used to treat asthma and chronic obstructive pulmonary disease, regulatory hurdles and extensive patent protection have slowed generic entry. With a lack of generic competition but considerable rivalry among competing brands, manufacturers have chosen to raise gross prices and compete using postsale rebates. (For the purposes of this chapter, we define gross drug prices as all point-of-sale payments at the pharmacy, including enrollee cost sharing and plan payments.) In contrast, for protected classes of drugs in which virtually all drugs must be covered, price competition is weakened, hindering plans' ability to negotiate rebates.
- **Part D's benefit structure and emphasis on premium competition.** Part D's current benefit structure leaves plan sponsors bearing relatively little insurance risk for their enrollees' drug spending. This limited risk is due in part to Part D's unusual benefit design—with its coverage gap and provision of Medicare reinsurance in its catastrophic phase. Trends in prescription use are also a contributing factor because high-cost biologics and specialty medications account for a mounting share of spending, and Medicare's payments to plans increasingly take the form of cost-based reinsurance. Because the program emphasizes premium competition, sponsors have had incentives to try to maximize rebates and keep premiums low. In a limited number of drug classes, this strategy has led some sponsors to select high gross-price, high-rebate drugs for their formularies over lower gross-price alternatives. In addition, many entities in the drug supply chain benefit from high gross prices because compensation for their services is often paid as a percentage of price.
- **Vertical integration of plan sponsors, PBMs, and pharmacies.** Since the start of Part D in 2006, plan sponsors and their PBMs have consolidated. Vertically integrated insurers with their own PBMs and specialty pharmacies now control a larger proportion of covered lives

and the dispensing of higher-priced drug products. Larger market shares of enrollment and dispensing tend to provide sponsors with greater bargaining leverage for postsale price concessions from both manufacturers and pharmacies.

While large rebates help to constrain premium increases, using rebates primarily to lower premiums also means that beneficiaries who use such drugs (or the Medicare program, in the case of Part D's low-income subsidy (LIS) enrollees) sometimes pay cost sharing that is higher than the drug's cost. In recent years, for about 8 percent of gross spending aggregated across all phases of the Part D benefit (9 percent of brand spending), the cost-sharing amounts set by plan sponsors exceeded net drug costs after deducting rebates. In those situations, at the time the prescription was filled, the plan effectively faced no liability for the prescription other than its administrative costs. Instead, the beneficiary or Medicare (on behalf of LIS beneficiaries) paid more than the total cost of the drug. For enrollees without the LIS, high cost sharing can affect whether they fill their prescriptions.

Our analysis focused on a range of drug classes and products for prescriptions filled between 2015 and 2021. While rebates vary considerably across drug classes and over time, we observed large rebates in classes that had strong brand-brand rivalry but lacked generic or biosimilar entry. In contrast, for protected classes of drugs in which virtually all drugs must be covered, price competition was weakened, hindering plans' ability to negotiate rebates. As a result, gross prices for drugs in many protected classes grew faster than for drugs in other classes, while rebates were significantly lower, often averaging less than 10 percent of gross prices.

Rebates obtained by large, vertically integrated plan sponsors increased over time and were larger than those received by other plan sponsors. Between 2015 and 2021, we observed compression in the rebates obtained by large sponsors for two out of the three drug classes we examined, consistent with the consolidation taking place among sponsors. However, compression in average rebates could also have resulted from the degree of maturity of therapeutic competition in those classes and payers' better understanding of the magnitude of potential rebates.

We found that rebates can vary widely for the same product among plans operated by the same sponsor. Even plans using the same formulary can face widely divergent costs for the same drug product after rebates. Some of that

variation reflects the fact that large sponsors operate plans that serve different enrollee markets, such as employer groups, Medicare Advantage–Prescription Drug plans, and different types of stand-alone prescription drug plans.

Vertical integration may pose a particular challenge for Part D as the market becomes increasingly concentrated among the largest sponsors that own (or are owned by) a PBM and pharmacies. For a limited number of drug categories, we found that payments and costs (after manufacturer rebates) were more likely to be higher at vertically integrated (VI) pharmacies compared with costs at other pharmacies, particularly when those prescriptions were filled for their own VI plans. Because Part D’s DIR reporting requirements do not include discounts or postsale fees retained by pharmacies that are paid by manufacturers, CMS may lack information about the true benefit costs of plans operated by plan sponsors that are vertically integrated with a PBM and pharmacies.

Our findings provide insights into current rebate practices while also highlighting how competitive dynamics and regulatory policies can affect drug pricing. However, the Inflation Reduction Act of 2022 includes numerous policies related to prescription drugs and the Part D benefit. As that law is implemented over the next several years, its changes to policy are likely to alter the drug-pricing landscape and affect the degree to which plan sponsors and manufacturers continue to use rebates. The Commission’s analyses of DIR data will serve as a baseline for future evaluations of how rebates are used in the Part D program. ■

Background

The final amounts that Part D plans pay for the prescriptions that their enrollees fill are often lower than prices at the pharmacy. This difference exists because the insurers that offer plans (plan sponsors) and their pharmacy benefit managers (PBMs) negotiate rebates and fees from drug manufacturers and pharmacies that take place after a prescription has been dispensed. Collectively, CMS refers to negotiated postsale rebates and fees as direct and indirect remuneration (DIR). To ensure that Medicare's payments to plans take those price concessions into account, CMS requires plan sponsors to report information about DIR (Centers for Medicare & Medicaid Services 2022).

The Consolidated Appropriations Act, 2021, included a provision giving the Commission access to DIR data, which are highly proprietary. The statute specifically prohibits presenting the data “in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler.” In addition, the law states that the Commission may not reveal plan-level dollar amounts of rebates and fees or the sources of those price concessions. This chapter presents the Commission's evaluation of DIR data to date and displays our results in a way that abides by the restrictions specified in law.

Last year, the Congress passed the Inflation Reduction Act of 2022 (IRA), which included policy changes related to prescription drugs that are likely to alter the drug-pricing landscape. One such provision is a redesign of the Part D benefit that reflects many of the Commission's 2020 recommendations to cap enrollees' out-of-pocket (OOP) spending and restore stronger incentives to Part D plan sponsors (Medicare Payment Advisory Commission 2020). Among other provisions, the law (1) establishes mandatory rebates for manufacturers of drugs sold to Medicare beneficiaries if the price of their drug rises faster than inflation, and (2) requires the Secretary of Health and Human Services to negotiate prices each year for a select number of drugs with the highest total Medicare spending. (The Secretary will select the first 10 drugs for negotiation in 2023, and negotiated prices for those drugs will be effective in 2026.) Changes adopted in the IRA may affect the magnitude of future

rebates and the circumstances under which Part D plan sponsors are able to negotiate for rebates with manufacturers.

What is DIR?

When a Part D enrollee fills a prescription at a pharmacy, the beneficiary pays the pharmacy the plan's required cost-sharing amount and the plan sponsor pays the pharmacy an amount based on the terms of its network contract; collectively, these point-of-sale payments are referred to as gross drug prices. For many years, the Commission has received and analyzed prescription drug event (PDE) data that are similar to claims and reflect gross drug prices. However, plan sponsors and their PBMs negotiate with drug manufacturers and with pharmacies for postsale rebates and other remuneration, or DIR (Figure 2-1, p. 72). DIR decreases the benefit costs that plan sponsors must pay for and, in turn, tends to keep plan bids lower than they otherwise would be.

Components of DIR

There are two major components of DIR: negotiated rebates from manufacturers and postsale fees to and from pharmacies.

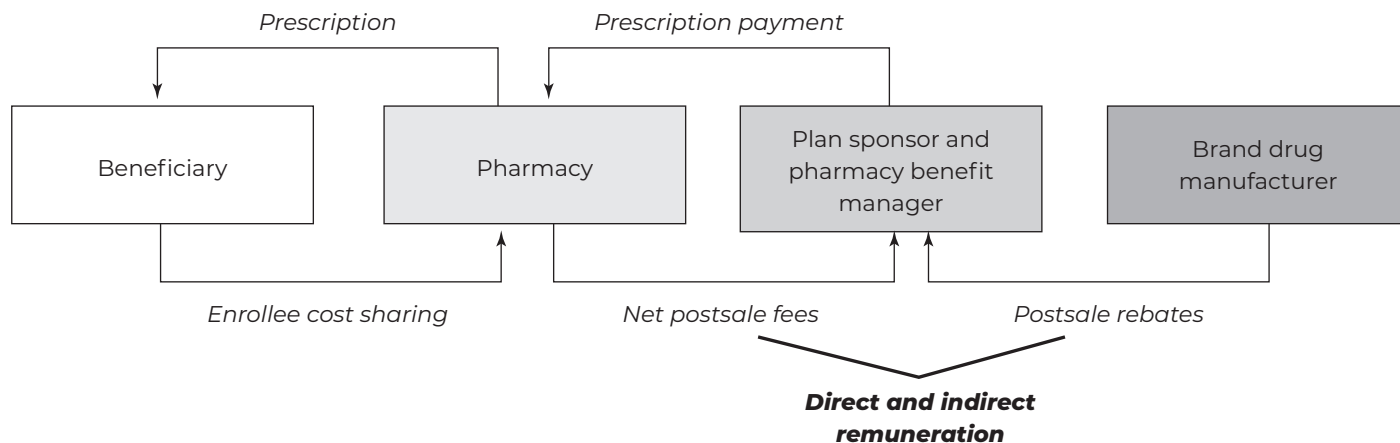
Manufacturer rebates

In general, manufacturers negotiate rebates and other postsale remuneration with PBMs for brand-name products. Typically, plans negotiate larger rebates for products that have therapeutic competitors in exchange for putting their drug on a plan's formulary and placing it in a position that helps the drugmaker win market share. In 2021, over 80 percent of gross Part D spending was for brand-name drugs and biologics, and more than three-quarters of that amount was attributable to products for which manufacturers provided rebates of 1 percent or more of gross prices. Manufacturers provide rebates for some generic prescriptions, but much less frequently. The magnitude of manufacturer rebates varies widely across therapeutic classes. Some brand-name drugs that face no competition have no rebates, while in classes such as diabetic agents that have several alternative therapies, rebates have exceeded 50 percent of pharmacy prices.

Historically, plan sponsors have not disclosed the rebates they receive from manufacturers to enrollees

**FIGURE
2-1**

Gross drug prices at the pharmacy do not reflect postsale rebates and pharmacy fees



Note: Postsale pharmacy payments can flow from a plan sponsor and its pharmacy benefit manager (PBM) to a pharmacy or vice versa. Thus far, in the aggregate, postsale payments from pharmacies to plan sponsors and PBMs have far surpassed those in the other direction.

Source: MedPAC depiction of Medicare Part D pharmacy transactions.

or the broader public. The opaqueness of rebate agreements has been the key reason why drug prices are not transparent. Patient advocates contend that greater price transparency and allocation of rebates at the point of sale would be useful to patients when they make purchasing decisions and could help to lower patient cost sharing and rein in manufacturer price increases. However, manufacturers and plan sponsors consider information about specific rebates to be highly proprietary because, they maintain, revealing that information could alter their negotiating leverage. If one plan sponsor were able to observe the size of a rebate a manufacturer negotiated with a second plan sponsor, the first could demand similar rebate terms. For this reason, the Congressional Budget Office, Federal Trade Commission, and others have suggested that transparency of agreements could compress the range of negotiated rebates and likely lower average rebate amounts (Congressional Budget Office 2008, Danzon 2015, Federal Trade Commission 2009).

In addition to DIR, manufacturers of brand-name drugs and biologics currently must provide a 70 percent discount on prescriptions filled in the

coverage-gap phase of the Part D benefit. This price concession is mandated as a condition of having the manufacturers' drugs paid for by Part D. Under the IRA, beginning in 2025, this coverage-gap discount will end and be replaced with mandated discounts of 10 percent below the redesigned Part D benefit's out-of-pocket (OOP) threshold and 20 percent above the threshold on brand-name and biological products (Medicare Payment Advisory Commission 2023).

Pharmacy DIR

Under Part D, plan sponsors cannot set up exclusive pharmacy networks, but they can include contract terms that try to achieve the same aims, often with postsale payments contingent on pharmacy performance. One reason pharmacies agree to these terms is to obtain preferred status in a plan's pharmacy network, which may increase their sales of prescription drugs and other "front-of-store" products. Plans charge lower cost sharing to attract more enrollees to pharmacies with preferred status. Examples of pharmacy DIR include incentive bonuses (such as those that encourage generic dispensing), fees

that are assessed on other measures that are set by the sponsor or its PBM (such as medication adherence), or other amounts that cannot reasonably be determined at the point of sale.

Because they are contingent on periodic evaluations of pharmacy performance, pharmacy DIR payments can flow from a plan sponsor and its PBM to a pharmacy or vice versa. On the whole, however, pharmacies have made aggregate postsale payments to plan sponsors and PBMs. Beginning in 2024, CMS is adopting a new definition of “negotiated price” to include pharmacy price concessions, including performance-based ones assessed after the point of sale. (The policy will not apply to manufacturer rebates.) This negotiated price will be the basis for assessing enrollee cost sharing when it takes the form of deductibles or coinsurance and will likely lower beneficiary cost sharing relative to current law.

Illustrative example of DIR in a pharmacy transaction

Consider the case of a beneficiary who fills a prescription for her medicine, which has a pharmacy price of \$200 for a 30-day supply. She pays the pharmacy her plan’s required 25 percent coinsurance (\$50) and the plan sponsor pays the pharmacy an amount agreed upon under their network contract (in this example, \$150). PDE data for this prescription would show a \$200 transaction: \$50 from the beneficiary and \$150 from the plan. However, in this example, the plan negotiated a rebate of \$25 per prescription from the drug’s manufacturer and a postsale fee of \$5 from the pharmacy. Thus, the net cost of this prescription is \$170: \$50 from the beneficiary and \$120 from the plan (the \$150 plan payment to the pharmacy minus the \$25 manufacturer rebate and the \$5 payment from the pharmacy to the plan).

What DIR data are collected and how are they used?

CMS requires Part D plan sponsors to report any postsale rebates or other remuneration they or their PBM receive from any source that decreases costs incurred by the plan directly or indirectly. Plan sponsors must submit two types of plan-level DIR data annually to CMS: summary-level and detailed reports. Summary reports provide aggregate data on

categories of DIR.¹ Detailed reports have information that is reported on a drug-by-drug basis (at the 11-digit national drug code (NDC-11) level) about (1) manufacturer rebates and (2) all other DIR in one combined category.

CMS uses reports from plan sponsors about their DIR to reduce a portion of what Medicare pays plans in reinsurance and reflect the plan’s net costs rather than pharmacy prices.² (Under Part D’s current benefit design, once an enrollee has reached the OOP threshold, Medicare covers 80 percent of the costs of each prescription.) Plan sponsors’ bids that they submit to CMS reflect DIR that they expect to retain and sponsors use some or all of that DIR to offset what would otherwise be higher premiums.

Between 2010 and 2021, DIR increased more than sevenfold

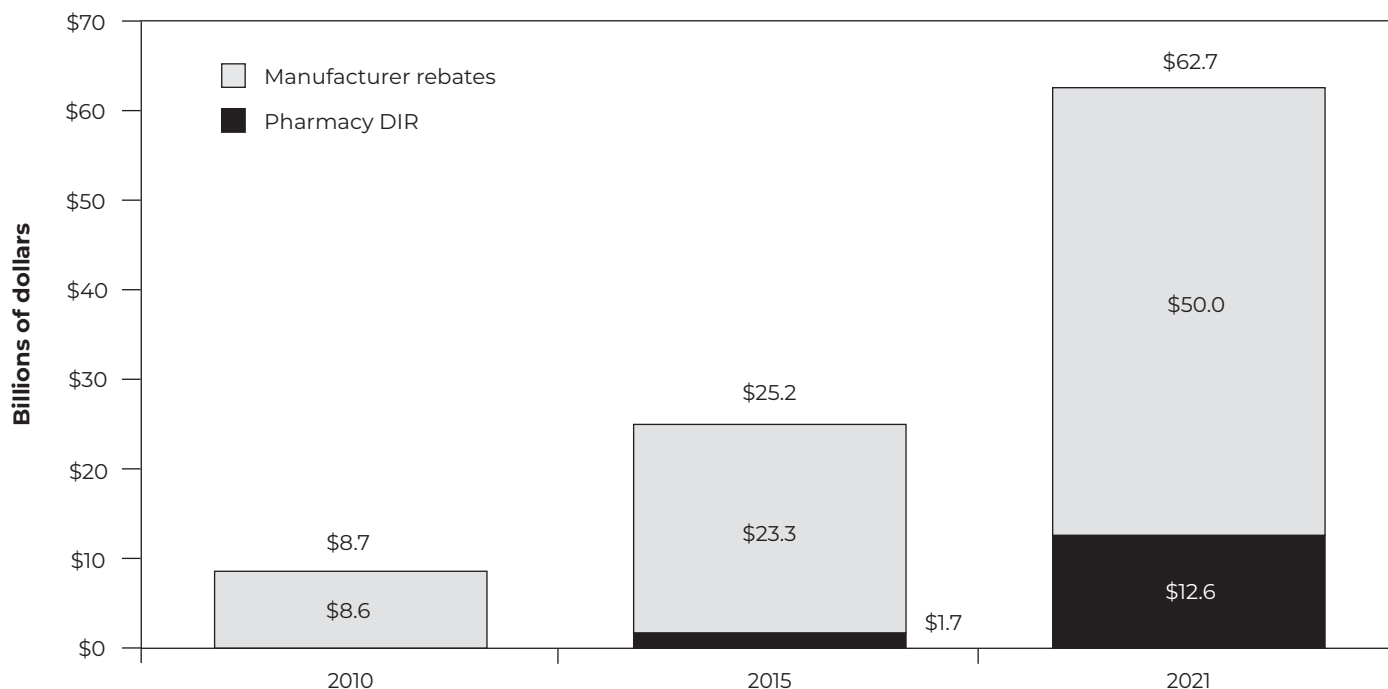
Between 2010 and 2021, the magnitude of DIR ballooned from \$8.6 billion to \$62.7 billion (Figure 2-2, p. 74). The vast majority of that total was consistently made up of manufacturer rebates. In 2010, rebates accounted for 99 percent of total DIR. However, by 2021, rebates’ share of total DIR declined to 80 percent as payments from pharmacies (pharmacy DIR) rose. With manufacturer rebates accounting for roughly 23 percent of gross Part D spending in 2021 and pharmacy DIR another 6 percent, total DIR equaled about 29 percent, up from 11 percent in 2010.

Despite this rapid expansion of DIR, manufacturer rebates negotiated by Part D plans tend to be lower than discounts and rebates obtained by other federal purchasers such as Medicaid or the Department of Veterans Affairs, for which steeper statutory price discounts and rebates apply.³ For example, for a subset of top-selling single-source drugs, average net prices obtained by Medicaid were about 35 percent of those obtained by Medicare Part D in 2017 (Congressional Budget Office 2021).

Under Part D, plan sponsors and their PBMs must report all rebates as DIR, including those retained by PBMs as part of their compensation. In recent years, PBMs for Part D plans have retained less than 1 percent of the rebates they have negotiated for plan sponsors, instead earning revenues through volume-based and per member fees (Government Accountability Office 2019).

**FIGURE
2-2**

DIR expanded rapidly in Part D, 2010–2021



Note: DIR (direct and indirect remuneration).

Source: MedPAC analysis of Medicare Part D direct and indirect remuneration data from CMS.

DIR constrains premium growth but can also lead to higher costs for some beneficiaries

In 2021, Medicare kept about one-third of the \$62.7 billion in DIR reported by plan sponsors to offset some of the program’s reinsurance subsidies. Plan sponsors can use the remaining DIR to offset what would otherwise be higher premiums or to lower cost sharing. Because DIR amounts have become so large, the way in which sponsors apply these amounts has distributional consequences across enrollees, particularly those who use rebated drugs, as well as cost implications for the Medicare program.

Lower Part D premiums for all enrollees and the Medicare program

Private plans compete for Part D enrollees. Ideally, beneficiaries evaluate several factors when they pick

a plan and reevaluate their selection periodically. Historically, Part D enrollees were thought to focus most on premiums when making their plan selection, and thus plan sponsors have had strong incentives to use DIR toward keeping premiums low.⁴ Between 2018 and 2022, average enrollee premiums declined from about \$32 per month to \$26 per month (Medicare Payment Advisory Commission 2022a).

When plan sponsors apply their share of DIR in this way, benefit costs that are paid by all Part D enrollees through premiums and by the Medicare program through general premium subsidies are lower than they otherwise would be. Medicare also subsidizes most or all premium costs for low-income subsidy (LIS) enrollees, and thus lower enrollee premiums reduce that component of program spending as well. In 2021, plan sponsors’ portion of DIR amounted to the equivalent of about \$850 per Part D enrollee.⁵

Higher cost sharing for enrollees who use rebated drugs and higher Medicare cost-sharing subsidies and reinsurance

One concern with using DIR to lower premiums for all enrollees is that the subset of enrollees who use rebated drugs may pay disproportionately high cost sharing relative to the net benefit cost of their medicines. In those situations, Medicare spends relatively more on reinsurance subsidies and on low-income cost-sharing subsidies.

For many rebated brand-name drugs on plan formularies, plan sponsors typically charge a fixed-dollar copayment during Part D's initial coverage phase. However, in the deductible, coverage-gap, and catastrophic phases, plans charge a percentage of a drug's gross price at the pharmacy rather than on its net-of-DIR price. CMS also permits plan sponsors to use a specialty tier with coinsurance of 25 percent to 33 percent for expensive therapies, and it is common for plan sponsors to use coinsurance on other formulary tiers. In those situations, enrollees who use rebated drugs pay disproportionate cost sharing. In our example above, the beneficiary paid 25 percent of the pharmacy price for her diabetes medicine (\$200), or \$50. That \$50 in cost sharing makes up about 29 percent of her medicine's final (net-of-DIR) cost after rebates and postsale fees (\$50 divided by \$170) rather than 25 percent (\$50 divided by \$200). As beneficiaries use more specialty drugs and biologics, the burden of this coinsurance and its application to gross prices rather than net costs increases. High patient cost sharing can pose a financial hurdle to treatment, potentially affecting beneficiaries' decisions to fill their prescriptions (Dusetzina et al. 2022).

Certain changes in the IRA are intended to address the problem of burdensome cost sharing. Beginning in 2024, enrollees will no longer be charged cost sharing above the OOP threshold, and in 2025, that threshold will be set at \$2,000.⁶ Plan sponsors will also be required to offer their enrollees the option to smooth cost-sharing payments over the year rather than charging different amounts depending on the benefit phase, as is now the case.

Because Part D provides LIS enrollees with cost-sharing assistance, most do not face similarly steep financial hurdles to treatment. However, Medicare pays for the difference between the plan's cost-

sharing requirements and the LIS enrollee's nominal copayments through Part D's low-income cost-sharing subsidy. As a result, disproportionately high cost sharing on rebated drugs increases Medicare program spending.

When enrollees pay disproportionately high cost sharing, they may reach Part D's catastrophic phase more quickly, at which point Medicare's reinsurance (currently) pays for 80 percent of each prescription.⁷ In the catastrophic phase of the benefit, plan sponsors are responsible for just 15 percent of spending. For some brand prescriptions filled in this phase (as well as the coverage-gap phase), the value of rebates and postsale fees can exceed plan liability. From our earlier example, say our beneficiary has reached Part D's catastrophic phase. When she fills her prescription, she pays 5 percent coinsurance (or \$10), the manufacturer pays a rebate of \$25, and the pharmacy pays the plan \$5. In the catastrophic phase, Medicare would pay \$160 in reinsurance (80 percent of \$200) and later recoup a portion of the DIR from the plan when CMS reconciles payments. At the time the prescription is filled, the plan would effectively face no liability for the prescription other than its administrative costs. As a result, plan sponsors can reduce their plan liability by including certain highly rebated brand-name drugs on their formulary, giving that drug preferred status even when an alternative therapy with a lower gross price is available. In those situations, plans' formulary placement decisions can increase costs for enrollees and Medicare.

In Part D, growth in brand prices has outpaced growth in rebates

Because enrollee cost sharing sometimes takes the form of coinsurance, the degree to which prices at the pharmacy for brand-name drugs have grown is significant. At the same time, monitoring the costs of providing Part D benefits net of DIR is important because these costs are relevant for enrollee premiums and Medicare's premium subsidies. We find that even with sizable and rapidly growing manufacturer rebates between 2015 and 2021, Part D plans' benefit costs for brand-name drugs and biologics increased.

To compare growth in prices at the pharmacy with costs net of DIR, we constructed gross and net indexes for brand-name drugs filled under Part D.⁸ One key difference between developing indexes of gross prices

and drug costs net of rebates relates to the flow of information about pharmacy prices versus DIR. Part D enrollees fill prescriptions every day of the year, which permits us to build monthly indexes of how prices for those prescriptions change. By contrast, CMS receives DIR information from plan sponsors through annual reports. Plan sponsors themselves likely receive DIR in a variety of ways, depending on their negotiated contracts, and we lack detailed information about the timing of those financial flows.⁹ For that reason, we made the distributional assumption to develop quarterly indexes of drug costs with DIR percentages spread uniformly throughout the year.

Our analysis found that, between 2015 and 2021, gross prices for all single-source drug and biologic prescriptions filled under Part D grew by 67 percent, compared with about 39 percent for prices net of manufacturer rebates.¹⁰ Changes in our indexes imply an average growth rate of 7.6 percent annually for gross prices, compared with 4.8 percent annually for prices net of rebates.

The fact that average Part D premiums remained low and even declined in the face of upward pressure from brand pricing suggests that other factors in addition to DIR likely played a role in constraining premium growth. Those factors included enrollees' broad use of generics, proportionately higher cost sharing for some Part D drugs, the entry of large cohorts of younger enrollees into Part D, and Medicare Advantage—Prescription Drug plans' (MA-PDs) use of some Medicare Advantage payments (so-called MA payment rebates) to offset Part D benefit costs.

Rebates vary across drug classes based on therapeutic competition and formulary coverage policies

Under the U.S. system of drug development and pricing, manufacturers of brand-name drugs are granted temporary monopolies through patents and licensing after demonstrating that their products are novel, safe, and effective. Those temporary monopolies take the form of marketing exclusivity—a period of time during which manufacturers face no generic or biosimilar products because such competitors cannot obtain licenses and enter the market. Manufacturers

are thus free to set the price of their products at levels they believe the market will bear, but they must also consider whether other products are therapeutic competitors. When faced with therapeutic competition, manufacturers sometimes offer rebates to payers in order to win market share. Once a drug's period of marketing exclusivity has ended, brand manufacturers face greater price competition if generics or biosimilars to their product enter the market. For this reason, some manufacturers have taken measures to extend exclusivity periods for their drugs by building “walls” of patents around a product and its manufacturing processes, paying generic and biosimilar manufacturers to delay market entry, and strategically managing the entry of follow-on products such as launching a new formulation that would not be subject to competition (Medicare Payment Advisory Commission 2023).

In 2021, manufacturer rebates averaged 23 percent of gross Part D spending, including spending for generics (which typically have no rebates). However, rebates were not uniform across specific brand products or across classes of drugs; they varied depending on the degree of therapeutic competition. For example, for diabetic therapies (a broad class that includes both oral treatments and injected insulin products), rivalry among brand-name products (especially insulins) has been strong and manufacturers provided rebates of more than 50 percent to plan sponsors in 2021, up from 30 percent to 39 percent in 2015 (Table 2-1). On a percentage basis, rebates were also high (40 percent or more in 2021) for anticoagulants, treatments for asthma and chronic obstructive pulmonary disease (COPD), and urinary incontinence agents—drug classes that have a high degree of therapeutic competition.

By contrast, for drug classes in which brand drugs face less competition, rebates are typically lower—for example, dermatological (antipsoriatic) products, in which rebates in 2021 ranged between 10 percent and 19 percent. Further, in Part D, for six “protected classes” of drugs, program rules require plans to cover “all or substantially all drugs,” thus shielding manufacturers from having to compete with one another as much as they might otherwise. Manufacturers have greater bargaining leverage for these drugs because of the mandatory coverage provisions of the protected-class policy. In 2021, sponsors were only able to negotiate rebates averaging less than 10 percent of gross prices

**TABLE
2-1**

Magnitude of rebates varies across therapeutic classes and over time, 2015 and 2021

Therapeutic class, ranked by gross Part D spending in 2021	2021			Comparative data from 2015	
	Gross spending* (in billions)	Negotiated rebates as a share of gross spending	Rank by net spending	Gross spending* (in billions)	Negotiated rebates as a share of gross spending
Diabetic therapy	\$39.7	≥50%	2	\$17.5	30% to 39%
Antineoplastics**	28.8	<10%	1	9.9	<10%
Anticoagulants	18.6	40% to 49%	3	3.7	10% to 19%
Asthma/COPD therapy agents	15.5	40% to 49%	4	9.0	20% to 29%
Disease-modifying anti-rheumatoid drugs	10.4	20% to 29%	5	3.7	10% to 19%
Antipsychotics (neuroleptics)**	7.5	10% to 19%	7	6.2	<10%
Antiretrovirals**	7.3	<10%	6	4.3	<10%
Antihypertensive therapy agents	6.9	10% to 19%	8	4.9	10% to 19%
Ophthalmic agents	5.6	30% to 39%	12	3.7	30% to 39%
Antihyperlipidemics	5.0	10% to 19%	9	7.8	20% to 29%
Multiple sclerosis agents	4.5	10% to 19%	11	4.6	<10%
Anticonvulsants**	4.2	<10%	10	4.4	10% to 19%
Dermatological (antipsoriatics)	3.6	10% to 19%	13	0.3	<10%
Antidepressants**	2.9	<10%	14	2.6	<10%
Urinary incontinence treatment agents	2.7	40% to 49%	18	1.7	30% to 39%
Subtotal, top 15 drug classes in 2021	163.2	27%		84.3	18%
Total, all drug classes	215.8	23%		137.4	17%

Note: COPD (chronic obstructive pulmonary disease). “Gross spending” reflects payments from all payers, including beneficiaries (through cost sharing), but does not include rebates and postsale fees from pharmacies and manufacturers that are not reflected in prices at the pharmacies. Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System. Components may not sum to totals due to rounding.

*Includes spending for both brand and generic products.

**Protected drug class.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

from manufacturers of brand-name antineoplastics, antiretrovirals, anticonvulsants, and antidepressants.

The magnitude of rebates in some therapeutic classes has changed significantly over time. For example, between 2015 and 2021, gross Part D spending for anticoagulants swelled from \$3.7 billion to \$18.6 billion, as newer and safer products entered the market at much higher prices than older therapies and larger

numbers of beneficiaries filled prescriptions for those products. During that same period, rebates for anticoagulant products also expanded—from an average range of 10 percent to 19 percent to 40 percent to 49 percent (Table 2-1). Rebates grew similarly for diabetic therapies, treatments for asthma/COPD, and other therapeutic classes. Meanwhile, the magnitude of rebates changed little for other categories, such as many protected-class drugs.

Table 2-1 (p. 77) displays top therapeutic classes ranked by gross Part D spending in 2021. However, because rebates vary across drug classes, rankings based on spending net of rebates and other price concessions may differ. For example, manufacturers of antineoplastics provided, on average, rebates of less than 10 percent, and thus that class ranked first in 2021 on a net-of-rebate spending basis, above diabetic therapies. Similarly, net spending on antiretrovirals (ARVs), for which manufacturers paid low rebates, was higher than that for antipsychotics and ranked ARVs in sixth rather than seventh place.

Factors affecting the prevalence and size of rebates

To better understand when and how manufacturers have used rebates in Part D, we analyzed three therapeutic subclasses that experienced rapid growth in rebates over the 2015 to 2021 period—medications for asthma/COPD, insulin, and tumor necrosis factor (TNF) inhibitors. While the details of each subclass differ, we found commonalities. Here we summarize what they had in common and then examine one case study of asthma/COPD treatments.

Each of the three selected subclasses demonstrated significant rivalry among brand products and limited entry of competing generic or biosimilar products. Lack of generic entry is notable because generics contain the same active ingredients as originator products and, in many cases, pharmacists can automatically substitute equivalent generics when they dispense a prescription.¹¹ To encourage pharmacies (which purchase the drugs) to make such substitutions, generic manufacturers often compete on the basis of lower list prices. In two of the subclasses, asthma/COPD products and insulins, generic entry was limited because many of the products were complex in that they combined one or more medications with a delivery device. Those drug-device combinations offered manufacturers opportunities for additional patents and provided regulatory hurdles before generic manufacturers could demonstrate “sameness” to the originator product. Both insulins and TNF inhibitors (a treatment for a variety of autoimmune diseases) are biologic products. Until recently, the pathway to approval for biosimilars has been challenging, and originator manufacturers have taken steps to stave off competition, delaying entry of biosimilars covered under Part D. In the case of TNF inhibitors,

prodigious numbers of patents have extended the market exclusivities of originator biologics, and some manufacturers have engaged in strategic behavior to further limit their competition. The biosimilar pathway to FDA approval was not available for insulin products until a statutory change that became effective in March 2020 (Food and Drug Administration 2020).¹²

For each of the three subclasses, gross prices at the pharmacy and manufacturer rebates both grew. Consistent with other literature, research found that competition among brand-name products did not result in downward pressure on prices at the pharmacy (Sarpawari et al. 2019). Rather, gross prices increased, and price competition occurred through postsale rebates. Rebates for insulins and asthma/COPD therapies grew enough that the average cost per prescription net of rebates declined during this period; the average cost per prescription net of rebates for TNF inhibitors still increased during this period, but not as fast as gross prices.

The expanded use of rebates took place over a period in which plan sponsors bore low and declining shares of risk for benefit spending. The limited risk resulted in part from Part D’s unusual benefit design, with its coverage gap and provision of Medicare reinsurance in its catastrophic phase (Medicare Payment Advisory Commission 2023). Trends in prescription use were also a contributing factor, as high-cost biologics and specialty medications accounted for a mounting share of spending and Medicare’s payments to plans increasingly took the form of cost-based reinsurance. For some brand prescriptions filled in Part D’s coverage gap and catastrophic phases, the value of rebates and postsale fees exceeds plan liability. In some instances, plan sponsors have placed certain highly rebated brand-name drugs in a favorable position on their formulary.

For the most highly rebated drugs in these three subclasses, cost sharing was disproportionately high and sometimes exceeded plans’ net drug ingredient costs. Cost sharing varies depending on the formulary status of the drug, the phase of the benefit in which the prescription is filled, and whether the beneficiary receives the LIS.¹³ Among prescriptions for the three subclasses of products we examined, cost sharing for insulins and asthma medications routinely constituted a higher share of net-of-rebate prices than cost sharing for TNF inhibitors. For some insulin and

asthma products, we found that cost sharing exceeded 50 percent of plans' net costs and sometimes even exceeded plans' net costs entirely. That is, at the time the drug was dispensed, beneficiaries and Medicare (on behalf of LIS enrollees) paid more than the net ingredient cost of the drug to the plan. In comparison, cost sharing for the TNF inhibitors we examined rarely exceeded 20 percent of plans' net costs. The IRA now limits Part D copayments to \$35 per month for insulin products, which would likely prevent cost sharing for insulin products from exceeding plans' net costs.¹⁴

Across all therapeutic classes and phases of the Part D benefit, we estimated that for about 8 percent of gross spending in 2021 (9 percent of spending on brand-name drugs), enrollee cost sharing was larger than plans' net ingredient costs for the drugs. About 75 percent of such prescriptions were filled by LIS enrollees, meaning that beneficiary cost-sharing liability was paid by Medicare's LIS. (For comparison, in 2021, about 45 percent of all brand or biologic prescriptions were filled by LIS enrollees.) LIS beneficiaries were more likely to fill these types of prescriptions because by law, under Part D's separate benefit structure for LIS enrollees, plans are responsible for a smaller share of benefit costs than for other enrollees. (Medicare's low-income cost-sharing subsidy pays for nearly all spending in the coverage-gap phase.) In such situations, plan sponsors may prefer to place products with higher rebates on their formularies, even if alternatives with lower gross prices are available. Of brand drug fills in which cost sharing was greater than net plan cost, 28 percent occurred within Medicare Advantage (MA) special needs plans (SNPs), most of which enroll only LIS beneficiaries who are dually eligible for Medicare and Medicaid. For comparison, MA SNPs account for 14 percent of all prescription fills for brand products. Prescriptions for diabetes and asthma/COPD therapies made up 70 percent of gross spending in which cost sharing exceeded plans' net ingredient costs.

Case study: Asthma inhalers

Asthma inhalers are a subclass of asthma/COPD products. As noted above, there are many similarities between insulin and inhaler products and the pricing strategies their manufacturers have employed. We estimate that, between 2015 and 2021, rebates in the broader asthma/COPD therapeutic class expanded from a range of 20 percent to 29 percent to a range

of 40 percent to 49 percent.¹⁵ The findings presented here provide a snapshot of some of the likely causes of growth and variation in rebates and coverage decisions found among products and across plan sponsors.

Significant brand-brand competition among asthma products

Inhalers have been widely available for many decades, and yet brand-name products continue to enter and dominate the market. The metered dose inhaler (MDI), still one of the most commonly used devices for treating asthma, was developed in the 1950s. The first versions of two of today's most commonly used rescue inhalers—Proventil and Ventolin—were introduced in 1981 (Stein and Thiel 2017). Asmanex, an inhaled corticosteroid, and Atrovent, a short-acting muscarinic antagonist, both originally introduced in 1986, are also still used today after being updated in the 2000s. Combivent Respimat, which combined the albuterol found in Proventil and Ventolin and the ipratropium bromide in Atrovent, was introduced in 1996; it had nearly 240,000 Part D users in 2020. Generic albuterol did not enter the market until 1995. Still, despite this generic being available for more than 25 years, more than 50 percent of gross Part D spending on albuterol products is for brand-name drugs (Centers for Medicare & Medicaid Services 2021). Over the past 70 years, many new types of inhalers have been introduced, and as of 2018, there were over 230 drug-device combinations to treat respiratory diseases (Biddiscombe and Usmani 2018).

One reason for so many asthma products on the market is that patients often require two types of products to treat their disease—one for sudden asthma attacks and one for long-term maintenance or prevention.¹⁶ Thus, there are different types of medicines used to treat asthma. In fact, there are four subclasses of short-acting asthma medications, four classes of long-acting medications, and two classes with products that combine short-acting and long-acting medicines.

Further, because of how the drugs are delivered, most inhalers are approved as drug-device combination products (like many insulins and commonly used TNF inhibitors), and some manufacturers pair an existing drug with a new delivery device so there are multiple products for a single active ingredient. For example, one recent study found that only one of the 62 inhalers

approved by the FDA over the past 35 years contained an active ingredient with a new mechanism of action (Feldman et al. 2022).

In 7 of the 10 subclasses of asthma products, at least 4 brand-name products are on the market; in just one subclass is there a single brand-name product with only generic competitors. In 6 of the 10 subclasses, brand-name products accounted for 75 percent or more of the Part D claims in that class in 2020 (Centers for Medicare & Medicaid Services 2021).

Regulatory hurdles inhibited generic competition

Brand-name products continue to dominate the inhaler market because generic competitors have only recently become available. Additionally, when generics from other manufacturers have been approved, manufacturers of the original product have often introduced their own authorized generics (or authorized their introduction by another manufacturer), thereby limiting generics' ability to gain a foothold and exerting more control over the degree of price competition (Jones et al. 2016).

Two key regulatory hurdles have slowed generic entry in the asthma market—the approval process for drug-device combinations and patent protections. Pursuit of approval for a drug-device combination is complicated because both the drug and delivery mechanism must undergo regulatory approval. As a result, such products often have much longer periods before generic competitors enter the market (Food and Drug Administration 2019).^{17,18}

Manufacturers of combination products also benefit from the fact that both the drug and device can be patented, and would-be competitors must wait for the patent protections on both to expire before they may sell a product that relies on any of those patents (Beall et al. 2016).¹⁹

A study examining patents for inhalers approved between 1986 and 2020 found that, among the 62 inhalers approved during this time, a median of 7 patents per inhaler were obtained prior to the product's approval, and over half were for the devices rather than the drug (Feldman et al. 2022). Following FDA approval, manufacturers of these 62 products have received an additional 68 patents. These device patents helped these products qualify for a median of 15.4 years

of protection at the products' time of approval, plus an additional 10 months for those patents received after approval. As a result of the substantial protection from competition, 53 of the 62 inhaler products approved over the past 34 years were brand-name products rather than generics.

Manufacturers have often further extended their protection from market competition by obtaining patents for new delivery mechanisms for an existing drug—a practice known as “device hopping.”²⁰ While updated delivery mechanisms may improve the patient experience by making it easier, safer, or more convenient to take the medicine, the effect on generic entry nonetheless remains.

Lack of generics allowed brand competition to take place through rebates rather than through list-price reductions

The most competitive subclass—both among brand-name products and from generics—is what is known as SMART therapies (single maintenance and reliever therapies), which combine a quick-acting inhaled corticosteroid (ICS) with a long-acting beta agonist (LABA). In 2021, three of the top four asthma medicines in Part D (by gross sales) were SMART therapies (Symbicort, Breo Ellipta, and Advair Diskus), each with gross sales over \$1 billion.²¹ Advair originally came to market in 2000, followed by Symbicort in 2006 and Breo Ellipta in 2013. Despite this direct competition, gross prices for each product have steadily increased, with Symbicort and Advair Diskus climbing 6.2 percent and 5.6 percent, respectively, on average from 2012 to 2021, and Breo Ellipta growing 4.8 percent annually from 2013 to 2021.

Even after the introduction of Wixela Inhub—the first true generic to Advair Diskus—downward pressure on gross prices was temporary and limited to Advair Diskus. Wixela entered the market at roughly half the price of Advair and after two years had more than half as many Part D claims as Advair Diskus. After years of steady price increases, the gross price of Advair Diskus declined slightly in both 2019 and 2020, though it remained closely aligned with that of Symbicort and Breo Ellipta. In 2021, however, even with the introduction of a second generic, the list price for Advair Diskus increased 8 percent from the year prior while the price for Wixela decreased 5 percent. These pricing strategies suggest that the generics are

competing with each other on list price while brand-name drugs continue to compete (even with generics) via rebates.

Formulary coverage decisions are influenced by rebates

Formulary coverage decisions by plan sponsors also suggest that rebates—rather than list prices—are driving competition and increasing program costs. A study examining coverage and costs for inhaler products across seven subclasses in Medicare Part D found that the product with the lowest total point-of-sale (POS) cost did not always have the highest rate of coverage (Tseng et al. 2017).²² For example, plans were much more likely to cover Proair (92 percent) than Ventolin (56 percent), despite Ventolin having a slightly lower total cost (\$47 vs. \$52 for Proair) and an even larger POS price advantage for the insurer—at least before rebates are provided. The same was true among ICS products: QVAR had the highest coverage rate despite three other products (Flovent, Asmanex, and Pulmicort) having lower total costs, including lower POS costs for the insurer. These coverage decisions are another example of the effects of the misaligned incentives created by the current benefit design in which plans bear little financial risk and benefit from the use of higher-priced, high-rebate drugs. The higher point-of-sale cost may increase beneficiary OOP costs and program spending, as beneficiaries reach the catastrophic phase more quickly.

Coverage of higher-priced products increased beneficiary cost sharing

When plan sponsors choose to cover higher-priced products, the amounts that beneficiaries must pay out of pocket and that Medicare must pay in low-income cost-sharing subsidies typically climb. For example, the aforementioned study examining costs and coverage of asthma products found that QVAR and Dulera had higher beneficiary OOP costs than other products in their respective classes with lower coverage rates (Tseng et al. 2017).

Our own analysis of Part D claims for certain asthma/COPD products in 2021 also shows that enrollee cost sharing can sometimes exceed plans' net costs (Figure 2-3, p. 82). In those circumstances, the sponsor did not incur any cost for covering the drug beyond its administrative expenses. Plan bids,

and therefore enrollee premiums and subsidies that Medicare pays to plans, reflect the amount of DIR they expect to receive. The actual DIR that plans collect may be higher or lower than what they anticipated at the time that they submitted their bids. Some or all of the excess amount collected may be retained by the plan as profit. For example, enrollees of all but one of the six plan sponsors studied had a median cost-sharing amount greater than 50 percent of the plan's cost net of rebates for LABA/ICS product D. The median cost-sharing amount for LABA/ICS product E was greater than 50 percent of the plans' net cost for all six plan sponsors.

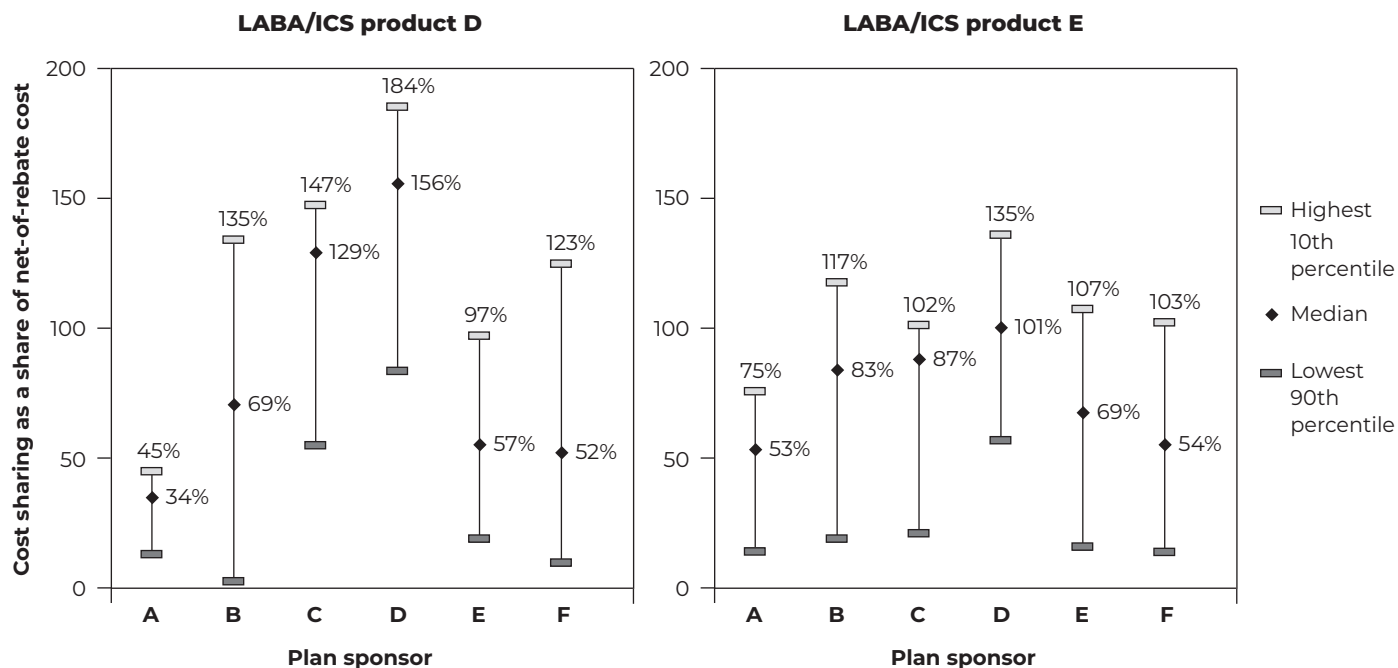
In summary, this case study shows the myriad factors—strong therapeutic competition and a benefit structure that limits plan liability for high-priced drugs while incentivizing the use of rebates to keep premiums low—that encourage higher rebates. The effects of plan sponsors' different organizational structures and their ability to obtain significant rebates on beneficiary cost sharing is further detailed below.

Protected-class drugs

Under Part D, plans are required to include on their formularies substantially all drugs in six classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. The “protected classes” policy was intended to ensure access to medications in those classes and prevent plan sponsors from designing formularies that discourage enrollment by beneficiaries who take medications in those classes. These drug classes were often used by Medicaid beneficiaries whose drug coverage was transferred to the Part D program when it began in 2006, and at the time, CMS had concerns about “the risks and complications associated with an interruption of therapy for these vulnerable populations” (Centers for Medicare & Medicaid Services 2014b, Centers for Medicare & Medicaid Services 2014c). Now, many of these drugs are used by a disproportionate share of beneficiaries receiving the LIS (27 percent of all Part D enrollees): Beneficiaries receiving the LIS make up 70 percent of Part D enrollees using antiretrovirals, 69 percent of those using antipsychotics, 46 percent using anticonvulsants, and 32 percent using antidepressants (Medicare Payment Advisory Commission 2022a).

FIGURE 2-3

Cost sharing for two asthma/COPD products often exceeded 50 percent of net ingredient costs, 2021



Note: COPD (chronic obstructive pulmonary disease), LABA (long-acting beta agonist), ICS (inhaled corticosteroid). Each vertical line depicts the range of each plan sponsor's aggregate enrollee cost sharing (for their plans) as a share of aggregate ingredient cost net of rebates.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

There are some exceptions to the protected-class coverage provisions. Part D plans are permitted to exclude coverage for the following: a brand-name product when a generic is available, extended-release formulations if an immediate-release formulation is available, and drugs for which multiple formulations exist and have the same route of administration (Centers for Medicare & Medicaid Services 2014c). Plans may impose utilization management tools, but not for enrollees already using these drugs, and never for antiretrovirals (Centers for Medicare & Medicaid Services 2019).

While access to necessary medicines remains a top concern for policymakers and regulators, CMS has expressed concern in recent years that the broad mandatory coverage results in higher Part D costs by “substantially limit[ing] Part D sponsors’ ability to

negotiate price concessions in exchange for formulary placement of drugs in these categories or classes” (Centers for Medicare & Medicaid Services 2014a). The agency has also posited that the policy results in overutilization of these medications, particularly for off-label indications. CMS has in the past proposed to limit the number of protected classes and provide plans greater flexibility related to coverage of protected-class drugs. In both cases, however, after stakeholders expressed concerns and opposition to the proposed policies, CMS chose not to finalize these proposals.²³

Mandatory coverage of protected classes limits price competition and rebates

Evidence shows that there can be some negative consequences to the limited ability of plans to manage utilization of products in the protected classes. Data suggest that pricing among products in some of the

**TABLE
2-2**

Spending and brand price growth varied among protected classes, 2015–2021

Therapeutic class ranked by gross Part D spending in 2021	Gross spending, 2021 (in billions)*	Share of net spending on brand-name drugs, 2021	Single-source brand-name drugs, AAGR, 2015–2021	
			Gross price	Net-of-rebate costs
Antineoplastics	\$28.8	95.0%	7.9%	7.6%
Antipsychotics (neuroleptics)	7.5	78.9	8.5	7.3
Antiretrovirals	7.3	97.6	6.7	6.6
Anticonvulsants	4.2	49.9	10.0	9.0
Antidepressants	2.9	22.7	9.4	6.0
Immunosuppressants	0.3	23.7	6.1	5.9
Subtotal, protected classes	51.0	85.7	8.0	7.5
Total, all drug classes	215.8	59.1	7.6	4.8

Note: AAGR (average annual growth rate).
*Includes spending for both brand and generic products.

Source: MedPAC and Acumen LLC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

protected classes tended to be less competitive than in nonprotected classes. Both gross prices and net-of-rebate costs of drugs in protected classes often grew faster than prices in nonprotected classes (Table 2-2), and postsale manufacturer rebates were smaller as a share of gross spending (Table 2-1, p. 77). Growth was significantly constrained, however, in some protected classes once generic substitution was accounted for, particularly antidepressants, anticonvulsants, and antipsychotics (Medicare Payment Advisory Commission 2022a).

Knowing the price and spending implications of the protected-class policy is also important for understanding how program spending might evolve over the next few years, particularly given that antineoplastics are one of the fastest-growing drug classes by spending. Analysts expect that 100 new oncology treatments will enter the market over the next 5 years, and few existing products will lose their marketing exclusivity during this period, which could increase spending on antineoplastics by 10.6 percent per year from 2022 to 2026 (IQVIA 2022). Given the upcoming changes to Part D’s benefit design, namely

the cap on beneficiaries’ OOP spending and increased plan liability, there will likely be increased demand for drugs for which plans may have limited bargaining leverage or tools to manage.

The relationship between gross prices and net-of-rebate costs varied widely among protected classes

Our price index shows that, between 2015 and 2021, gross prices for all Part D–covered single-source brand-name drugs grew at an average annual rate of 7.6 percent, while the prices of such drugs in protected classes grew at a slightly higher average annual rate of 8.0 percent (Table 2-2). Among the protected classes, gross prices grew fastest among anticonvulsants and antidepressants, at an average annual rate of 10.0 percent and 9.4 percent, respectively.

Rebates in protected classes were typically much smaller as a share of gross prices than in nonprotected classes. While most of the protected classes ranked among the top 15 therapeutic classes of drugs covered under Part D by gross spending, average rebates for 4 of these classes were less than 10 percent, compared

with an average of 38 percent for the nonprotected classes in the top 15 (data not shown).

Although some classes experienced significant growth in rebates between 2015 and 2021, the practical effect on net costs varied, depending on the value of gross spending and the share of spending on brand-name products in a class. For example, from 2015 to 2021, the difference between gross and net indexes for antidepressants grew 23 percentage points, but because brand spending and rebates in that class were relatively small, rebates still represented less than 10 percent of gross spending (Table 2-1, p. 77, and Table 2-2, p. 83). Conversely, during the same period, rebates for antineoplastics grew more than 800 percent, but the impact on net costs was minimal. This is because, for this class, gross spending on brand-name drugs, which accounted for over 90 percent of total gross spending, also grew rapidly during the same period. Thus, the growth in net costs for antineoplastics was much larger than for antidepressants, despite much larger rebate growth for antineoplastics.

Even when more significant brand-brand competition exists within a protected class, predicting when rebates will be offered can be difficult. Consider the varying dynamics of different subclasses of one protected class. In one subclass, there were multiple brand-name products and nearly two-thirds of the products had rebates, though still less than the average for all drug classes. Most of those rebates were for products with the highest spending and the highest cost per prescription in the class. In another subclass, only about one-third of the products had a rebate; however, the products with the largest average rebate as a share of gross spending were toward the bottom of the cost and spending distribution of the subclass. In the subclass with the largest number of products, only 14 percent had any rebate and the largest average rebate for a given product was quite small. These examples further illustrate that there are distinct differences in rebate offerings, particularly when coverage of all products in a class is required.

Given the limited rebates available for protected-class drugs, in addition to the high rate of growth in gross prices, net-of-rebate costs for single-source brand-name protected-class drugs have grown between 2015 to 2021 nearly as fast as gross prices for all single-source brand-name drugs (averaging 7.5 percent per year vs. 7.6 percent per year) (Table 2-2, p. 83).

Generic availability in protected classes has had varying effects on prices

The availability of generics has often constrained price growth of protected-class drugs, but not always. Of the 5 protected classes ranked among the top 15 by gross spending in 2021, 4 had a higher generic dispensing rate than the average for the top 15 (85 percent). These high generic dispensing rates can be partially attributed to plans' coverage decisions since plans are allowed to exclude coverage of brand-name products when generics are available. A study from 2018 found that, across the protected classes, 40 percent of brand-name products were not covered, compared with no more than 25 percent for generics (Partnership for Part D Access 2018). Still, the share of net spending attributed to brand-name products was 86 percent in the protected classes, relative to 59 percent among all drug classes, indicative of the overall high prices of brand-name drugs in the protected classes (Table 2-2, p. 83).

But the effect of generic availability on pricing varied widely across classes, as research has shown that market size and the type of product can have a considerable effect on how influential generics will be in a given market (Frank et al. 2021). Consider, for example, antineoplastics and antipsychotics. In 2021, these two classes both had high generic dispensing rates (88 percent and 91 percent, respectively). The Commission's price indexes found that accounting for generic substitution in both classes yields cumulative price growth rates considerably lower than that of single-source branded products alone, but the effect was far greater for antipsychotics than for antineoplastics: Generic substitution for antipsychotics yielded prices in 2021 that were roughly half of what they were in 2010, while prices for antineoplastics still grew by 67 percent after accounting for generics. A key difference regarding antineoplastics is that generic use across the many subclasses was quite varied and many subclasses saw the introduction of a considerable number of new therapies; thus the overall effect of generics was closer to that of antiretrovirals, where generics were used much less frequently.

Antiretrovirals had a generic dispensing rate of just 18 percent, and nearly all net spending in this class was for brand-name products (Table 2-2, p. 83). From 2010 through 2021, prices for antiretrovirals grew 71 percent after accounting for the relatively limited generic

substitution. The text box on pp. 86–87 provides more information on some of the market dynamics at play in this class.

Use of high cost sharing and utilization management in protected classes

Aside from encouraging the use of generic drugs, plans may also use various forms of utilization management (UM) of brand-name drugs to moderate spending in the protected classes. UM can consist of requiring prior authorization from the insurer before allowing coverage of a brand-name drug over a generic, the use of step therapy under which a patient is required to first try a less expensive (often generic) product before being provided coverage of the more expensive product if the first one fails, or placing higher-priced products on higher formulary tiers with greater cost-sharing requirements to encourage use of less-expensive products on the lower tiers.

A study by Avalere found that UM strategies used by Part D plan sponsors from 2014 to 2018 reduced use of products by an average of roughly 75 percent in four out of the five protected classes where UM was allowed compared with when no UM tools were in place (Avalere 2020).²⁴ A separate Avalere study found that 78 percent of brand-name protected-class products were placed on nonpreferred tiers compared with 66 percent of protected-class generics (Partnership for Part D Access 2018). Prior authorization was required for 49 percent of brand-name products in protected classes. The high rate of UM among protected-class products reflects plans' limited ability to control costs and negotiate rebates for these products.

Plan sponsors with vertically integrated PBMs have gained market share and negotiating leverage

About 300 organizations operate Part D plans: Most offer only MA-PDs and about 50 operate stand-alone prescription drug plans (PDPs). Sponsors use PBMs (either a subsidiary firm or an unaffiliated firm under contract) to conduct administrative and clinical services, such as developing formularies, processing claims, establishing networks of pharmacies, and negotiating with drug manufacturers and pharmacies

for postsale rebates and fees. PBMs combine purchasing leverage across payers to create stronger competition among therapies and counter drug manufacturers' pricing power. By aggregating certain functions for payers, PBMs may also achieve economies of scale, such as in claims processing or mail-order dispensing. However, PBMs also benefit from growth in the list prices of drugs, and the complexity of drug pricing makes it difficult for payers to evaluate how well contracted PBMs have performed at managing drug spending (Garthwaite and Morton 2017). The largest plan sponsors are vertically integrated with PBMs and typically operate their own mail-order and specialty pharmacies.

Large Part D plan sponsors received a disproportionate share of DIR

Combined, the two largest plan sponsors by enrollment (UnitedHealth and Humana) operated plans that have accounted for about 40 percent of total Part D enrollment each year since 2007 (including both PDP and MA-PD enrollees). Over time, however, other sponsors gradually expanded their market shares through horizontal mergers and acquisitions. Several also consolidated vertically, merging with or acquiring health plans, PBMs, and pharmacies, which contributed to their bargaining leverage.

Between 2010 and 2021, the proportion of beneficiaries enrolled in plans offered by each year's top five plan sponsors expanded from about 53 percent to 74 percent (Figure 2-4, p. 88). Those sponsors accounted for similar (if slightly larger) shares of gross Part D spending. Companies with the most Part D enrollees have consistently obtained, on average, greater shares of all DIR through their larger negotiating leverage. For example, in 2010, plan sponsors with 53 percent of Part D enrollees obtained 66 percent of Part D DIR. By 2021, however, the top five companies sponsored plans with 74 percent of Part D enrollees and obtained 81 percent of DIR.

The differential between DIR negotiated by large and smaller plan sponsors can be substantial. Each year between 2010 and 2021, the top five plan sponsors were able to negotiate manufacturer rebates that grew from about 13 percent to 24 percent of their plans' gross spending (Figure 2-5, p. 88). In 2021, rebates obtained by top sponsors ranged from 20 percent to

Antiretroviral medications

Antiretrovirals are one of the six protected classes and are used to treat and prevent human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). When CMS has considered expanding flexibilities for protected-class drugs, HIV drugs have typically been excluded to maintain the strongest coverage protections, and HIV drugs are the only protected class for which current regulations prohibit any use of prior authorization or step therapy (Centers for Medicare & Medicaid Services 2019, Centers for Medicare & Medicaid Services 2014c).

Truvada was approved by the Food and Drug Administration (FDA) in 2004 as a treatment for HIV, combining two existing medications into a single, once-daily pill; in 2012, it received approval as a preventive therapy (pre-exposure prophylaxis, or PrEP) for individuals at risk but not yet infected (Centers for Disease Control and Prevention 2012). These approvals were important advances in efforts to end the HIV epidemic. The price of Truvada and limited generic uptake, however, has undermined the possibility of success by making it inaccessible for many. Further, because Medicare is estimated to cover roughly half of the federal government's cost for HIV care, these high prices are straining

the sustainability of the program (Kaiser Family Foundation 2016).

The first generic for Truvada reached the market in October 2020, and 10 more were available by April 2021. Research by the FDA shows that when there are 10 or more generics available, the median generic price falls to between roughly 1 and 2 percent of the brand's list price (Food and Drug Administration 2022). While it did not happen immediately, generic prices for Truvada are now in this range. This change has left policymakers and patient advocates wondering why generic uptake has been limited.

There are several potential explanations for the limited generic use. Oftentimes brand-name products will continue to dominate a market even after generic competition because their manufacturers offer steep rebates, but that is not the case here: As with most protected classes, rebates for antiretrovirals are low (averaging less than 10 percent). Instead, two other factors seem to be primarily responsible for low generic uptake. First, Gilead developed another drug, Descovy, to treat and prevent HIV, which it began marketing to Truvada patients by highlighting findings that

(continued next page)

25 percent of their gross spending (data not shown). By comparison, plan sponsors with fewer enrollees obtained considerably less DIR, even though some smaller sponsors contract with PBMs owned by the top sponsors to negotiate on their behalf. In 2010, smaller sponsors received manufacturer rebates that were about 5 percentage points lower as a share of their gross spending. That difference grew to nearly 7 percentage points by 2015 but declined back to about 5 percentage points by 2021. Between 2015 and 2021, smaller plan sponsors negotiated much less pharmacy DIR than the top five plan sponsors, and the larger

sponsors' differential grew steadily, plateauing after 2019 (data not shown).

Market focus of each plan sponsor affects how they structure formularies and manage pharmacy benefits

In 2021, the top five plan sponsors as ranked by enrollment each owned a PBM (Table 2-3, p. 89). Some sponsors used their wholly owned subsidiary to perform all PBM functions, while others outsourced activities such as claims processing or rebate negotiations to unaffiliated PBMs. Certain

Antiretroviral medications (cont.)

Descovy was less likely to cause bone-related and kidney-related problems; this is sometimes referred to as product hopping, as discussed in earlier case studies (Dickson and Killelea 2021). One notable fact that stands out in this case is that the research underlying the development of Descovy actually began years before Truvada was approved but was allegedly put on hold when Truvada was approved, despite the company's earlier reporting that initial results were favorable. Over the next few years, Gilead filed for multiple patents related to the active ingredient eventually used in Descovy. Then, in the same year that Gilead entered a settlement agreement with Teva for the eventual launch of its generic version of Truvada, Gilead published the results of its research related to Descovy from more than a decade prior showing that it may be safer and more effective than Truvada. Descovy was approved by the FDA in 2016, four years before generic Truvada was scheduled to enter the market; one year before Teva's generic entry, Descovy received approval as a PrEP preventive therapy. Gilead engaged in similar practices to encourage Stribild patients to switch to Genvoya.

In Medicare Part D, claims for Descovy quickly overtook those of Truvada and stalled generic use. In 2021, when 11 generic products for Truvada were on the market, there were nearly 14 times more claims for Descovy than Truvada and nearly 5 times more claims than for generic Truvada (Centers for Medicare & Medicaid Services 2021).

Another explanation for low generic use may be the high share of users receiving the low-income subsidy (LIS). In 2014, 77 percent of Medicare beneficiaries with HIV qualified for the LIS (Kaiser Family Foundation 2016). The Commission has previously discussed the lack of incentives for LIS beneficiaries to use generic products over their brand-name counterparts (Medicare Payment Advisory Commission 2020).

The 340B Drug Pricing Program—and the ability of providers to acquire drugs at costs far below their reimbursement rates—may also play a role in the continued high market share of brand-name HIV products, particularly given the 340B status of Ryan White HIV Clinics (Killelea and Horn 2023). ■

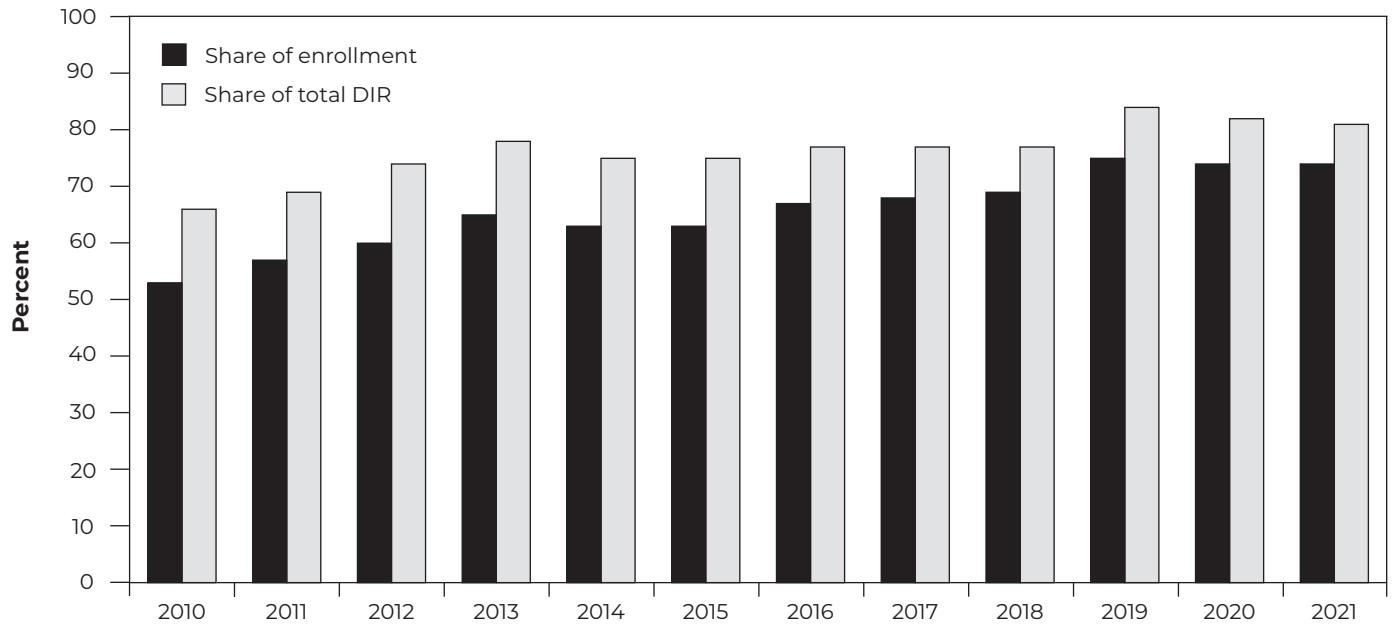
plan sponsors and their PBMs have an exclusive arrangement; for example, Humana Pharmacy Solutions serves only Humana's health plans. In addition to serving their parent organizations, other PBMs—most notably OptumRx, CVS Caremark, and Express Scripts—market their services to smaller plan sponsors, some of which compete with the PBM's parent.

The largest plan sponsors differ regarding which segments of the Part D market they focus on. Large sponsors often use multiple formularies to distinguish among benefit types or to tailor benefits for specific populations. For example, all of the largest sponsors operate separate formularies for stand-alone PDPs and MA-PDs, the latter of which often include additional

coverage beyond Part D's basic benefit. For PDPs, large sponsors typically offer two types of enhanced plans, segmenting enrollees (under separate formularies) between one with a lower premium (to compete for enrollees who have lower drug spending and are more sensitive to premiums) and another with a higher premium (Medicare Payment Advisory Commission 2022c). Large sponsors operate formularies for employer group waiver plans (EGWPs), which tend to offer more generous coverage, separately from other Part D plans with which they must compete directly for enrollees. Some large sponsors focus more heavily on LIS enrollees, who have nominal copayments set by law and tend to use more brand-name drugs.

**FIGURE
2-4**

Both Part D enrollment and DIR became more concentrated among each year's top five plan sponsors ranked by enrollment, 2010-2021

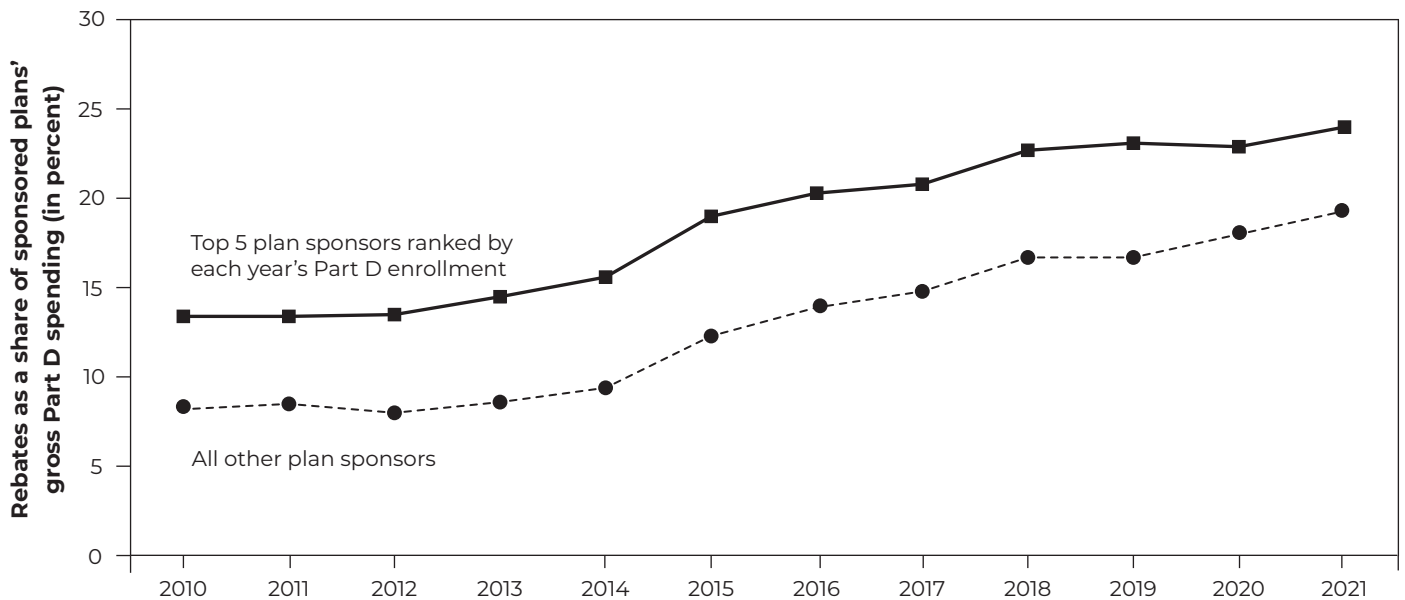


Note: DIR (direct and indirect remuneration). Enrollment totals are from July of each year. The composition of plan sponsors in the top five varied from year to year, particularly in earlier years.

Source: MedPAC analysis of Medicare Part D reconciliation and enrollment data from CMS.

**FIGURE
2-5**

Part D plan sponsors with the largest enrollment negotiated higher manufacturer rebates, on average, 2010-2021



Note: Enrollment totals are from July of each year.

Source: MedPAC analysis of Medicare Part D reconciliation and enrollment data from CMS.

**TABLE
2-3**

Largest plan sponsors emphasized different segments of the Part D market and were vertically integrated, 2021

Plan sponsor	Vertically integrated PBM	Is PBM exclusive to affiliated sponsor?	Total enrollment of sponsor's plans (in millions)	Sponsor's share of all Part D enrollment (in percent)	Share of sponsor's enrollment (in percent)			LIS share of enrollment (in percent)
					EGWPs	Excluding EGWPs PDPs	MA-PDs	
UnitedHealth Group	OptumRx	No	11.0	23%	16%	33%	51%	25%
Humana	Humana Pharmacy Solutions	Yes	8.1	17	7	43	50	27
CVS Health (Aetna)	CVS Caremark	No	7.7	16	22	56	22	28
Centene	Centene Pharmacy Services	Yes	5.3	11	0	78	22	36
Cigna	Express Scripts	No	3.8	8	44	41	15	25
All Part D			48.5	100	15	40	44	27

Note: PBM (pharmacy benefit manager), EGWP (employer group waiver plan), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug plan), LIS (low-income subsidy). Enrollment numbers from April 2021. In 2021, PBMs owned by Centene and Anthem (now Elevance) conducted some PBM services internally and outsourced other services to CVS Caremark. Subsequent to 2021, Centene decided to divest PBM operations and outsource many of those services.

Source: MedPAC analysis of Medicare Part D enrollment data from CMS; Fein 2023.

Targeting different sectors of the market affects the characteristics of plan sponsors' covered populations and how they structure their formularies, with implications for the magnitude of rebates and pharmacy fees each can negotiate. For example, a formulary for an enhanced plan with lower cost sharing or less utilization management of drugs on its preferred tiers may increase patient adherence to medicines and thus boost manufacturers' drug sales. Brand manufacturers may be willing to offer higher rebates to secure a preferred position on such a formulary. However, a drugmaker may be less willing to negotiate rebates on a formulary that includes more drug options within the same class because it would be subject to more therapeutic competition.

How rebates varied across large plan sponsors and their plans

To examine how rebates varied, we analyzed DIR data on rebates obtained by large plan sponsors for brand-name drugs from drug classes that had some degree of brand-brand therapeutic competition. We first assessed 10 drug classes in detail using 2020 data and then evaluated rebates over time (2015 vs. 2021) for the three drug classes described earlier in this chapter (TNF inhibitors, insulins, and asthma/COPD agents). We used variation in the dollar amount of rebate per prescription as our measure of interest.

Variation in rebates across large plan sponsors

Most broadly, we found that both a drug's gross price and its average rebate varied across plan sponsors, but

rebates varied far more. For example, among the largest sponsors in 2020, prices at the pharmacy for one TNF inhibitor tended to vary by about 10 percent while median rebates varied by as much as 2.5 times that of the sponsor with the lowest median rebate. That wider variation in rebates likely reflects differences in the drug's formulary placement relative to its therapeutic alternatives across plans.

For the three drug classes that we analyzed over time (between 2015 and 2021), the magnitude of rebates per prescription grew. However, in two of the three classes, variation in rebates among large plan sponsors declined over the same period. One might expect compression of variation in rebates as the market structure of plan sponsors grew more consolidated and vertically integrated. At the same time, therapeutic competition among the drug products in those classes matured, and payers and manufacturers may have become more aware of the magnitude of rebates negotiated by others.

Variation in rebates across plans operated by the same large plan sponsor

Next, we assessed whether plans operated by the same sponsor had similar rebates. Average rebates for the products we examined varied less among plans operated by the same plan sponsor than across plan sponsors. For example, for four of six plan sponsors, the variation in average rebate for one TNF inhibitor was less than half of the overall variation across all plans. Nevertheless, wider variation existed in some cases. For two large plan sponsors, variation in the average rebate for one asthma/COPD product was nearly as large across their plans as across all Part D plans. We expected to observe considerable variation when large sponsors operate plans for different sectors of the market—for example, for EGWPs, MA-PDs, and three types of stand-alone PDPs. For the limited number of drug products and classes we examined, we did not observe systematic differences in rebates across types of plans.

We also examined variation among each sponsor's plans that used the same formulary. Because a drug's formulary position plays an important role in rebate negotiations, we expected to observe rebates of similar magnitude when plans shared the same formulary. While plans with the same formulary tended to receive similar rebates per prescription, there were instances in which large differences remained. For example,

one plan sponsor used the same formulary for many of its plans, yet average rebates for those plans varied by as much as the variation observed across all of the sponsor's plans, including those with different formularies. We also found that plans using a particular formulary sometimes received widely divergent rebates on one product (e.g., a TNF inhibitor) but similar rebates on another (e.g., an asthma/COPD product), suggesting that patterns of variability in rebates may be specific to a product.

When comparing rebates obtained between 2015 and 2021, we found that, for some large sponsors, variation in the rebates across each sponsor's plans and across its formularies widened over time. (We observed this even though, over the same period, there was some compression in the overall average rebate amounts obtained by large plan sponsors.) Greater variation may reflect that, over that time period, plan sponsors merged with other companies. Sponsors operated newly acquired plans and formularies alongside plans that were already in their portfolio, some of which may have had significant differences in approaches.

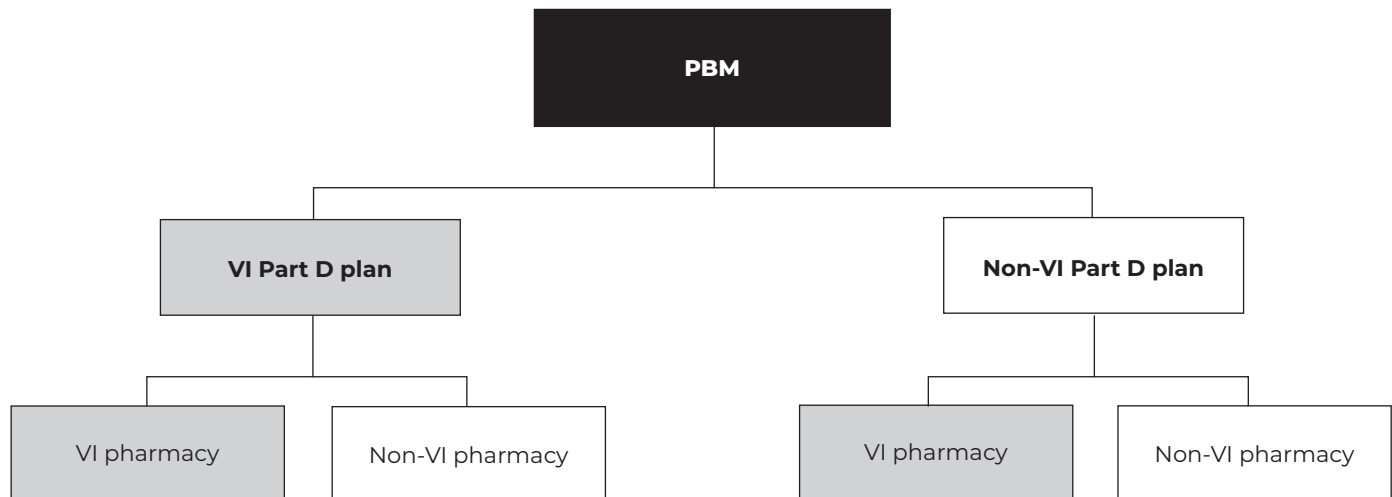
Part D enrollees are increasingly served by vertically integrated PBMs and their pharmacies

The mix of drugs used by the Medicare population has been shifting toward more expensive specialty drugs and biologics. While Part D enrollees continue to obtain most of their medications at retail pharmacies, a growing share of prescriptions was dispensed at mail-order pharmacies (nearly 16 percent in 2021, up from just over 11 percent in 2015).²⁵ Specialty pharmacies accounted for less than 1 percent of prescription volume in both 2015 and 2021, but their share of gross Part D spending grew from less than 7 percent to over 11 percent during this period. Combined, mail-order and specialty pharmacies accounted for over 20 percent of gross spending in 2021, up from about 14 percent in 2015.

Many of the largest plan sponsors participating in Part D are vertically integrated with their own PBMs and operate mail-order, specialty, and sometimes retail pharmacies (Figure 2-6). Vertical integration may reduce transaction costs between the upstream and downstream entities or increase visibility into highly proprietary information about drug prices, allowing sponsors to overcome information asymmetry.

**FIGURE
2-6**

An example of a vertically integrated PBM serving both a VI plan and a non-VI plan



Note: PBM (pharmacy benefit manager), VI (vertically integrated).

Source: MedPAC depiction of a hypothetical structural relationship among entities involved in providing the Medicare Part D benefit.

But a PBM that both administers pharmacy benefits for a payer and operates a pharmacy may have conflicting interests: On the one hand, payers contract with the PBM to lower pharmacy benefit costs. On the other hand, the pharmacy revenues depend on greater prescription volume. As with other participants in the drug supply chain (e.g., wholesalers), pharmacies often benefit from higher list prices. Other concerns relate to potentially anticompetitive behavior (Greaney 2019, Younge 2023). For example, a health plan that also owns pharmacies and a PBM could attempt to use inflated transfer prices between a PBM and its pharmacies to raise the costs of rivals dependent on that PBM or its pharmacies (Medicare Payment Advisory Commission 2023).²⁶

CMS requires Part D plan sponsors to report PBM-negotiated rebates so that Medicare’s payments to plans reflect the actual benefit costs net of all postsale rebates and fees. Over time, as more payers have required PBMs to fully pass through rebates, revenue sources for PBMs have shifted toward fees for services such as administering rebates and clinical programs to increase adherence. Pharmacies that dispense

specialty pharmaceuticals can also receive discounts and service fees directly from manufacturers. In 2022, the difference between prices at specialty and mail pharmacies and their acquisition costs for the drugs accounted for over 50 percent of overall gross profit for the largest PBMs (Fein 2023).²⁷ Under Part D, these discounts and fees received by PBM subsidiaries, such as mail-order and specialty pharmacies, are not reported to CMS, and as a result, the prices established between the PBM and its pharmacies are less transparent to CMS (Office of Inspector General 2021).

In 2021, nearly 90 percent of Part D enrollees were served by the four largest PBMs

In 2021, the four largest PBMs—CVS Health’s Caremark, UnitedHealth Group’s OptumRx, Humana Pharmacy Solutions, and Cigna’s Express Scripts—provided services to nearly 90 percent of Part D enrollment. Caremark, OptumRx, and Express Scripts provided PBM services to both their own Part D plans and to other (unaffiliated) plans. However, they varied in the extent to which they acted as an external PBM to other plan sponsors, with the share of enrollees in unaffiliated plans ranging from less than 20 percent

**TABLE
2-4**

Part D market shares of vertically integrated pharmacies have grown over time, 2015–2021

	2015	2018	2021	AAGR
Standardized prescriptions, millions				
Vertically integrated pharmacies*	570	713	872	7.3%
Other pharmacies	<u>1,550</u>	<u>1,720</u>	<u>1,832</u>	2.8
Total	2,119	2,433	2,704	4.1
<i>Share of prescriptions dispensed by vertically integrated pharmacies</i>				
	27%	29%	32%	
Gross spending, billions				
Vertically integrated pharmacies*	37.7	49.8	70.3	10.9
Other pharmacies	<u>99.7</u>	<u>118.3</u>	<u>145.4</u>	6.5
Total	137.4	168.1	215.7	7.8
<i>Share of spending for prescriptions dispensed by vertically integrated pharmacies</i>				
	27%	30%	33%	

Note: AAGR (average annual growth rate). Prescriptions are standardized to a 30-day supply. "Gross spending" reflects payments from all payers, including beneficiaries (through cost sharing), before accounting for postsale rebates and fees received from pharmacies and manufacturers. *Vertically integrated pharmacies are defined as those that are owned by the four largest pharmacy benefit managers—CVS Health's Caremark, UnitedHealth Group's OptumRx, Humana Pharmacy Solutions, and Cigna's Express Scripts. All four pharmacy benefit managers operate mail-order and specialty pharmacies. In addition, CVS Caremark and OptumRx also operate retail pharmacies (Fein 2023).

Source: MedPAC analysis of Medicare Part D prescription drug event data from CMS and pharmacy data from the National Council for Prescription Drug Programs.

to just under half. In contrast, Humana Pharmacy Solutions, the internal PBM of Humana Inc., provides services exclusively to Part D plans operated by Humana Inc. (Guardado 2022). They also differed in the segments of the Part D market that they focused on. For example, in 2021, the share of Part D enrollees in EGWPs ranged from less than 10 percent to over 40 percent of all enrollees served by a given PBM. For the three PBMs that serve both VI and other (unaffiliated) plans, larger employers were more likely to contract directly with the insurers or PBMs (i.e., be classified as a VI plan).

An increasing share of Part D prescriptions are dispensed at vertically integrated pharmacies

All four PBMs operate mail-order and specialty pharmacies. In addition, CVS Caremark and Optum Rx also operate retail pharmacies (Fein 2023). Between 2015 and 2021, the share of prescriptions dispensed at these PBM-operated pharmacies grew from about a

quarter to nearly one-third of all Part D prescriptions (Table 2-4). This growth likely reflects the increasing concentration of enrollment in plans that are operated by the largest PBMs, mergers and acquisitions of pharmacies by these PBMs, and consumers choosing to fill their prescriptions at chain pharmacies.²⁸

The shares of prescriptions and spending accounted for by the VI pharmacies are smaller than the combined market share for these four PBMs (about 90 percent of Part D enrollment). The lower shares are primarily due to Part D rules that limit plans' ability to use restrictive pharmacy networks.

First, in Part D, CMS requires plan sponsors to allow any pharmacy that is willing to accept the sponsor's terms and conditions to participate in their pharmacy network (known as the any-willing-pharmacy rule). Further, CMS regulation requires convenient access for beneficiaries by prohibiting plan sponsors from

**TABLE
2-5**

Vertically integrated and other pharmacies mostly dispensed medications in the same broad therapeutic categories, 2021

Vertically integrated pharmacies		Other pharmacies	
Therapeutic category	Share of total gross spending	Therapeutic category	Share of total gross spending
1 Endocrine	20%	1 Endocrine	21%
2 Antineoplastics	13	2 Antineoplastics	14
3 Cardiovascular therapy agents	11	3 Central nervous system agents	11
4 Hematological agents	10	4 Hematological agents	9
5 Respiratory therapy agents	10	5 Respiratory therapy agents	8
6 Analgesic, anti-inflammatory, or antipyretic	7	6 Anti-infective agents	7
7 Central nervous system agents	7	7 Cardiovascular therapy agents	7
8 Multiple sclerosis agents	4	8 Analgesic, anti-inflammatory, or antipyretic	6
9 Anti-infective agents	3	9 Gastrointestinal therapy agents	4
10 Dermatological	3	10 Dermatological	3
Total, top 10 therapeutic classes by spending	88	Total, top 10 therapeutic classes by spending	89

Note: Vertically integrated pharmacies are defined as pharmacies that are owned by the four largest Part D plan sponsors (CVS Health, Cigna, Humana, and UnitedHealth Group) that own an "in-house" PBM along with mail-order, specialty, and sometimes retail pharmacies.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

restricting access to certain Part D drugs to specialty pharmacies within their network. An exception to this rule is allowed if a manufacturer of a specialty drug has limited the distribution of its product to certain authorized pharmacies (see text box on manufacturer-designated limited distribution networks, p. 94). In this case, Part D enrollees can fill that prescription only at one of the designated specialty pharmacies.

Second, Part D plans may offer mail-order prescriptions, but CMS requires a level playing field between mail-order and network pharmacies in that at least one retail pharmacy must be able to dispense prescriptions with 90-day supplies. However, a plan sponsor could require an enrollee obtaining a 90-day prescription at a network retail pharmacy to pay higher cost sharing than the cost-sharing amount applicable at a mail-order pharmacy (Code of Federal Regulations 2005).

Vertically integrated pharmacies mostly dispensed medications in the same broad therapeutic categories as other pharmacies

In 2021, classes of medications dispensed at VI pharmacies, in terms of broad therapeutic categories, were nearly identical to those dispensed at other (unaffiliated) pharmacies, with endocrine therapies (mostly consisting of diabetic therapies) and antineoplastics topping the list based on gross spending for both types of pharmacies (Table 2-5). The only categories that did not appear in both lists were multiple sclerosis agents (in VI pharmacies' top 10) and gastrointestinal therapy agents (in other pharmacies' top 10).

The share of gross spending accounted for by VI pharmacies varied across therapeutic classes (Figure 2-7, p. 95). VI pharmacies accounted for a relatively large share of spending for cardiovascular therapy

Manufacturer-designated limited distribution networks

Some pharmaceutical manufacturers manage some or all of their specialty medications through limited distribution. Under limited distribution, medications are dispensed by a small number of pharmacies (or network of pharmacies), typically selected based on quality and performance in areas such as clinical expertise, medication adherence and patient support services, and data collection and reporting capabilities (CSI Specialty Group 2019).

Manufacturers use limited distribution networks (LDNs) for a number of reasons. Specialty drugs may require special protocols for handling and dispensing. In some cases, pharmacists may need to educate the patients about use of the drug. For expensive drugs with limited shelf life, LDNs help ensure that the pharmacy services a large enough patient population to supply the drug in a timely manner. Manufacturers also collect data from specialty pharmacies as part of their Risk Evaluation and Mitigation Strategy (REMS) program, or as a way to monitor adherence and effectiveness. Using a smaller network of specialty pharmacies can help streamline such data collection.

Large specialty pharmacies—such as Accredo, CVS Caremark, and Optum specialty pharmacies—are a few of the most common pharmacies that are often part of LDNs (Blue Cross Blue Shield of Florida 2023, Wong 2021). Limited-distribution drugs are typically expensive and have complex regimens to manage, with a higher risk of serious side effects. Many are therapies used to treat cancer, multiple sclerosis,

and autoimmune conditions. Examples of limited-distribution drugs that are exclusively dispensed by large specialty pharmacies include:

- Orkambi (lumacaftor/ivacaftor), used for the treatment of cystic fibrosis (Accredo specialty pharmacy);
- Actemra (tocilizumab), used for rheumatoid arthritis and other inflammatory conditions (Accredo specialty pharmacy and CVS specialty pharmacy); and
- Copiktra (duvelisib), used for the treatment of chronic lymphocytic leukemia (Optum specialty pharmacy).

When a large specialty pharmacy is not included in the limited distribution network, it may enter into bilateral agreements with other specialty pharmacies to fill prescriptions for each other.

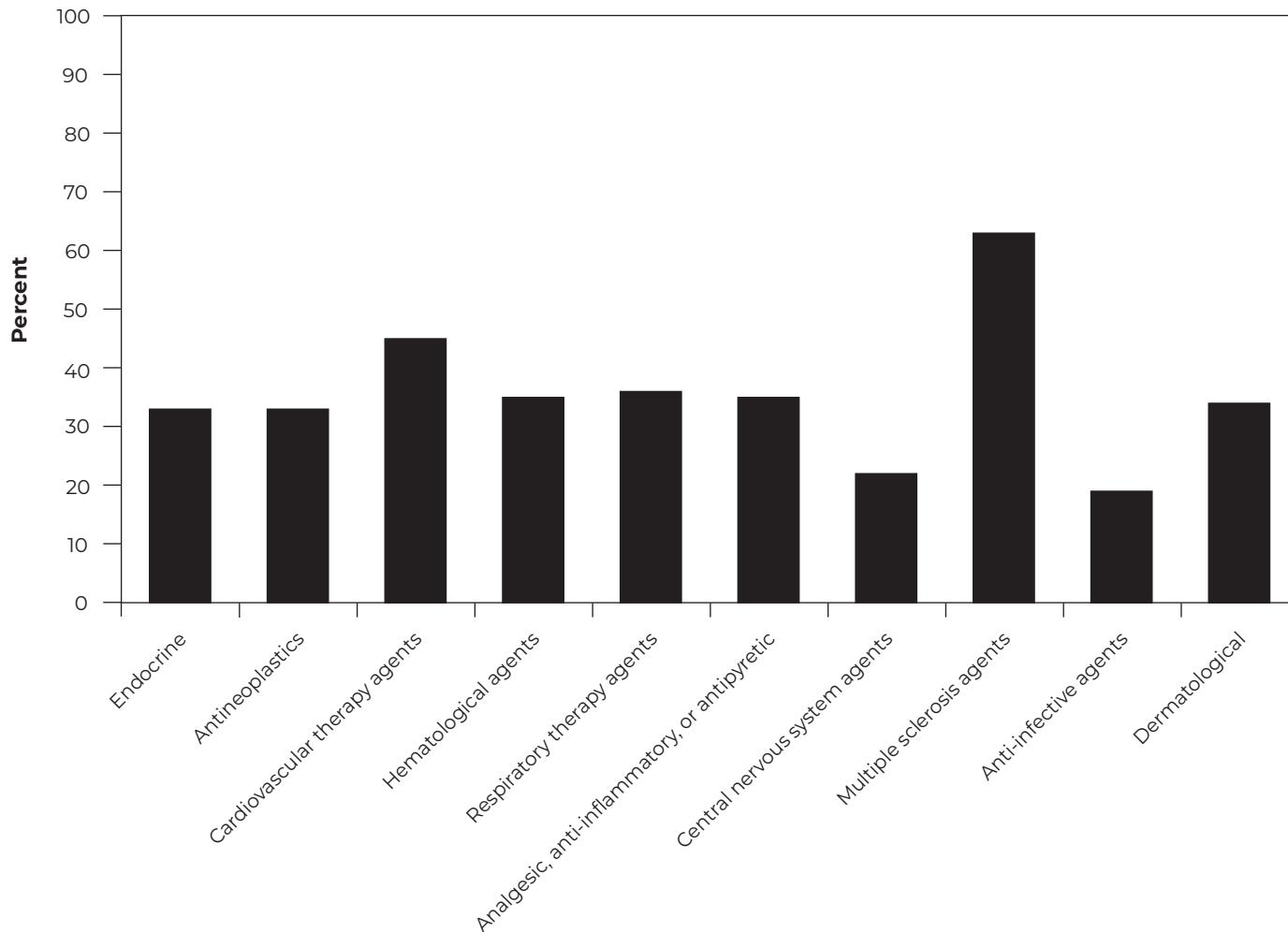
A concern about limited distribution is that when only a small number of specialty pharmacies dispense a drug, the PBM and payer may not be able to negotiate competitive discounts in pharmacy payment rates. There is also a broader concern that manufacturers may misuse the LDNs to increase drug prices and obstruct access to competing drugs (Karas et al. 2018). Some manufacturers cite the Food and Drug Administration's (FDA's) REMS requirement to limit generic and biosimilar drug developers from obtaining the drug products needed for their FDA drug applications (Karas et al. 2018). ■

agents and multiple sclerosis agents. In some cases, differences in ranking of therapeutic categories, such as cardiovascular therapy agents (ranked third under VI pharmacies' list vs. seventh under other pharmacies' list), may reflect differences in the

mix of drugs in those categories. For example, VI pharmacies may dispense more expensive pulmonary antihypertensive therapies, while other pharmacies may have a larger share of prescriptions that are mostly generic antihypertensive drugs, such as angiotensin-converting enzyme inhibitors.

**FIGURE
2-7**

Vertically integrated pharmacies' share of gross Part D spending varied across the top 10 therapeutic classes, 2021



Note: Vertically integrated pharmacies are defined as pharmacies that are owned by the four largest Part D plan sponsors (CVS Health, Cigna, Humana, and UnitedHealth Group) that own an “in-house” PBM along with mail-order, specialty, and sometimes retail pharmacies.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

Does vertical integration lower Part D costs?

Health plans have integrated with and built up large PBMs that have significant market power to negotiate rebates with pharmaceutical manufacturers and achieve economies of scale in mail dispensing. At the same time, a PBM may face conflicting interests as a PBM providing services to the payer and as an owner of a pharmacy facing financial incentives to increase dispensing of drugs, particularly those with higher pharmacy spreads (Herman 2022).

In our analysis, we examined pharmacy payments and plan costs at VI and other (non-VI) pharmacies for 2021 to gain insights into whether and how Part D enrollees and Medicare are affected by vertical integration of PBMs with plans and pharmacies. We defined VI pharmacies as those that are operated by the largest Part D plan sponsors’ “in-house” PBMs, including mail-order, specialty, and, for some sponsors, retail pharmacies. We compared the prescriptions dispensed at pharmacies owned by the four largest

Methodology for vertical integration analysis

Our analysis was limited to plans served by the four largest PBMs—CVS Caremark, Express Scripts, Humana Pharmacy Solutions, and Optum Rx. We examined six categories of drugs—disease-modifying anti-rheumatoid drugs (DMARDs), multiple sclerosis agents, two categories of antineoplastics (antiandrogen therapies and protein-tyrosine kinase inhibitors), antiretrovirals, and pulmonary antihypertensive therapies. In 2021, these six categories of drugs had the highest volume, spending, or both at pharmacies designated as specialty pharmacies.²⁹ Three of the six categories (two antineoplastics and antiretrovirals) are in protected classes.

For each PBM, we compared average payments to pharmacies (before accounting for any rebates or postsale fees) and plan costs net of manufacturer rebates. We did not account for pharmacy direct and indirect remuneration (DIR) in this analysis because plans are not required to report pharmacy DIR amounts specific to individual pharmacies. We evaluated transactions between:

- VI plans and their own VI pharmacies,
- VI plans and other (non-VI) pharmacies,
- Non-VI plans and VI pharmacies, and
- Non-VI plans and non-VI pharmacies.

We refer to these four types of transactions as “plan-pharmacy type.” Three of the four PBMs have all

four types of transactions, while Humana Pharmacy Solutions has only two plan-pharmacy types, “VI plans and VI pharmacies” and “VI plans and other (non-VI) pharmacies,” because it only serves its own (Humana) health plans.

For each PBM and plan-pharmacy type, we calculated the average gross prices (payments to pharmacies) and costs net of rebates for each product (e.g., Enbrel Sureclick[®] (a DMARD)) in the six drug categories:

- average gross payments to pharmacies—total amounts paid at the pharmacy from all payers, including beneficiaries, before postsale rebates and fees, per standardized prescription; and
- average plan costs net of rebates—average gross payments to pharmacies minus average manufacturer rebates per standardized prescription, assuming that, for a given plan and product, the average rebate amount per prescription was the same regardless of the type of dispensing pharmacy (VI vs. non-VI).

We then calculated weighted average gross payments and plan costs net of rebates using the standardized prescription volume for “VI plans and VI pharmacies,” for each drug category (six), for each PBM (four), and by plan-pharmacy types. Using the same weights allows us to compare average payment rates and costs across the four plan-pharmacy types without the effects of any differential mix of products across plan-pharmacy types.

(continued next page)

VI organizations participating in Part D—CVS Health, UnitedHealth Group, Humana, and Cigna—with those dispensed at other pharmacies to see whether the behaviors of the VI plan sponsors differed systematically between the affiliated and unaffiliated plans and pharmacies (see text box on analytical method). Our analysis included 24 distinct comparisons (hereafter

referred to as cases) of average gross payments at different plan-pharmacy types for four PBMs and six drug categories. Similarly, we analyzed 24 cases of average costs net of rebates. Our findings are directionally consistent with the hypothesis that a VI entity can financially benefit from higher payments to their VI pharmacies.

Methodology for vertical integration analysis (cont.)

Using a hypothetical PBM A, we developed three cases, drug category 1, drug category 2, and drug category 3 (Table 2-6). Each case has four transaction types, for which we calculated a weighted average of gross prices across all products. To compare gross prices across the four transaction types, we converted the average gross prices into relative prices by dividing by the average gross price paid by VI plan to VI pharmacy (VI-VI). That is, gross prices are 1.0 for a VI-VI transaction. A value greater than 1.0 indicates that the gross prices were higher than VI-VI transaction type, and vice versa.

For each case, the table indicates the transaction type with the highest and lowest average gross prices with a single asterisk and double asterisks, respectively (Table 2-6). Focusing on one case (drug category 1), the average gross price paid by the VI plan to the VI was the highest (a relative price of 1.0), while the average gross price paid by the non-VI plan to the non-VI pharmacy was the lowest (a relative price of 0.92). In this hypothetical example, PBM A paid the highest gross price for VI-VI transactions in two out of three cases. ■

**TABLE
2-6**

An illustrative example of three “cases” for PBM A

		Ratio: Average gross price per prescription (relative to VI-VI)		
		Drug category 1	Drug category 2	Drug category 3
VI plan	VI pharmacy	1.000*	1.000*	1.000**
	Non-VI pharmacy	0.970	0.900	1.040*
Non-VI plan	VI pharmacy	0.950	0.800**	1.030
	Non-VI pharmacy	0.920**	0.850	1.020
Highest average gross cost (*)		VI-VI	VI-VI	VI-non-VI
Lowest average gross cost (**)		non-VI-non-VI	non-VI-VI	VI-VI

Note: VI (vertically integrated).

Source: MedPAC depiction of hypothetical payment rates between plans and pharmacies.

Non-VI pharmacies were more likely to have received the lowest payments

We found that, in 2021, a PBM’s average gross payments across the plan-pharmacy types could vary by as much as 88 percent. However, it was more common for payments to be within 10 percent of each other.

The average costs net of rebates, on the other hand, varied more widely, with nearly 40 percent of the cases varying by more than 30 percent.

While results varied by PBM and by drug category, there were notable patterns. For example, we found that average gross payments to pharmacies were

**TABLE
2-7**

Pharmacy payments and net costs were more likely to be the lowest at non-VI pharmacies and the highest for VI pharmacies filling prescriptions for VI plans, 2021

Type of plan	Type of pharmacy	Average gross payments to pharmacies				Average plan costs net of rebates			
		Highest		Lowest		Highest		Lowest	
		Number of cases	Share of cases	Number of cases	Share of cases	Number of cases	Share of cases	Number of cases	Share of cases
VI	VI	11	46%	2	8%	17	71%	3	13%
	Non-VI	10	42	8	33	5	21	7	29
Non-VI	VI	3	13	4	17	1	4	8	33
	Non-VI	0	0	10	42	1	4	6	25
Total number of cases		24	100	24	100	24	100	24	100

Note: VI (vertically integrated). VI pharmacies are defined as pharmacies that are owned by the four largest Part D plan sponsors (CVS Health, Cigna, Humana, and UnitedHealth Group) that are vertically integrated with an “in-house” PBM along with mail-order, specialty, and sometimes retail pharmacies.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

more likely to be the highest for transactions between VI plans–VI pharmacies (11 cases, or 46 percent of all cases) and VI plans–non-VI pharmacies (10 cases, or 42 percent of all cases) (Table 2-7). There were no cases where the average gross pharmacy payments were the highest for non-VI plans–non-VI pharmacies. Non-VI pharmacies were more likely to have received the lowest payments (42 percent for non-VI plans–non-VI pharmacies and 33 percent for VI plans–non-VI pharmacies). Results were similar for protected-class drugs, with non-VI pharmacies receiving the lowest payments in 10 out of 12 cases (83 percent) (data not shown).

In a majority of cases, plans’ net costs were the highest for VI pharmacies filling prescriptions for VI plans

For the average net plan costs, we found that, in 71 percent of the cases (17 of 24), net costs were the highest at VI plans–VI pharmacies, meaning that, for these cases, vertical integration may have resulted in higher costs to Part D and their plan enrollees (Table 2-7).³⁰ For these 17 cases, VI pharmacies’ market share did not seem to be the factor affecting plans’ net costs:

Their market share ranged from less than 20 percent to about 60 percent. VI plans–VI pharmacies had the lowest costs in only three cases. For protected-class drugs, VI plans–VI pharmacies had the highest cost for all but one case (data not shown).

Key takeaways

For a limited number of drug categories, we found that costs net of manufacturer rebates were more likely to be higher at VI pharmacies compared with costs at other pharmacies, particularly when those prescriptions were filled for their own VI plans. Our findings are directionally consistent with the hypothesis that a VI entity financially benefits from higher (gross) payments to their VI pharmacies. In addition to higher gross revenues, higher payments could be financially advantageous if a manufacturer’s payments (e.g., service fees for patient adherence data) to VI pharmacies were based on gross prices paid at the pharmacy, thus contributing to higher spreads.

For a drug product for which VI pharmacies received discounts or fees from manufacturers, higher net costs to the VI Part D plan may not necessarily mean

that the product actually had higher net costs to the vertically integrated organization as a whole. For example, profits at a VI plan's VI pharmacy could offset the plan's higher costs incurred for those prescriptions. Part D's DIR reporting requirement, however, does not include manufacturer discounts or fees retained by pharmacies. If the payments and costs at VI pharmacies are, on average, higher than at non-VI pharmacies, an increase in the share of Part D prescriptions dispensed at VI pharmacies could mean higher Part D costs.

There are a few caveats. First, our findings are pertinent only to the six categories of drugs we examined. Second, our analysis focused on the four largest PBMs and their pharmacies. PBMs vary widely in their business models, and an examination of pharmacy payments and net costs for other, smaller PBMs could lead to different findings.

Looking ahead

Our findings provide insights into current rebate practices while also highlighting how competitive dynamics as well as regulatory policies can affect drug pricing. However, last year, the Congress passed the IRA, which included policy changes related to prescription drugs that are likely to alter the drug-pricing landscape. Among other provisions, the law (1) establishes mandatory rebates for manufacturers of

drugs sold to Medicare beneficiaries if the price of their drug rises faster than inflation, and (2) requires the Secretary of Health and Human Services to negotiate prices each year for a select number of drugs with the highest total Medicare spending. (The Secretary will select the first 10 drugs for negotiation in 2023, and negotiated prices for those drugs will be effective in 2026.) The IRA also restructures Part D's benefit design in significant ways, some of which are consistent with the Commission's 2020 recommendations for the program (Medicare Payment Advisory Commission 2020). For example, beginning in 2024, enrollees will no longer pay cost sharing in Part D's catastrophic phase; the threshold for that phase will be lowered to \$2,000 in 2025. Beginning in 2025, capitated payments will replace much of what is now Medicare's cost-based reinsurance, restoring stronger incentives for plan sponsors to manage drug spending. By better aligning plan incentives with those of Medicare and its beneficiaries, the changes are expected to reduce plans' incentives to place high-gross-price, high-rebate drugs on their formularies.

Changes adopted in the IRA will thus affect the magnitude of future rebates and the circumstances under which Part D plan sponsors are able to negotiate rebates with manufacturers. The analyses in this chapter will serve as a baseline from which to evaluate changes in the pricing and rebate practices as the provisions of the IRA are implemented. ■

Endnotes

- 1 The summary report also includes other categories of fees that take place between manufacturers and PBMs or between PBMs and pharmacies. In recent years, such fees were trivial—less than one-half of 1 percent of all DIR. Ultimately, all information the Medicare program has about Part D DIR is derived from the same source: information that plan sponsors submit to CMS. We did not conduct audits of plan sponsors, and there are no external sources of information that we can use to test the data's validity (Ippolito and Levy 2022). Nevertheless, based on the comparisons with other publicly available data, the DIR data received by the Commission seem generally complete.
- 2 CMS also uses DIR data to calculate whether each plan should make or receive risk-corridor payments. For background on Part D's payment system, see our *Payment Basics on Part D payment* (Medicare Payment Advisory Commission 2022b) and the Commission's March 2023 report (Medicare Payment Advisory Commission 2023).
- 3 Both programs can negotiate additional price concessions beyond the statutorily mandated amounts based on inclusion in preferred formularies.
- 4 However, data from the 2020 Medicare Current Beneficiary Survey suggest that among the factors beneficiaries consider when choosing their plan, more reported considering OOP costs (30 percent) than premiums (26 percent), perhaps because average base beneficiary premiums have remained low and even declined in recent years.
- 5 We calculated this amount from the aggregate portion of DIR that plan sponsors retained in 2021 (about two-thirds) after CMS reconciled Medicare's reinsurance payments to plans, divided by aggregate Part D enrollment months, and then multiplied by 12.
- 6 The \$2,000 cap will be indexed based on the annual increase in average Part D drug expenditures per beneficiary.
- 7 Under the IRA provisions that redesign Part D's basic benefit, beginning in 2025, Medicare will pay 20 percent reinsurance on brand-name and biologic prescriptions in the catastrophic phase and 40 percent for generics. Plan sponsors will bear risk for 60 percent of spending in the catastrophic phase, and manufacturers of brand and biologic products will provide a 20 percent discount.
- 8 For years, the Commission has used PDE data to construct Part D price indexes that show how prices faced by beneficiaries at the pharmacy have changed over time (Medicare Payment Advisory Commission 2023). Gross indexes reflect all amounts paid to pharmacies at the point of sale for Part D prescriptions before retrospective rebates and fees. Using the detailed drug-level DIR data, we developed indexes of Part D costs for brand-name drugs net of rebates (net indexes) using methods consistent with the Commission's indexes for gross prices. The indexes measure growth in postlaunch prices and costs and do not reflect rising launch prices of new products.
- 9 For example, some sponsors may negotiate quarterly rebate payments from manufacturers, while others might be more frequent. Rebates could be lower at the start of the year and larger at the end of the year once a manufacturer's product has reached a certain volume of claims. If a manufacturer has raised its price for a drug above a certain threshold later in the year, it may rebate that incremental price increase to the plan. Sponsors and their PBMs may use monthly or quarterly "true-ups" of payments with chain pharmacies or the pharmacy services administrative organization that represents independent pharmacies. There may be bonuses or risk-sharing payments from sponsors to pharmacies and manufacturers after the benefit year's end.
- 10 Because pharmacy DIR can apply to both generic and brand-name drugs but manufacturer rebates apply only to the latter, for this index, we focused exclusively on the effect of growth in rebate dollars.
- 11 The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) identifies drug products approved on the basis of safety and effectiveness. "Highly rated generics" refer to A-rated generic drugs that have been determined to be bioequivalent to the brand drug, while other (B-rated) generic drugs are considered not to be bioequivalent.
- 12 The Biologics Price Competition and Innovation Act of 2009, included in the Affordable Care Act of 2010, required that certain drug products previously approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (such as insulin) would be deemed to be approved as a biologic under Section 351 of the Public Health Service Act after a 10-year period for purposes of opening a regulatory approval pathway for biosimilars of such products. While follow-on insulins had been approved under Section 505(b)(2), until this change went into effect, manufacturers could not rely on the abbreviated biosimilar pathway for drugs approved under Section 505.
- 13 Under the defined standard benefit, cost sharing ranges from 5 percent in the catastrophic phase of the benefit to 100 percent in the deductible phase, and for beneficiaries who receive the LIS, 100 percent in the coverage gap.

- Most LIS beneficiaries pay nominal copayments set in law; Medicare pays for the remainder of the plans' cost-sharing requirements on their behalf. In 2021, cost sharing paid by beneficiaries and Medicare's LIS totaled \$49.3 billion. Of that total, \$31.4 billion (nearly 64 percent) was paid by Medicare in low-income cost-sharing subsidies.
- 14 Each of the three largest brand-name insulin manufacturers (Eli Lilly, Novo Nordisk, and Sanofi) announced list-price cuts of 70 percent to 80 percent for several of their older insulin products in March 2023. While manufacturer price cuts are likely to have little effect on Part D beneficiary cost sharing because of the new monthly OOP cap, the cuts may significantly reduce rebates received by plans and thus have potential implications for plan premiums.
 - 15 Other organizations such as the Government Accountability Office have consistently estimated comparable rebate magnitudes (Government Accountability Office 2019).
 - 16 For example, people with asthma may use a maintenance inhaler once or twice per day but keep a rescue inhaler for sudden onset of symptoms.
 - 17 As the FDA notes on its website, "Because combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different FDA Centers, they raise challenging regulatory, policy, and review management challenges. Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management."
 - 18 One requirement for drug-device combination generic approval is that users of the product must be able to use the generic product as easily as they can the original without any additional training or intervention. This requirement can be challenging for generic manufacturers to prove and makes the approval process for a drug-device combination product more costly and burdensome relative to noncombination small-molecule drug products.
 - 19 A study examining the length of marketing exclusivity derived from patents for 49 drug-device combination products (specifically, products to treat asthma/COPD, insulin, and allergic reactions) found that more than half of the products had device patents that shielded them from competition beyond what would be provided by the product's patents for its active ingredient, with a median of 4.7 years of additional protection. Another 14 products listed only device patents, and the median length of protection remaining from those patents from the time of the study was 9 years. Of the 49 products studied, 18 had patents for the original drug compound that expired prior to 2000 but still had a patent offering market protection as of 2015.
 - 20 For example, GlaxoSmithKline received 35 years of marketing exclusivity following FDA approval of its fluticasone inhaler, first introduced as Flovent in 1996, by subsequently introducing Flovent Rotadisk in 1997, Flovent Diskus in 2000, Flovent HFA in 2004, and reformulating as Arnuity Ellipta in 2014 with a protected patent through 2030.
 - 21 Breo Ellipta and Advair Diskus are both manufactured by GlaxoSmithKline.
 - 22 Of the products listed here, Proair, Ventolin, and Pulmicort each have generic competitors.
 - 23 In 2014, CMS proposed to provide a drug class protected status only if a delay in obtaining a medication is likely to result in serious health consequences and the clinical needs of patients treated with one or more medications in that drug class cannot be met unless all Part D drugs in that class are included in a plan formulary. CMS determined that three classes—immunosuppressants for transplant rejection, antidepressants, and antipsychotics—did not meet both proposed criteria, though antipsychotics would be spared from removal because of the clinical risk associated with untreated psychotic illness. In 2018, CMS proposed allowing plans to (1) use prior authorization or step therapy to ensure that the drug is being used for a protected-class indication, including for patients already using it; (2) exclude a drug from the formulary if it is solely a new formulation of an existing single-source drug, regardless of whether the older formulation remains on the market; and (3) exclude a drug from the formulary if the drug's price increased faster than inflation. The Commission generally supported these proposals, noting the importance of balancing the goals of beneficiary access and welfare with Part D plans' tools to manage the drug benefit and appropriately constrain costs.
 - 24 Utilization management is not allowed in Part D for antiretrovirals.
 - 25 Type of pharmacy is based on pharmacy information recorded on Part D's prescription drug event data.
 - 26 When money transfers from one part of the company to another, insurers may keep more of the premiums they collect. This is sometimes referred to as intercompany elimination (Herman 2022). In the case of Part D, if a beneficiary enrolled in a Part D drug plan operated by one sponsor fills a prescription through that same sponsor's specialty pharmacy, any profit made at the pharmacy is also a profit for the parent company. Higher payments to the pharmacy (transfer price) may contribute to higher overall profit for the company.

- 27 In the case of a pharmacy that is vertically integrated with a PBM, all else equal, any fees or rebates that are received by the pharmacy could increase the profits obtained by the pharmacy.
- 28 For example, in 2019 UnitedHealth Group's Optum Rx acquired the largest independent specialty pharmacy (Minemyer 2019). In 2020, Aetna Specialty Pharmacy was combined with CVS Specialty after CVS Health acquired Aetna in late 2018 (Richman 2018).
- 29 Specialty pharmacies were identified based on pharmacy type codes reported in National Council for Prescription Drug Programs' pharmacy database.
- 30 The plan-pharmacy type with the highest (or the lowest) net costs can differ from the type with the highest (or the lowest) gross payments because of differences in the average rebates obtained by vertically integrated (VI) plans and non-VI plans. Separately, we also investigated whether pharmacy DIR as a percentage of gross spending was higher or lower for VI plans relative to non-VI plans in the six drug categories. We found no consistent pattern: For some PBMs and drug categories, the percentage of pharmacy DIR was similar, but there were other cases in which the average percentage of pharmacy DIR was higher for VI plans.

References

- Avalere. 2020. Impact of protected class utilization management in Medicare Part D. <https://avalere.com/wp-content/uploads/2020/06/Impact-of-Protected-Class-Utilization-Management-in-Medicare-Part-D-.pdf>.
- Beall, R. F., J. W. Nickerson, W. A. Kaplan, et al. 2016. Is patent “evergreening” restricting access to medicine/device combination products? *PLoS One* 11, no. 2: e0148939.
- Biddiscombe, M. F., and O. S. Usmani. 2018. Is there room for further innovation in inhaled therapy for airways disease? *Breathe* 14, no. 3 (September): 216–224.
- Blue Cross Blue Shield of Florida. 2023. Limited distribution drugs (LDD). http://www.bcbsfl.com/DocumentLibrary/Providers/Content/Rx_LimitedDistributionDrugs.pdf.
- Centers for Disease Control and Prevention. 2012. CDC statement on FDA approval of drug for HIV prevention. <https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Final Medicare Part D DIR reporting guidance for 2021. Memo from Jennifer R. Shapiro, Director, Medicare Plan Payment Group, to all Part D sponsors. March 30.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021. Medicare Part D drug spending dashboard and data. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>.
- Centers for Medicare & Medicaid Services. 2019. Medicare Advantage and Part D drug pricing final rule (CMS–4180–F). Fact sheet. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014a. Medicare Program: Contract year 2015 policy and technical changes to the Medicare Advantage and the Medicare prescription drug benefit programs. Proposed rule. *Federal Register* 79, no. 7 (January 10): 1917–2073.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014b. Medicare program; contract year 2015 policy and technical changes to the Medicare Advantage and the Medicare prescription drug benefit programs. Proposed rule. *Federal Register* 79, no. 7 (January 10): 1918–2073.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014c. *Prescription drug benefit manual. Chapter 6: Part D drugs and formulary requirements*. Baltimore, MD: CMS.
- Code of Federal Regulations. 2005. Access to covered Part D drugs. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-C/section-423.120>.
- Congressional Budget Office. 2021. *A comparison of brand-name drug prices among selected federal programs*. Washington, DC: CBO. <https://www.cbo.gov/publication/57007>.
- Congressional Budget Office. 2008. *Increasing transparency in the pricing of health care services and pharmaceuticals*. Washington, DC: CBO.
- CSI Specialty Group. 2019. *2019 state of specialty pharmacy report*. Sanford, FL: CSI Specialty Group.
- Danzon, P. 2015. Pharmacy benefit management: Are reporting requirements pro or anti-competitive? *International Journal of the Economics of Business* 22, no. 2: 245–261.
- Dickson, S., and A. Killelea. 2021. Intentionally delayed pharmaceutical innovation under perverse incentives: Gilead’s HIV pipeline as a case study. *Health Affairs Forefront*, June 16.
- Dusetzina, S. B., H. A. Huskamp, R. L. Rothman, et al. 2022. Many Medicare beneficiaries do not fill high-price specialty drug prescriptions. *Health Affairs* 41, no. 4 (April): 487–496.
- Federal Trade Commission. 2009. Letter from FTC staff to the Hon. James Seward on N.Y. Senate Bill 58. March. http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.
- Fein, A. 2023. *The 2023 economic report on U.S. pharmacies and pharmacy benefit managers*. Philadelphia, PA: Drug Channels Institute. https://drugchannelsinstitute.com/products/industry_report/pharmacy/.
- Feldman, W. B., D. Bloomfield, R. F. Beall, et al. 2022. Patents and regulatory exclusivities on inhalers for asthma and COPD, 1986–2020. *Health Affairs* 41, no. 6 (June): 787–796.
- Food and Drug Administration. 2022. Generic competition and drug prices. Silver Spring, MD: FDA. <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>.

- Food and Drug Administration. 2020. Insulin gains new pathway to increased competition. Silver Spring, MD: FDA. <https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition>.
- Food and Drug Administration. 2019. About combination products. Silver Spring, MD: FDA. <https://www.fda.gov/combination-products/about-combination-products>.
- Frank, R. G., T. G. McGuire, and I. Nason. 2021. The evolution of supply and demand in markets for generic drugs. *Milbank Quarterly* 99, no. 3 (September): 828–852.
- Garthwaite, C., and F. Morton. 2017. Perverse market incentives encourage high prescription drug prices. *ProMarket* blog. November 1. <https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/>.
- Government Accountability Office. 2019. *Medicare Part D: Use of pharmacy benefit managers and efforts to manage drug expenditures and utilization*. Washington, DC: GAO. <https://www.gao.gov/products/gao-19-498>.
- Greaney, T. L. 2019. Testimony before the Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy and Consumer Rights on “Your doctor/pharmacist/insurer will see you now: Competitive implications of vertical consolidation in the healthcare industry.” June 12.
- Guardado, J. R. 2022. *Policy research perspectives: Competition in commercial PBM markets and vertical integration of health insurers with PBMs*. Chicago, IL: American Medical Association. <https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf>.
- Herman, B. 2022. The health insurer will see you now: How UnitedHealth is keeping more profits, as your doctor. *Stat News*, December 5. <https://www.statnews.com/2022/12/05/unitedhealth-keeping-profits-as-your-doctor-insurer/>.
- Ippolito, B., and J. Levy. 2022. Best practices using SSR health net drug pricing data. *Health Affairs*.
- IQVIA. 2022. *Global oncology trends 2022*. Parsippany, NJ: IQVIA. <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2022>.
- Jones, G. H., M. A. Carrier, R. T. Silver, et al. 2016. Strategies that delay or prevent the timely availability of affordable generic drugs in the United States. *Blood* 127, no. 11 (March 17): 1398–1402.
- Kaiser Family Foundation. 2016. Medicare and HIV. Fact sheet. <https://www.kff.org/hiv/aids/fact-sheet/medicare-and-hiv/>.
- Karas, L., K. M. Shermock, C. Proctor, et al. 2018. Limited distribution networks stifle competition in the generic and biosimilar drug industries. *American Journal of Managed Care* 24, no. 4 (April 1): e122–e127.
- Killelea, A., and T. Horn. 2023. At last, generic HIV prevention drugs promise savings and access—but also reveal precarious financing. *Health Affairs* (February 17).
- Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2022a. *A data book: Health care spending and the Medicare program*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_SEC_v2.pdf.
- Medicare Payment Advisory Commission. 2022b. *Payment basics: Part D payment system*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_PartD_FINAL_SEC.pdf.
- Medicare Payment Advisory Commission. 2022c. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Minemyer, P. 2019. UnitedHealth Group to acquire specialty pharmacy Diplomat in \$300M deal. *Fierce Healthcare*, December 9. <https://www.fiercehealthcare.com/payer/unitedhealth-group-to-acquire-specialty-pharmacy-diplomat-300m-deal>.
- Office of Inspector General, Department of Health and Human Services. 2021. *CMS should strengthen its prescription drug event guidance to clarify reporting of sponsor margin for Medicare Part D bids*. A-03-17-00001. Washington, DC: OIG.
- Partnership for Part D Access. 2018. *Medicare Part D’s six protected classes policy: A balanced approach to provide patients access to medications while allowing powerful tools to control costs*. Washington, DC: Partnership for Part D Access.
- Richman, E. 2018. CVS closes \$69B acquisition of Aetna in a “transformative moment” for the industry. *Fierce Healthcare*, November 28. <https://www.fiercehealthcare.com/payer/cvs-closes-69-billion-acquisition-aetna>.
- Sarpattwari, A., J. DiBello, M. Zakarian, et al. 2019. Competition and price among brand-name drugs in the same class: A systematic review of the evidence. *PLoS Medicine* 16, no. 7 (July): e1002872.

Stein, S. W., and C. G. Thiel. 2017. The history of therapeutic aerosols: A chronological review. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* 30, no. 1 (February): 20–41.

Tseng, C. W., J. Yazdany, R. A. Dudley, et al. 2017. Medicare Part D plans' coverage and cost-sharing for acute rescue and preventive inhalers for chronic obstructive pulmonary disease. *JAMA Internal Medicine* 177, no. 4 (April 1): 585–588.

Wong, A. 2021. Limited distribution drugs: A guide to networks and specialty pharmacies. GoodRx Health, December 22. <https://www.goodrx.com/healthcare-access/pharmacies/limited-distribution-drugs>.

Younge, J. 2023. United States ex rel. Ellsworth Assoc., LLP v. CVS Health Corp., No. 19-2553, 2023 BL 78873 (E.D. Pa. Mar. 10, 2023), Court Opinion. *Bloomberg Law*, March 10.

