

CHAPTER 13

The Medicare prescription drug program (Part D): Status report

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Chapter summary

In 2021, Part D paid for outpatient prescription drug coverage on behalf of more than 49 million Medicare beneficiaries. For Part D plan enrollees, Medicare subsidizes about three-quarters of the cost of basic benefits. Part D also includes a low-income subsidy (LIS) that provides assistance with premiums and cost sharing to about 13 million individuals with low income and assets. The 2020 and 2021 benefit years were extraordinary due to the coronavirus pandemic and its toll on Medicare beneficiaries and health care providers. However, Medicare beneficiaries experienced comparatively less disruption in access to medicines than in access to other types of health care services. One snapshot survey found that during the winter of 2020 to 2021, among the 7 percent of beneficiaries who reported forgoing care in the past few months, 29 percent of this subset had missed a regular check-up and 32 percent had missed treatment for an ongoing condition due to the pandemic, but only 9 percent had forgone prescription drugs or medications.

In 2020, Part D program expenditures totaled \$105.3 billion, accounting for about 11 percent of Medicare spending. Of that amount, enrollees paid \$13.6 billion in plan premiums for basic benefits. Above and beyond program spending, Part D plan enrollees paid \$17.6 billion in cost sharing plus additional amounts in premiums for enhanced benefits.

In this chapter

- Enrollment, plan choices in 2021, and benefit offerings for 2022
- Plan sponsors and their tools for managing benefits and spending
- Drug pricing
- Program costs
- Beneficiaries' access to prescription drugs
- Quality in Part D

Since its inception in 2006, Part D has changed in important ways. Enrollment has moved gradually toward Medicare Advantage–Prescription Drug plans (MA–PDs) that provide combined medical and drug coverage. In absolute numbers, enrollment in stand-alone prescription drug plans (PDPs) began to decline in 2019; in 2021, Part D enrollees were split evenly between PDPs and MA–PDs. Prescription drug use and spending have also changed dramatically. Part D enrollees have greatly expanded their use of generics, while a relatively small percentage of prescriptions for high-cost biological products (referred to as *biologics* hereafter) and specialty medications accounts for a mounting share of spending. Medicare’s payments to Part D plans have changed as well. Whereas fixed-dollar payments per enrollee used to make up most of Part D’s subsidies, over time, a growing share has taken the form of cost-based reimbursements to plans through Medicare’s reinsurance. The financial risk that plans bear, as well as their incentives to control costs, has declined markedly. In 2020, the Commission recommended major changes to the Part D benefit design and Medicare’s subsidies to restore the role of risk-based, capitated payments that was present at the start of the program and to provide some drag on drug price increases.

Nearly 300 organizations sponsor Part D plans, but most beneficiaries are enrolled in plans sponsored by a handful of large health insurers. Most large sponsors are vertically integrated with their own pharmacy benefit manager (PBM), and many also operate mail-order and specialty pharmacies. Formularies remain plan sponsors’ most important tool for managing drug benefits. Generally, pharmaceutical manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood of winning market share over competing drugs. Plan sponsors also use provisions in network contracts with pharmacies that require postsale recoupments or payments for meeting performance metrics. Plan sponsors and PBMs have negotiated rebates and pharmacy fees that have grown as a share of Part D spending.

Enrollment in 2021 and benefit offerings for 2022—In 2021, about 76 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 2 percent obtained drug coverage through employer-sponsored plans that received Medicare’s retiree drug subsidy. We estimate that the remaining 22 percent of beneficiaries were divided equally between those who had drug coverage from other sources and those with no coverage or coverage less generous than Part D.

Between 2020 and 2021, enrollment in PDPs declined from 25.5 million to 24.0 million, while enrollment in MA-PDs grew from 21.9 million to 24.3 million. As a result, in 2021, just over 50 percent of enrollees were in MA-PDs compared with 30 percent in 2007. The number of enrollees who receive the LIS has grown more slowly than the broader Part D population. In 2021, LIS enrollees made up 27 percent of total enrollment compared with 39 percent in 2007.

For 2022, beneficiaries continue to have a broad choice of plans, with growth in MA-PDs more than offsetting a contraction in the number of PDPs. Compared with 2021, sponsors are offering 7 percent more MA-PDs open to all beneficiaries and 19 percent more MA-PDs tailored to specific populations (special needs plans) but 23 percent fewer PDPs, due primarily to mergers among plan sponsors. In 2022, 2,159 plans (about one-third) are participating in the Center for Medicare and Medicaid Innovation's Part D Senior Savings Model that covers certain insulins at cost sharing of no more than \$35 per one-month supply. Most Part D plans use a five-tier formulary with differential cost sharing between preferred and nonpreferred drugs, as well as a specialty tier for high-cost drugs. For 2022, the base beneficiary premium rose by less than 1 percent over 2021 to \$33.37, reflecting the relatively small increase in the total average estimated cost for basic benefits after taking postsale rebates and discounts into account. However, individual plans' premiums vary substantially. In 2022, 198 premium-free PDPs are available to enrollees who receive the LIS, or roughly one-quarter of all PDPs. Although that total is a 24 percent drop from 2021, all regions have at least four premium-free PDPs for LIS enrollees.

Part D program costs—Between 2007 and 2020, Part D program spending increased from \$46.2 billion to \$91.7 billion (average annual growth of 5.5 percent). Medicare's reinsurance (which covers 80 percent of spending in the catastrophic phase of the benefit after rebates) continues to be both the largest and fastest-growing component of program spending, at an annual average rate of about 15 percent since 2007. As a result, between 2007 and 2020, the portion of the average basic benefits paid to plans through the capitated direct subsidy plummeted from 54.7 percent to 13.5 percent. In 2020, fewer enrollees reached the benefit's catastrophic phase, due in large part to a statutory increase in the out-of-pocket threshold. High-cost enrollees (those whose spending reaches the benefit's catastrophic phase) accounted for 62 percent of Part D spending, up from about 40 percent before 2011. In 2020, average prices continued to grow more slowly than

in prior years, owing to the decline in prices of generic drugs. However, generics' share of prescriptions has plateaued at about 90 percent since 2017, and further opportunities for generic substitution may be limited because a significant portion of brand products are protected from competition through longer periods of market exclusivity, extensive patent protection, or both. Inflation in prices for brand-name drugs and biologics will likely continue to drive spending upward. In 2020, over 443,000 enrollees (11.6 percent of high-cost enrollees) filled a prescription for which a single claim was sufficient to meet the out-of-pocket threshold, up from just 33,000 in 2010.

Beneficiary access and quality in Part D—The quality of prescription drug care requires a balance between beneficiary access and medication management. For many conditions, effective treatment may hinge primarily on access and adherence to prescription drugs. For this reason, Medicare evaluates Part D plan formularies and network pharmacies. Data from CMS audits and Part D appeals processes suggest that beneficiaries are less likely to encounter access issues for most drugs than in previous years. However, among beneficiaries without the LIS, high cost sharing for expensive therapies can be a barrier to access. At the same time, Medicare beneficiaries take an average of nearly five prescription drugs daily and are at higher risk for adverse drug events associated with polypharmacy. Thus, it is also critically important that Part D plans help to manage medication therapies.

CMS collects quality and performance data to monitor plan sponsors' operations and to evaluate access to medicines, enrollee experience, and patient safety. A subset of these data form part of a 5-star rating system to help beneficiaries evaluate their plan options. For 2022, average star ratings for Part D plans increased substantially, but much of that increase reflects changes CMS made in how it calculated the ratings to address the coronavirus pandemic. While average star ratings for MA-PDs continue to exceed those of PDPs, the trend among MA-PD sponsors of consolidating contracts leads us to question the validity of MA-PD ratings.

By law, Part D plans are required to carry out medication therapy management (MTM) programs and programs to manage opioid use. In 2017, CMS began testing an Enhanced MTM model to see if new payment incentives and regulatory flexibilities would spur PDPs to improve their MTM interventions and reduce Medicare spending. Although the entire five-year demonstration is not yet complete, over the first three years, CMS found no significant

reductions in Medicare spending for Part A and Part B services, a net increase in Medicare spending after accounting for model payments, and mixed effects on quality measures. ■

Background

Each year, the Commission provides a status report on Part D that examines several performance indicators: enrollment, plan benefit offerings, market structure, drug pricing, program costs, beneficiaries' access to medications, and quality. In 2021, the Part D program paid for outpatient prescription drug coverage on behalf of more than 49 million Medicare beneficiaries. Private Part D plans are available broadly: Dozens of stand-alone prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug plans (MA–PDs) are offered in every region of the country. Nearly 9 in 10 elderly Part D enrollees report that they are satisfied with the program and with their plan (*Medicare Today* 2021).

For Part D plan enrollees, Medicare subsidizes about three-quarters of the cost of basic benefits, defined as Part D's standard benefit or benefits with the same average value. Separately, Part D includes a low-income subsidy (LIS) that pays for much of the cost sharing and premiums on behalf of nearly 13 million individuals with low income and assets. In 2020, Part D expenditures totaled \$105.3 billion on an incurred basis, accounting for about 11 percent of Medicare spending (Boards of Trustees 2021). Of that amount, Medicare spending for the LIS totaled \$33.1 billion: \$29.3 billion for cost sharing and \$3.8 billion for premiums. Of the \$105.3 billion spending total, Part D enrollees paid \$13.6 billion in plan premiums for basic benefits. Above and beyond program spending, enrollees paid \$17.6 billion in cost sharing plus additional amounts in premiums for enhanced benefits.

In 2020 and 2021, the coronavirus pandemic profoundly affected the health of Medicare beneficiaries and their use of health care services. However, the pandemic's effects on prescription drug use and spending under Part D have been less pronounced than its effects on other health care services (see text box on the effects of the pandemic, p. 473).

Part D's approach

Medicare's payment system for Part D is different from payment systems under Part A and Part B. In Part D, Medicare pays competing private plans to deliver outpatient drug benefits to beneficiaries, whether they

enroll in a PDP or MA–PD. Instead of setting prices administratively, Medicare bases payments on bids submitted by plan sponsors. Plan sponsors establish networks of pharmacies and apply formularies—lists of drugs the plan will cover that use differential cost-sharing tiers—to manage enrollees' use of and spending for prescription drugs. For drug classes that have competing therapies, plan sponsors negotiate with biopharmaceutical manufacturers to place brand-name drugs on the plan's formulary, potentially on a preferred (lower) cost-sharing tier, in return for postsale rebates.

Benefit design

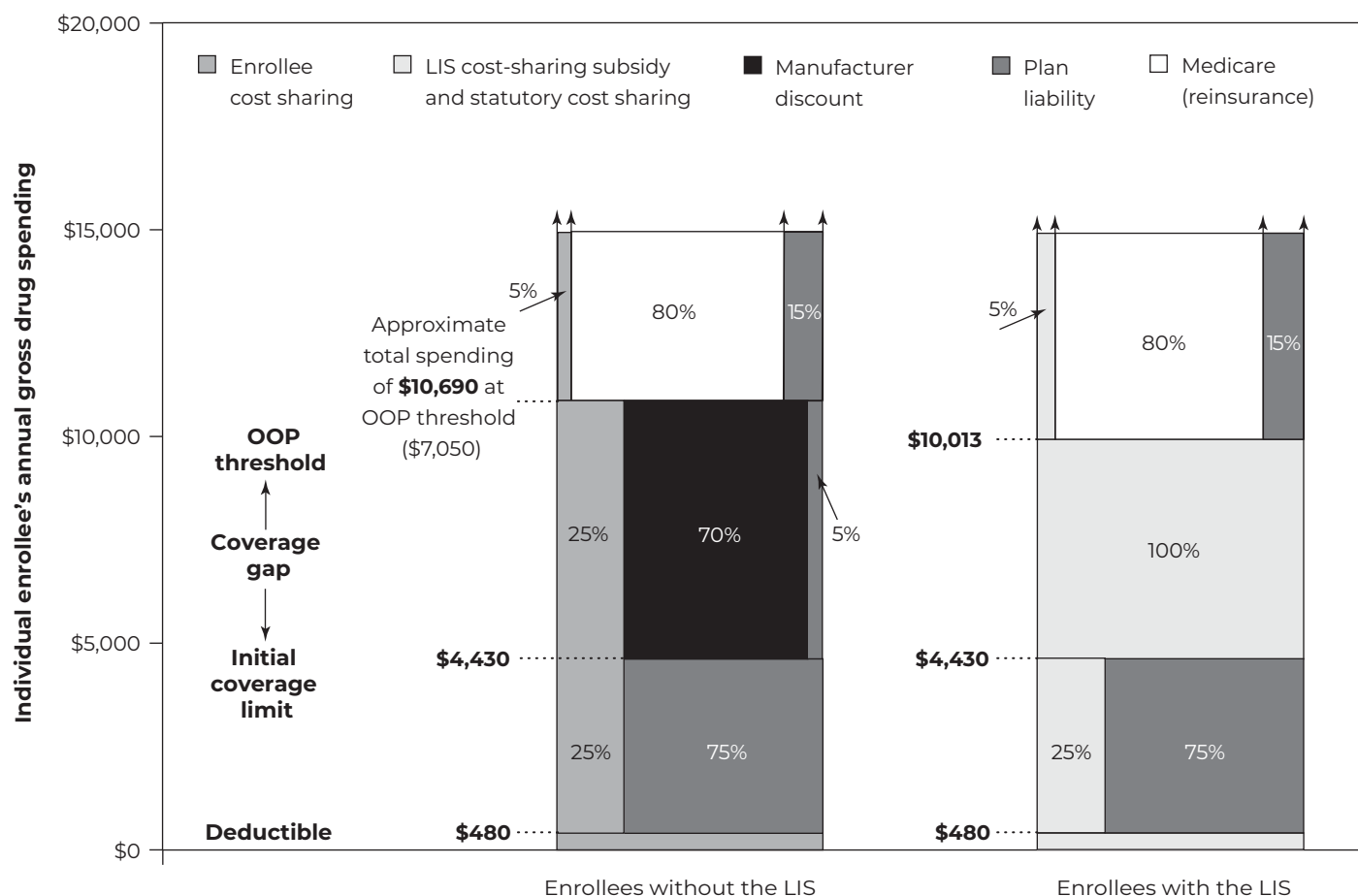
Medicare law defines a standard Part D basic benefit, but in practice, plan sponsors offer alternative benefit designs with equivalent or more generous coverage. Most LIS enrollees pay nominal copayments throughout the benefit; Part D's LIS pays for the remainder of plans' cost-sharing requirements on their behalf. Changes in law have altered the design of the standard benefit for most Part D enrollees (those without the LIS, 73 percent in 2021), but those changes did not apply to those who receive the LIS. As a result, there are two distinct standard Part D benefit designs.

Part D's defined standard benefit For the majority of Part D enrollees (those without the LIS), Part D's defined standard benefit covers 75 percent of drug spending above a deductible and all but 5 percent coinsurance once an enrollee reaches an out-of-pocket (OOP) threshold (Figure 13-1, p. 472). Each year, the standard benefit's parameters change at the same rate as the annual change in beneficiaries' average drug expenses. For 2022, the deductible in Part D's standard benefit is \$480 and enrollees pay 25 percent coinsurance until reaching an OOP threshold of \$7,050. That threshold is based on “true OOP” costs because it excludes beneficiary cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies and more generous (enhanced) benefits from the beneficiary's Part D plan.

In the past, enrollees without the LIS whose spending exceeded an initial coverage limit were responsible for paying each subsequent prescription's full price at the pharmacy (i.e., 100 percent cost sharing) until they reached an OOP threshold. This range of spending is known as the coverage gap or donut hole.¹ Under

**FIGURE
13-1**

Part D has two distinct benefit structures, for enrollees with and without the LIS, 2022



Note: LIS (low-income subsidy), OOP (out-of-pocket). For enrollees without the LIS, the coverage gap is depicted as it would apply to brand-name drugs, which are eligible for a 70 percent manufacturers' discount in the coverage gap. There is no discount for generic prescriptions, and thus cost sharing in the coverage gap is 25 percent and plans are responsible for 75 percent. Because of this difference, total covered drug spending at the OOP threshold depends on the mix of brand and generic prescriptions each individual fills while in the coverage gap. The dollar amount shown (\$10,690) was estimated by CMS for an individual with an average mix of drugs who does not receive Part D's LIS and has no other supplemental coverage. The bar depicting LIS enrollees reflects full rather than partial LIS coverage. LIS enrollees do not receive brand discounts from manufacturers. Beneficiaries who receive full Medicaid and Medicare benefits and have incomes less than or equal to 100 percent of the federal poverty level pay no deductible, copayments of no more than \$1.35 per generic prescription, \$4.00 per prescription for other drugs, and no copayments above the OOP threshold. Other beneficiaries who receive full Medicaid and Medicare benefits pay no deductible, copayments of no more than \$3.95 per generic prescription, \$9.85 per prescription for other drugs, and no copayments above the OOP threshold. Institutionalized enrollees pay no cost sharing. Beneficiaries who receive partial LIS assistance pay a deductible of \$99.00, 15 percent coinsurance up to the OOP threshold, and thereafter copayments of \$3.95 per generic prescription and \$9.85 per prescription for other drugs.

Source: MedPAC depiction of Part D benefit structure for 2022.

recent program changes, enrollees no longer face higher cost sharing in the coverage gap; however, plans continue to identify whether a prescription is filled in that benefit phase because, under changes in law, enrollees without the LIS are eligible for a 70

percent discount from manufacturers on brand-name prescriptions in the coverage gap. No discount is applied to prescriptions for any generic drugs or for brand-name prescriptions filled by LIS enrollees. In 2022, brand discounts begin when an enrollee without

Effects of the coronavirus pandemic on Part D

Although the coronavirus pandemic has had tragic and disproportionate effects on Medicare beneficiaries, enrollees in Medicare Part D experienced relatively less disruption of access to medicines compared with access to other types of health care services. A nationally representative survey of community-dwelling Medicare beneficiaries found that during the winter of 2020 to 2021, among the 7 percent of beneficiaries who reported forgoing care in the past few months, 29 percent of this subset had missed a regular check-up and 32 percent had missed treatment for an ongoing condition due to the pandemic, but only 9 percent had forgone prescription drugs or medications (Centers for Medicare & Medicaid Services 2021g).

In March 2020, as state and local governments placed restrictions on the operation of many businesses, most grocery stores and retail pharmacies were permitted to stay open, which helped to maintain access to medicines. With CMS's encouragement, Part D plan sponsors expanded access to 90-day supplies of prescriptions, which enrollees filled through both mail and retail pharmacies. Due to restrictions on in-person office visits and hospital stays, the pandemic had a larger effect on initiation of new drug therapies than on prescription refills for chronic conditions. Nevertheless, across all payers, the number of U.S. prescriptions dispensed in 2020 (adjusted to standardize their days' supply) rose by 1.9 percent and sales grew by 4.3 percent (Long 2021). Among Medicare Part D enrollees, in 2020, the average number of prescriptions dispensed per member

per month (adjusted for days' supply) rose by 0.5 percent, slightly lower than growth rates in 2018 and 2019. In 2020, per member Part D spending (before rebates and discounts) increased by 4.8 percent—about the same as growth observed in the previous two years.

The coronavirus pandemic affected Part D plans differently from its effects on Medicare fee-for-service providers. Much of plans' revenues do not depend on how frequently enrollees seek health care services because Medicare pays Part D plans monthly capitated amounts. Those payments are based on plan sponsors' bids for the cost of providing prescription drugs rather than updates to administered prices. Plans submitted their bids for 2020 benefits in June 2019, well before the pandemic began. Ultimately, plans' 2020 bids ended up being significantly lower than actual costs, and because of Part D's symmetric risk corridors around plan bids, Medicare shared in plans' losses and made \$1.5 billion in risk-corridor payments to plans (Liu 2021).

For the 2021 and 2022 benefit years, sponsors submitted Part D bids to CMS amid the public health emergency. It is unclear what specific assumptions about use and spending plans incorporated into their bids. However, nationwide, the average bid for basic benefits in each of those years was 1 percent higher than that for the previous year. Because Part D's risk corridors are symmetric, they provide protection for plans that underbid relative to actual costs and allow the program to recoup a portion of profits if actual drug spending is lower than expected. ■

the LIS has reached \$4,430 in cumulative drug spending and continue until the individual reaches \$7,050 in combined OOP spending plus brand discounts. Above this OOP threshold, enrollees pay the greater of 5 percent coinsurance or \$3.95 to \$9.85 per prescription.

Benefit for LIS enrollees For low-income beneficiaries, Medicare's LIS pays for the difference between cost-sharing amounts set by each plan and nominal copayments set by law (Figure 13-1). In 2022, most individuals receiving the full LIS pay between \$0 and

\$3.95 per prescription for generics and between \$0 and \$9.85 per prescription for brand-name drugs. A small share of LIS enrollees (about 3 percent) with slightly higher levels of income or assets receives a partial subsidy.² If, for example, a plan normally charges a \$40 copayment to fill a brand prescription, a full LIS enrollee would pay up to \$9.85 and Medicare's LIS would pay \$30.15. Because 100 percent of the costs in the coverage gap count toward the OOP threshold, LIS beneficiaries reach the catastrophic phase at a lower level of spending than other enrollees do. Above the OOP threshold, LIS enrollees pay no cost sharing.

Plan sponsors typically use alternative benefit designs

In practice, the defined standard benefit is used primarily to set the average value of basic benefits that plan sponsors must offer under alternative benefit designs. Most sponsors structure basic benefits in ways that differ from the defined standard benefit, such as setting the deductible lower than \$480 or using tiered copayments rather than coinsurance. Some plans encourage use of lower-cost medicines by not applying a deductible when a prescription is filled with certain preferred generics. However, alternative designs must demonstrate that they have the same average value as the defined standard benefit for an enrollee of average health. CMS also sets maximum cost-sharing amounts for drug tiers to ensure that a sponsor's plan design is not discriminatory.³ Once a sponsor offers a PDP with basic benefits in a region, it can also offer up to two "enhanced" PDPs that combine basic with supplemental coverage. For 2022, estimated OOP costs in a sponsor's basic and enhanced plans must differ by at least \$22 per month.

Two avenues for premium competition

The hallmark of Part D is that private plans compete for enrollees based on premiums, formularies, pharmacy networks, and quality of services. There are two pathways through which premium competition takes place: rivalry to attract members and competition to keep premiums at or below benchmarks that reflect the maximum amount Medicare will contribute toward LIS enrollee premiums.

General premium competition Part D plan sponsors compete to attract enrollees through low premiums, but sponsors do not set their premiums directly. Instead, sponsors submit bids to CMS that represent

their revenue requirements (including administrative costs and profit) for delivering basic benefits to an enrollee of average health. CMS then calculates a nationwide enrollment-weighted average bid from all the bid submissions. From this average, enrollees pay a portion as a base beneficiary premium (\$33.37 per month in 2022) plus (or minus) any difference between their plan's bid and the nationwide average bid (Medicare Payment Advisory Commission 2021b). If enrollees pick an enhanced plan, the enrollee must pay the full price for the supplemental coverage (i.e., Medicare does not subsidize it). This approach is designed to give sponsors the incentive to control enrollees' spending so that they can bid low and keep premiums attractive. At the same time, sponsors must balance this incentive with beneficiaries' desire to have access to medications. A plan with a very limited number of covered drugs might not attract enrollees.

Competition to keep premiums below LIS benchmarks

Sponsors also compete to keep the premiums for some plans at or below regional LIS benchmarks. When policymakers developed the premium subsidy for LIS enrollees, they wanted to encourage enrollment in less expensive plans while ensuring that low-income beneficiaries had access to coverage. Policymakers balanced these goals by creating a subsidy with two key features: (1) a benchmark that limits how much Medicare contributes toward a beneficiary's premium and (2) automatic enrollment of LIS enrollees in PDPs with premiums at or below the benchmark. CMS calculates separate LIS benchmarks for each of Part D's 34 regions and updates them annually. Each LIS benchmark equals a region's average premium for basic coverage; plans that offer basic coverage and have premiums at or below the benchmark are premium free to LIS enrollees.^{4,5}

This approach to setting Part D's LIS premium subsidy was intended to provide incentives for plan sponsors to control drug spending and bid low. LIS enrollees who have not selected a plan themselves are automatically enrolled in a benchmark PDP to which CMS assigns them randomly. Once LIS enrollees select a plan themselves, CMS no longer reassigns them to a new plan. Instead, the agency sends them letters about premium-free plan options. Many plans offered by larger sponsors have kept their benchmark status from year to year or have opted to forgo a

de minimis amount of their premium in order to retain LIS enrollees.⁶ Nevertheless, each year there is some turnover in benchmark plans. If LIS enrollees are in a PDP with a premium that will exceed the benchmark and have not chosen a plan other than their assigned PDP, CMS reassigns them randomly to a new benchmark PDP.⁷ If sponsors bid at or near the benchmark, they can gain or maintain market share for LIS enrollees without having to incur marketing expenses. Some aspects of how CMS calculates benchmarks and auto-enrolls beneficiaries temper premium competition (Medicare Payment Advisory Commission 2021c).

For plan sponsors, auto-enrollees make up an important component of the PDP market. In contrast, MA-PDs cannot receive auto-enrollees. In 2019, 62 percent of the 7.3 million LIS beneficiaries in PDPs had been placed in their plans through the auto-enrollment and reassignment processes. As of December 2021, CMS expected to reassign randomly about 248,000 LIS beneficiaries for benefit year 2022 (Liu 2021).⁸ However, CMS also auto-enrolls LIS beneficiaries who are new to Part D among plans with premiums below regional benchmarks. Between 2015 and 2019, an average of 875,000 beneficiaries were randomly assigned to a benchmark PDP annually; roughly 85 percent were new Part D enrollees who had not yet selected a plan. As LIS enrollees remain in Part D, an increasing share choose a PDP themselves or enroll in an MA-PD and become ineligible for CMS reassignment.

Concerns about Part D and recommended changes

Over time, changes to Part D's benefit design combined with trends in prescription drug pricing and spending have led to concerns about whether plan sponsors have incentives for cost control that are as strong as they were at the start of the program. In 2020, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit and restore stronger incentives.

Brand discounts in the coverage gap distort relative prices

Changes in law phased out the coverage gap for enrollees who do not receive the LIS. Much of this benefit expansion was financed by requiring manufacturers of brand-name drugs or biological

products including biosimilars (referred to as *biologics* hereafter) to discount prices in the coverage gap. While those steps lowered OOP costs for some beneficiaries, the manufacturer discount artificially lowers prices for brand-name drugs relative to generics, reducing incentives to use generics. Those incentives are further undermined because the 70 percent discount is treated as though it were the enrollee's own OOP spending. As a result, enrollees without the LIS reach Part D's catastrophic phase more quickly when they use brand-name drugs than when they use generics. Brand and biologic manufacturers benefit when enrollees reach the catastrophic phase because they no longer need to provide the 70 percent discount.

Reduced plan liability undermines plans' formulary incentives

Plan sponsors bear little liability for spending in the coverage gap and catastrophic phases under either of Part D's two distinct benefit structures. In the coverage gap, sponsors are responsible for just 5 percent of brand spending for enrollees without the LIS and bear no liability for LIS enrollees. Sponsors cover 15 percent of spending in the catastrophic phase. Meanwhile, sponsors receive postsale rebates and discounts that, according to CMS's Office of the Actuary, are projected to average about 31 percent of total drug costs in 2022 (Boards of Trustees 2021). For some brand prescriptions filled in the coverage gap and catastrophic phases, the value of rebates and discounts can exceed plan liability. As a result, plan sponsors may reduce their plan liability by including certain brand-name drugs on their formulary and giving those drugs preferred status. However, those formulary placement decisions can also increase costs for enrollees and Medicare (Dusetzina et al. 2021b, Dusetzina et al. 2019).

Marked decline in plan risk over time

The share of benefit spending for which plan sponsors are at risk has declined markedly over time. We estimate that between 2007 and 2020, the share of payments for which plan sponsors were at risk (made up of capitated direct subsidy payments and enrollee premiums) declined from 75 percent to 37 percent (see Figure 13-5, p. 495), while cost-based reimbursement through reinsurance rose from 25 percent to 63 percent. This decrease in plans' liability undermines

incentives for plan sponsors to manage benefits and negotiate lower drug prices.

Expanded role of high-priced drugs has driven growth in reinsurance

At the start of Part D in 2006, most spending was attributable to brand prescriptions for widely prevalent conditions such as high cholesterol and depression. Blockbuster drugs for such conditions lost patent protection toward the end of that decade and many Part D enrollees switched to generic versions of their medicines. As those brand revenues fell, manufacturers turned to developing orphan drugs, biologics, and other high-priced specialty drugs for smaller patient populations. These trends have changed the distribution of Part D spending. Between 2007 and 2020, the share of gross Part D spending attributable to specialty-tier drugs grew from less than 6 percent to nearly 28 percent.⁹ At the same time, increased generic use kept growth in average Part D drug prices to about 3 percent per year while prices of brand-name drugs and biologics grew by 14 percent annually. (Based on analysis by Commission staff, even after accounting for manufacturer rebates, the average prices of brand-name drugs and biologics grew by an annual 13 percent during this period.) As a result, an increasing share of Part D spending is in the benefit's catastrophic phase, in which Medicare pays 80 percent of costs through reinsurance. Between 2010 and 2020, the share of Part D spending attributable to the catastrophic phase jumped from 20 percent to 42 percent. Higher prices, reflecting both price increases for existing products and the use of new expensive drugs, have been the primary driver of the growth in catastrophic spending.

Some enrollees have high OOP spending

In Part D, CMS permits plan sponsors to use up to two specialty tiers with coinsurance of 25 percent to 33 percent for expensive therapies. Enrollees without the LIS who fill prescriptions for specialty-tier drugs often must pay thousands of dollars at the start of each benefit year before reaching the OOP threshold. Above that threshold, enrollees without the LIS pay 5 percent coinsurance with no OOP maximum. Because some specialty-tier drugs have extremely high prices, in 2020, about 443,000 beneficiaries reached that threshold with a single prescription fill. At the same time, the gap between brand prices charged at the pharmacy and prices net of manufacturers' rebates has widened. Brand-name drugs that do not have direct

competitors in their therapeutic class or that are required to be on formulary, including many specialty drugs, tend to have lower rebates (Hwang et al. 2021). However, when patients use rebated drugs, they pay coinsurance that is effectively higher (as a percentage of a drug's price net of all price concessions) than the stated coinsurance rate. The higher effective coinsurance results from manufacturers providing rebates to plans after patients fill their prescriptions; plans charge enrollees coinsurance based on the higher "gross" price they pay at the pharmacy. High patient cost sharing can pose a financial hurdle to treatment, potentially affecting certain beneficiaries' decisions to fill their prescriptions. Yet because prices for certain drugs are so high, even coinsurance applied to net-of-rebate prices would remain unaffordable to many beneficiaries.

Weak incentives for LIS enrollees to select lower-cost medicines

Although the LIS helps to ensure access to medicines for low-income beneficiaries, its limits on cost sharing also give LIS enrollees weaker incentives to use lower-cost drugs and make it more difficult for plan sponsors to manage drug spending. For enrollees without the LIS, plan sponsors set tiered cost sharing to provide strong incentives to select lower-cost drugs: for example, a \$5 copayment for generics compared with \$40 to fill a prescription for a preferred brand-name drug (or higher amounts for nonpreferred drugs). In this example, for an enrollee without the LIS, the savings associated with choosing a generic would be \$35 (\$40 minus \$5). By comparison, because an LIS enrollee pays a maximum of \$3.95 for a generic prescription and up to \$9.85 for any brand-name drug, their OOP savings from taking a generic over a brand would be just \$5.90 (\$9.85 minus \$3.95). Similarly, LIS enrollees have no incentive to use a plan's preferred brand-name drug rather than nonpreferred ones (or nonformulary ones obtained through an exceptions process) because they would pay the same \$9.85 copayment regardless.

The Commission's recommendations for improving Part D

In its June 2020 report to the Congress, the Commission recommended major changes to the Part D program that would restructure its defined standard benefit as follows:¹⁰

- For spending below the catastrophic threshold, eliminate the manufacturers' coverage-gap discount that currently applies to enrollees without the LIS and remove the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible for 75 percent of spending for benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing.
- For catastrophic spending, reduce Medicare's reinsurance by shifting insurance risk to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become responsible for at least 30 percent of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent. The policy would also provide enrollees with greater financial protection by adding an annual cap on beneficiaries' OOP costs.

The Commission recommended phasing in the reduction in Medicare's reinsurance payments and increased plan liability for catastrophic spending. Sponsors would incorporate lower expected Medicare reinsurance subsidies and higher expected benefit liability into plan bids. In turn, Medicare's capitated payments to plans would increase to incorporate their new, higher share of spending below and above the catastrophic threshold.

To help plan sponsors manage overall drug spending more effectively, the Commission recommended that the Congress establish a higher copayment amount under the LIS for nonpreferred and nonformulary drugs. In addition, plan sponsors would be provided with greater formulary flexibility for drugs in the protected classes. The Commission also recommended that plans be allowed to establish preferred and nonpreferred tiers for specialty-tier drugs to encourage their enrollees to use lower-priced therapies. CMS began permitting sponsors to use two specialty tiers in 2022.

The Commission's recommended reforms would result in higher capitated payments for all enrollees, with a larger impact, in dollar terms, for LIS beneficiaries. However, given the structure of the risk-adjustment

model, CMS would need to recalibrate its model to ensure that, on average, capitation rates were adequate for both LIS enrollees and other Part D beneficiaries.

Given plans' greater insurance risk associated with catastrophic spending under these reforms, policymakers could consider modifying the Part D risk corridors to temporarily provide plan sponsors with greater protection during a transition to the new benefit structure. While the enhanced protection would be available to all plans, in practice, the protection would be particularly valuable for smaller plans and plan sponsors that do not have the scale to spread the insurance risk or the capital to reinsure themselves.

Enrollment, plan choices in 2021, and benefit offerings for 2022

A growing proportion of Medicare beneficiaries has enrolled in MA-PDs while the share in stand-alone PDPs has declined. Over the program's first decade, a portion of enrollment shifted from retiree drug plans outside of Medicare to Part D plans set up for employer groups.

In 2021, over three-quarters of Medicare beneficiaries were in Part D plans or employer plans that received the retiree drug subsidy

In 2021, 48.3 million individuals—about 76 percent of Medicare's total enrollment—were enrolled in Part D plans (Table 13-1, p. 478). That share is up from 54 percent in 2007 but has plateaued in recent years. Another 2 percent of beneficiaries obtained drug coverage through non-Medicare employer-sponsored plans that received Medicare's retiree drug subsidy (RDS) for serving as the primary provider. (The RDS is paid from the Part D program.) Based on Medicare data from 2018, we estimate that the remaining 22 percent of Medicare beneficiaries were divided roughly equally between those who had creditable drug coverage from other sources and those with no coverage or coverage less generous than Part D (data not shown).

The distribution of Part D enrollment has moved gradually toward MA-PDs (including special needs plans (SNPs)). The number of enrollees in PDPs began

**TABLE
13-1****Part D enrollment trends by plan type, 2007–2021**

| | 2007 | 2013 | 2020 | 2021 | Average annual growth rate 2007–2021 |
|--|-------------|-------------|-------------|--------------|--------------------------------------|
| Total Medicare enrollment (in millions) | 44.4 | 52.5 | 62.6 | 63.7 | 3% |
| Part D enrollment (in millions) | | | | | |
| Part D plans | 24.2 | 35.4 | 47.0 | 48.3 | 5 |
| Non-Medicare employer plans under the RDS* | <u>7.1</u> | <u>3.3</u> | <u>1.2</u> | <u>1.1</u> | –12 |
| Total Part D | 31.3 | 38.7 | 48.2 | 49.4 | 3 |
| <i>Part D plans' share of total Medicare enrollment</i> | <i>54%</i> | <i>67%</i> | <i>75%</i> | <i>76%</i> | <i>N/A</i> |
| <i>Total Part D share of total Medicare enrollment</i> | <i>70%</i> | <i>74%</i> | <i>77%</i> | <i>78%**</i> | <i>N/A</i> |
| Part D plan enrollment by plan type (in millions) | | | | | |
| PDP | 16.9 | 22.5 | 25.1 | 24.0 | 3 |
| MA–PD | 7.2 | 12.9 | 21.9 | 24.3 | 9 |
| <i>Share of plan enrollees in MA–PD</i> | <i>30%</i> | <i>36%</i> | <i>47%</i> | <i>50%</i> | <i>N/A</i> |
| EGWP (PDP and MA–PD, in millions) | 1.8 | 6.0 | 7.2 | 7.4 | 11 |
| <i>Share of plan enrollees in EGWP</i> | <i>7%</i> | <i>17%</i> | <i>15%</i> | <i>15%</i> | <i>N/A</i> |
| Full LIS enrollment (in millions) | | | | | |
| PDP | 8.0 | 8.3 | 6.7 | 6.0 | –2 |
| MA–PD | <u>1.3</u> | <u>2.8</u> | <u>6.1</u> | <u>6.8</u> | 12 |
| Subtotal | 9.4 | 11.2 | 12.8 | 12.8 | 2 |
| <i>Share of LIS enrollees in MA–PDs</i> | <i>14%</i> | <i>25%</i> | <i>48%</i> | <i>53%</i> | <i>N/A</i> |
| <i>LIS enrollees as a share of all Part D plan enrollees</i> | <i>39%</i> | <i>32%</i> | <i>27%</i> | <i>27%</i> | <i>N/A</i> |

Note: RDS (retiree drug subsidy), N/A (not applicable), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), EGWP (employer group waiver plan), LIS (low-income subsidy). Figures based on enrollment as of April 1 of each year with the exception of 2007 (as of July 1, 2007). In addition to beneficiaries who receive full LIS assistance, a small number receive partial assistance (0.2 million in 2021). See endnote 2. Totals may not sum due to rounding.

*Excludes federal government and military retirees covered by either the Federal Employees Health Benefit Program or the TRICARE for Life program.

**Based on distributional information from CMS's 2018 Part D denominator file, we estimate that the remaining 22.4 percent of beneficiaries not enrolled in Part D are divided roughly equally between those who receive comparable drug coverage through other sources (such as the Federal Employees Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs) and those who had no drug coverage or had coverage less generous than Part D.

Source: MedPAC based on Table IV.B7 and Table V.B3 of the 2021 annual report of the Boards of Trustees of the Medicare trust funds and CMS Part D enrollment data as of April 1, 2021.

to decline in 2019, and by 2021, Part D enrollees were split evenly between PDPs and MA–PDs. This move toward MA–PDs is consistent generally with more rapid growth in MA enrollment compared with traditional fee-for-service (FFS) Medicare. Between 2007 and

2021, enrollment in MA–PDs grew an average 9 percent annually compared with 3 percent in PDPs.

Membership in employer group waiver plans (EGWPs)—Part D plans established for Medicare-eligible retirees of certain employers—grew quickly over the program's

first decade but has slowed subsequently.¹¹ EGWPs can take the form of PDPs or MA-PDs. Between 2007 and 2021, enrollment in EGWPs grew by an annual average of 11 percent, reflecting the shift from employers operating plans that receive the RDS to Part D plans established for their retirees.

In 2021, 12.8 million beneficiaries (27 percent of Part D enrollees) received the full LIS. Of these individuals, 8.1 million were eligible for both Medicare and full Medicaid benefits (data not shown) (Boards of Trustees 2021). The remainder qualified either because they received benefits through the Medicare Savings Programs or Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. Compared with other Part D enrollees, LIS enrollees are more likely to be female; more than twice as likely to be Black, Hispanic, or Asian or Pacific Islander; and over seven times more likely to be under age 65 (Medicare Payment Advisory Commission 2021a).

Between 2007 and 2021, LIS enrollment grew at a comparatively slow average of 2 percent per year, and the share of Part D enrollees who received the LIS fell from 39 percent to 27 percent (Table 13-1). For the first time, in 2021, a majority of LIS enrollees (53 percent) were in MA-PDs; the rest were in PDPs. In past years, most individuals receiving the LIS were enrolled in traditional FFS Medicare rather than MA. However, LIS enrollment in MA-PDs has grown rapidly—especially in SNPs—while LIS enrollment in PDPs has declined (Boards of Trustees 2021).

Beneficiaries' enrollment decisions in 2021

Most enrollees are in plans that are actuarially equivalent to Part D's defined standard benefit or are enhanced in some way, rather than in plans that follow the defined standard benefit.

MA-PD enrollees were more likely to be in enhanced plans than PDP enrollees

Enrollees in MA-PDs tend to have more generous benefits than enrollees in PDPs. The key reason is that MA-PD plan sponsors are permitted to use a portion of their Medicare Advantage (MA) (Part C) payments to supplement their Part D benefits (e.g., by lowering deductibles) or lower Part D premiums.¹²

In 2021, about half of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments, while the other half had enhanced benefits (Table 13-2, p. 480). No PDPs used the defined standard benefit. Enrollees in MA-PDs, excluding SNPs, were overwhelmingly in enhanced plans. Typically, enhanced plans reduce or eliminate the deductible used in the defined standard benefit. In MA-PDs, 54 percent of enrollees had no deductible in their plan's benefit design. By comparison, only 14 percent of PDP enrollees and 6 percent of SNP enrollees were in plans with no deductible.

Although many PDP and SNP enrollees were in plans with less generous benefit structures, other plan features and the LIS reduced cost sharing for some enrollees. For example, 61 percent of PDP enrollees and 36 percent of SNP enrollees were in plans that do not apply a deductible to prescriptions filled from certain cost-sharing tiers, such as preferred generic drugs (data not shown). Additionally, most SNP enrollees are dual-eligible beneficiaries who automatically receive the LIS, which covers most of their cost sharing. Plans that enroll larger shares of LIS enrollees are more likely to use the standard benefit's deductible because the LIS largely covers those costs, and SNPs are more likely to use the defined standard benefit because LIS enrollees have nominal copayments, which limits the effectiveness of a formulary with tiered cost sharing.

Average enrollee premiums fell in 2021

Despite significant growth in spending on catastrophic benefits, premiums for basic Part D benefits have remained low, staying within a few dollars of \$30 per month since 2010. Many factors explain this stability, including growth in manufacturer rebates and postsale pharmacy fees, a higher coverage-gap discount for brand-name drugs, and the entry into Part D of relatively large cohorts of younger enrollees who typically have lower prescription drug costs. Additionally, growth in Part C payments used to offset Part D premiums and supplemental drug benefits offsets what enrollees would otherwise pay themselves through premiums. Finally, in most years, actual reinsurance costs have exceeded the amount plan sponsors estimated in their bids.¹³ Because enrollee premiums are based on plans' expected amounts, that discrepancy lowers enrollee premiums. As a result,

**TABLE
13-2**

MA-PD enrollees were much more likely to be in enhanced plans, 2021

| | PDP | | General MA-PD | | SNP | |
|-------------------------|-----------------------------------|---------|-----------------------------------|---------|-----------------------------------|---------|
| | Number of enrollees (in millions) | Percent | Number of enrollees (in millions) | Percent | Number of enrollees (in millions) | Percent |
| Total | 19.7 | 100% | 16.9 | 100% | 3.5 | 100% |
| Type of benefit | | | | | | |
| Defined standard | 0.0 | 0 | 0.1 | 1 | 1.9 | 53 |
| Actuarially equivalent* | 9.8 | 50 | 0.1 | 1 | 0.4 | 11 |
| Enhanced | 10.0 | 50 | 16.6 | 99 | 1.3 | 37 |
| Type of deductible | | | | | | |
| Zero | 2.7 | 14 | 9.1 | 54 | 0.2 | 6 |
| Reduced | 4.5 | 23 | 7.2 | 43 | 0.4 | 10 |
| Defined standard** | 12.5 | 63 | 0.5 | 3 | 3.0 | 84 |

Note: MA-PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). “General MA-PD” enrollment excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B–only plans. In 2021, 87 percent of SNP enrollees were in plans for dual-eligible (Medicare and Medicaid) beneficiaries, 11 percent in plans for beneficiaries with certain chronic conditions, and 2 percent in plans for institutionalized individuals. Totals may not sum due to rounding.

*Includes “actuarially equivalent standard” and “basic alternative” benefits.

**Deductible of \$445 in 2021.

Source: MedPAC analysis of CMS landscape, plan report, and enrollment data.

the growth in Medicare’s reinsurance subsidy has also contributed to the slower growth in enrollee premiums.

In 2021, monthly beneficiary premiums averaged about \$26 across all types of plans (basic and enhanced, stand-alone PDP and MA-PD), a 3 percent decline from the prior year. The premiums for individual plans vary widely around that average, from \$0 for many MA-PDs to \$205 for the most expensive enhanced PDP. The \$26 average reflects plan sponsors’ extensive use of Part C rebate dollars to offset premium costs that MA-PD enrollees would otherwise pay themselves. In 2021, MA-PD enrollees paid an average of just \$15 per month but received an additional \$40 of basic and supplemental drug benefits through Part C rebates (Medicare Payment Advisory Commission 2021a). PDP enrollees paid an average of \$38 per month.

The average premiums described above omit two other factors that can affect the premium amounts enrollees

pay. First, higher-income individuals have a lower federal subsidy of their Part D benefits.¹⁴ In 2021, about 8 percent of enrollees were subject to the income-related premium, compared with less than 3 percent in 2011 (Liu 2021). Second, individuals enrolling outside their initial enrollment period must have proof that they had drug coverage as generous as the standard benefit to avoid the late enrollment penalty (LEP) that would be added to their premiums for the duration of their Part D enrollment.¹⁵ In 2021, nearly 5 percent paid the LEP, up from about 1 percent in 2007 (Liu 2021).

Large cost-sharing differences between preferred generics and other drugs

PDPs with the largest enrollment tend to use formularies with five tiers: preferred generic, other generic, preferred brand, nonpreferred drug, and a specialty tier for high-cost drugs. The cost-sharing

amounts for those tiers differ. For 2021, PDPs that were available nationwide generally kept generic copayments very low: Median copayments were zero for preferred generics and \$5 for prescriptions filled from other-generics tiers (Cubanski and Damico 2020). Although cost sharing varied significantly by plan, in 2021, the top 10 PDPs with the largest enrollment generally used copayments on the order of \$40 for preferred brand-name drugs and a median coinsurance rate of 40 percent for nonpreferred drugs. Those plans tended to charge 25 percent coinsurance for specialty-tier drugs.

Benefit offerings for 2022

For 2022, beneficiaries continue to have a wide choice of plans, with growth in MA-PD offerings more than offsetting a reduction in the number of PDPs. For 2022, plan sponsors offered 3,365 general MA-PDs and 1,130 SNPs—7 percent and 19 percent more plans, respectively, than in 2021. That rapid growth reflects interest among plan sponsors in gaining a share of MA's expanding enrollment. By contrast, in 2022, plan sponsors are offering 766 PDPs, 23 percent fewer than the previous year, due primarily to mergers among plan sponsors.¹⁶

In each of the nation's 34 PDP regions, beneficiaries continue to have broad choice. Options range from 19 PDPs in New York to 27 PDPs in Arizona, along with dozens of MA-PDs in most areas. The number of MA plans available to a beneficiary varies by the county of residence, with the average beneficiary having 36 MA plans available.¹⁷

As in previous years, MA-PDs are much more likely than PDPs to offer more generous coverage in the form of enhanced benefits due largely to the ability of MA-PDs to apply Part C rebates to drug benefits. Among MA-PDs, SNPs continue to be an exception to this overall trend: They are much more likely to use the defined standard benefit or the same deductible amount as the standard benefit. However, most SNP enrollees receive cost-sharing assistance through the LIS.

For 2022, CMS calculated that Part D's base beneficiary premium—enrollees' share of the monthly national average expected cost for basic benefits—is \$33.37, less than a 1 percent increase (31 cents) from 2021. However, premiums for individual Part D plans can vary substantially from the base beneficiary premium

because they reflect any difference between the sponsor's bid and the national average bid, as well as any enhanced (supplemental) benefits the plan offers. In addition, in 2022, MA-PD sponsors are applying an average of \$47 per month of Part C rebate dollars to lower their Part D premiums compared with \$40 per month the prior year (an 18 percent increase).

Sixteen stand-alone products are marketed nationally under the same plan name in all or most of Part D's 34 PDP regions that offer a variety of benefit structures to appeal to different segments of the market. Combined, these plans account for nearly 90 percent of PDP enrollment. If enrollees remained in those plans, most (but not all) saw an increase in their 2022 premiums averaging \$5 to \$6 per month, or nearly 14 percent (Cubanski and Damico 2021).

In 2022, the benchmarks that reflect the maximum amount Medicare will pay for premiums on behalf of LIS beneficiaries range from \$25 in Texas to nearly \$43 in the Idaho-Utah region. Compared with 2021 levels, the number of zero-premium PDPs available to LIS enrollees in 2022 dropped by 24 percent to 198 plans—consistent with the overall decline in numbers of PDPs offered. That total equals about one-quarter of all PDPs. All regions have at least four zero-premium PDPs available, while Arizona has a high of nine such PDPs.

Plan sponsors and their tools for managing benefits and spending

Nearly 300 organizations sponsor Part D plans, but most beneficiaries are enrolled in plans sponsored by a handful of large health insurers. In addition to their role as insurers, plan sponsors carry out marketing, enrollment, customer support, claims processing, coverage determinations, and exceptions and appeals processes. Other key functions are performed by plans' pharmacy benefit managers (PBMs): developing formularies, establishing pharmacy networks, and negotiating with manufacturers and pharmacies for postsale rebates and discounts. Most large plan sponsors are vertically integrated with their own PBMs and many also operate mail-order and specialty pharmacies. Smaller plan sponsors typically contract for PBM services. By law, the Medicare program is

prohibited from becoming involved in negotiations among sponsors, drug manufacturers, and pharmacies.

For the delivery of outpatient drug benefits, PBMs do not take physical possession of prescription medicines; pharmacies do. Pharmacies typically buy drugs from wholesalers and specialty drug distributors, dispense prescriptions to plan members, and are paid by PBMs for the difference between a negotiated amount and the member's cost sharing. In Part D, plan sponsors use additional contract provisions that require postsale recoupments from or payments to a pharmacy or group of pharmacies based on various performance metrics.

Final prices that plan sponsors pay for prescription drugs are usually lower than manufacturers' list prices, and the size of the discount sponsors obtain varies depending on negotiations for postsale rebates. Sponsors and their PBMs gain bargaining leverage with manufacturers through the relative size of their market shares of enrollees and by influencing market shares of drug products through their formularies. In drug classes that have competing therapies, PBMs negotiate with brand manufacturers for rebates that the manufacturers pay after each prescription has been filled. In this way, final prices that manufacturers obtain for their drugs are individualized by payer. The Congressional Budget Office estimates that in 2017, rebates and discounts in Part D averaged 12 percent for brand-name specialty drugs and 47 percent for brand-name nonspecialty drugs, which often have larger numbers of competing therapies (Congressional Budget Office 2021). PBMs (and manufacturers) consider rebates highly confidential because broader knowledge about the magnitude of discount could affect what competitors demand in their own negotiations with manufacturers, compressing (and for some payers reducing) rebates.

Formulary management and manufacturer rebates

Formularies remain plan sponsors' most important tool for managing drug benefits. Sponsors and their PBMs decide which drugs to include and exclude, which cost-sharing tier is appropriate for each drug, and whether a drug will be subject to utilization management—quantity limits, step therapy, and prior authorization. Those decisions require that plan sponsors strike a

balance between providing access to medications and encouraging enrollees to use preferred therapies.

CMS requires plan sponsors to cover the types of drugs commonly needed by Part D enrollees as recognized in national treatment guidelines, and the agency reviews each plan's formulary as part of the process of deciding whether to approve its bid. For most drug classes, plans must cover at least two distinct drugs that are not therapeutically equivalent or bioequivalent, as well as “all or substantially all drugs” in six protected classes—anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Generally, manufacturers pay larger rebates when a sponsor positions a drug on its formulary in a way that increases the likelihood of winning market share over competing drugs. For example, a manufacturer might pay a base rebate for including the product on a plan's formulary but might pay larger rebates if the drug is on a preferred tier or if prior authorization requirements are waived. Producers of brand-name drugs with no therapeutic substitutes or drugs that are required to be on formulary might provide no rebates or small rebates. An analysis of 2016 data provided by a group of Part D plan sponsors found that only about a third of brand-name drugs had more than nominal manufacturer rebates (Johnson et al. 2018). Rebates were largest in drug classes in which brand-name drugs competed directly with one another or when the brand drug faced competition from three or more generics. A separate analysis of 2019 Part D spending on 78 brand-name cancer drugs (a protected class) found that 40 percent likely had no rebates (Hwang et al. 2021). Payers and PBMs also negotiate “price-protection” provisions under which manufacturers rebate a drug's midyear price increases above a specified threshold.

Medicare policy can affect rebates. The Part D requirement to cover all protected-class drugs likely reduces plan sponsors' bargaining leverage with manufacturers; rebates are less easily obtained and smaller, on average, for brand-name drugs in protected classes. In the study described above, of 124 brand-name drugs in protected classes, only 16 received rebates, and among those drugs, rebates averaged 14 percent of point-of-sale prices compared with 30 percent for all brand-name drugs (Johnson et al. 2018).

Pharmacy networks and postsale fees

In commercial plans, sponsors often try to encourage enrollees to use pharmacies that dispense prescriptions at lower cost. For example, enrollees in some (non-Medicare) employer plans are required to fill prescriptions within an exclusive network of retail pharmacies, refill prescriptions by mail, and fill prescriptions with a 90-day supply.

Part D law and CMS guidance limit plan sponsors' ability to use those approaches. Most notably, plan sponsors must permit within their networks any pharmacy that is willing to accept the sponsors' terms and conditions; that is, plan sponsors cannot use exclusive pharmacy contracts.¹⁸ Plan sponsors must also demonstrate that their network of pharmacies meets access standards. Similarly, plan sponsors may not set up a narrower network of specialty pharmacies.¹⁹ However, traditional access standards may be less applicable to specialty pharmacies because typically they fill prescriptions primarily through home delivery.

Sponsors can, however, designate a subset of network pharmacies that offer preferred (lower) cost sharing. In 2022, 98 percent of PDPs use preferred cost-sharing pharmacies (Fein 2021a). The strategy of designating certain pharmacies as preferred has the potential to lower costs for Medicare and enrollees if it encourages enrollees to fill prescriptions at pharmacies that, for example, may be more effective at encouraging generic drug use. Researchers found that over the period from 2011 to 2014, Part D enrollees without the LIS were highly sensitive to preferred cost sharing, and the approach reduced overall drug spending by about 2 percent (Starc and Swanson 2021a, Starc and Swanson 2021b). However, tiered pharmacy networks have been controversial because of concerns that some members have less access to preferred pharmacies. If LIS enrollees have less opportunity to use preferred pharmacy networks, the tiered network strategy could lead to higher Medicare spending because Medicare pays for most or all of LIS enrollees' cost sharing.

Although Part D sponsors cannot set up exclusive pharmacy networks, they can include other network contract terms that try to achieve the same aims—terms that have largely led to postsale payments from pharmacies to plans. The terms can include fees

that are periodic payment reconciliations related to drug reimbursement rates, performance-based fees that are assessed on quality measures, or fees that are a condition for participating as a preferred cost-sharing pharmacy (Fein 2016). While participants in preferred networks gain more prescription volume, the pharmacies are essentially agreeing to lower and less predictable reimbursements from plans, which for some pharmacies has made participation in preferred networks much less desirable. In 2022 and in some previous years, many independent pharmacies have chosen not to participate (Fein 2021c).

According to CMS, between 2013 and 2017, pharmacies' net postsale payments (one component of what is referred to in Part D as direct and indirect remuneration, or DIR) to Part D plan sponsors soared from \$229 million in 2013 to over \$9.5 billion by 2020 (Centers for Medicare & Medicaid Services 2022, Centers for Medicare & Medicaid Services 2018). Some pharmacies argue that plan sponsors base these "pharmacy DIR" payments on metrics that are hard to anticipate or are unobtainable.²⁰ CMS initially stated that it would require plan sponsors to report the measures they use to evaluate pharmacy quality, but the agency did not include such measures within its final reporting requirements for plans (Centers for Medicare & Medicaid Services 2021j, Centers for Medicare & Medicaid Services 2021l).

Large plan sponsors are vertically integrated

Vertical integration between health plans and major PBMs—including large PBM-owned mail-order and specialty pharmacies—has been a central piece of many company strategies. The strategy offers the combined companies a number of advantages. Different from a vertically integrated company, a PBM operating under contract to a health plan could have an incentive to design formularies that reduce or minimize drug spending, even when prescriptions could prevent or forestall other health care spending. Health plans may find it beneficial to purchase a PBM and internalize trade-offs between drug and medical expenses (Garthwaite 2019).

Vertical mergers with PBMs also give health plans access to large amounts of prescription claims that, unlike most other provider claims, are typically adjudicated in real time. These data can be used to

monitor patient adherence, predict enrollees' use of services, encourage service use at lower-cost sites of care, and potentially coordinate care among prescribers.

Through vertical mergers, health plans can also gain access to PBM information about net prices for drugs—both for generics (because PBM mail-order pharmacies obtain steep discounts from manufacturers) and brand-name medications (through PBM data about manufacturer rebates). Because of the complexity of drug pricing, the highly proprietary nature of rebates, and imperfect competition among PBMs, information about net prices for drugs has been difficult to obtain through contracts (Lieberman et al. 2017, Scott Morton and Boller 2017). Some employers and payers argue that when they draw up contracts with PBMs to act as agents on their behalf, the asymmetric information held by large PBMs and their market power have made contracts hard to monitor and costly to enforce (Hargrave 2017). A health plan may find it less expensive to overcome the information asymmetry by purchasing the PBM (Garthwaite 2019).

However, it remains unclear whether vertical integration will ultimately benefit plan enrollees and payers such as Medicare. For example, one concern raised in the premerger review of CVS Health's purchase of Aetna (although not addressed by the Department of Justice) was that the combined firm would attempt to decrease access to or raise prices at CVS's retail pharmacies or CVS Caremark's PBM services against competing health plans that do not own a PBM (Greaney 2019).²¹ Inflated transfer prices between a PBM and its mail and specialty pharmacies could be a mechanism for raising rivals' costs.

Even if vertical mergers between health plans and PBMs made those companies more efficient or improved care coordination, enrollees and Medicare would not necessarily experience lower spending and premiums. Such a result would depend on the degree of competition among plans in MA and Part D markets—both of which have enrollment that is fairly concentrated (Schwartz et al. 2020).

Health plans' vertical mergers do not necessarily overcome poor incentives inherent in Medicare's Part D program. Currently, Part D's structure provides incentives for plan sponsors to include high-cost,

high-rebate drugs on formularies because plans bear relatively little liability in the coverage gap and catastrophic phase (Dusetzina et al. 2021b, Fein 2020b). Those incentives remain whether a plan sponsor writes a contract with an outside PBM or acquires the PBM as a subsidiary.

In addition, in 2020, 75 percent of U.S. specialty product spending was dispensed by four specialty pharmacies fully or partially owned by the largest PBMs (Fein 2021b). According to one estimate, specialty pharmacy dispensing accounted for 32 percent of PBMs' total gross profits in 2019, up from 17 percent in 2015 (Fein 2020a). CMS and commercial payers have less visibility into the prices established between upstream and downstream entities of vertically integrated organizations.²² For example, the Department of Health and Human Services Office of Inspector General (OIG) recently described one Part D plan sponsor that did not negotiate reimbursement contracts with its wholly owned pharmacies. OIG cautioned that margin amounts included in the sponsor's payments to its pharmacies for ingredient costs accrued to the sponsor but could not be identified and separated from pharmacy costs. In turn, the lack of clarity prevents CMS from being able to evaluate whether the entire margins included in the sponsor's Part D bids are reasonable (Office of Inspector General 2021).

Drug pricing

Growth in prices at the pharmacy counter—referred to here as gross or point-of-sale (POS) prices—has been the focus of much attention. Most Part D enrollees primarily use generic drugs, and many (but not all) generic prices remain low. However, enrollees without the LIS who use brand-name drugs often feel the effects of rising POS prices when they pay a deductible or coinsurance, especially the relatively small share of enrollees who use high-priced specialty drugs. At the same time, drug prices net of postsale rebates and discounts affect the premiums paid by all Part D enrollees and subsidized by the Medicare program.

All levels of the drug supply chain include incentives that drive POS prices higher, particularly when payments are based on a percentage of prices (Fein

**TABLE
13-3****Overall Part D POS prices grew more slowly in 2020 than in previous years**

| | Price index as of December | | | Average annual percent change* | | |
|--|----------------------------|------|------|--------------------------------|-------|------|
| | 2018 | 2019 | 2020 | Before 2019 | 2019 | 2020 |
| All drugs and biologics | 1.86 | 1.91 | 1.96 | 4.9% | 2.6% | 2.6% |
| Single-source brand-name drugs and biologics | 3.36 | 3.55 | 3.74 | 9.8 | 5.7 | 5.2 |
| Generic drugs | 0.17 | 0.15 | 0.14 | -12.8 | -11.0 | -9.3 |
| After accounting for generic substitution | 1.14 | 1.11 | 1.13 | 1.0 | -2.1 | 1.3 |

Note: POS (point of sale). Chain-weighted Fisher price indexes. Prices reflect total amounts paid to pharmacies before rebates or discounts from manufacturers and pharmacies. Indexes are measured at the median of the distribution relative to prices as of January 2006. Price indexes shown are rounded.

*Changes for 2019 and 2020 reflect growth in price index since the December of previous year calculated using unrounded data.

Source: Acumen LLC analysis for MedPAC.

2018, Feldman 2018, Garthwaite and Morton 2017, Sood et al. 2021). Meanwhile, manufacturers now focus on developing drugs and biologics for smaller patient populations that are launched at high prices and may not have direct therapeutic competitors. Over time, these factors, combined with the consolidation of supply-chain participants, have put upward pressure on POS prices (Sood et al. 2020).

In 2007, aggregate postsale rebates and discounts (what is referred to in Part D as DIR) offset less than 10 percent of total Part D drug spending (Boards of Trustees 2015). However, by 2019, DIR had grown to 26.5 percent of the \$183 billion in gross Part D spending, or over \$48 billion (Boards of Trustees 2021).²³ Manufacturer rebates make up the vast majority (more than 80 percent in 2019), with the remainder paid primarily by pharmacies in postsale fees and discounts. The widening gap between prescription prices at the pharmacy and prices net of rebates and discounts raises concerns about the worsening of plans' formulary incentives and a shift in financial risk from plan sponsors to beneficiaries and the Medicare program.

Prices paid at the point of sale

Prices paid at the pharmacy are an important indicator of Part D's costs because POS prices affect beneficiary

cost sharing and the rate at which enrollees reach Part D's catastrophic phase. To examine growth in POS prices, the Commission contracted with Acumen LLC to construct a series of volume-weighted price indexes that reflect total amounts paid to pharmacies for Part D prescriptions, including ingredient costs and dispensing fees. The indexes reflect POS prices before retrospective rebates and discounts and are measured at the median of the distribution.

In 2020, average prices grew more slowly than in prior years

Between 2006 and 2020, prices for all drugs and biologics, measured by individual national drug codes (NDCs), rose by an average of 96 percent (an index value of 1.96) (Table 13-3).²⁴ Overall, drug prices grew more slowly in 2019 and 2020 (2.6 percent each year) than price growth observed before 2019 (averaging 4.9 percent annually).

Because generic drugs account for 90 percent of all prescriptions, decreases in generic prices help moderate overall price growth. Our price index for generic drugs has shown consistent decline in the past and continued to do so in 2020. However, the rate of decrease in generic prices slowed in both 2019 and 2020, from an average annual decrease of nearly 13 percent before 2019 to -11.0 percent and -9.3 percent

**TABLE
13-4****In 2020, the average POS price of brand-name drugs and biologics was nearly 38 times that of generic drugs**

| | 2007 | 2010 | 2015 | 2017 | 2019 | 2020* | Average annual growth rate 2007-2020 |
|---|-------|-------|-------|-------|-------|-------|--------------------------------------|
| Aggregate figures | | | | | | | |
| Gross spending, billions | \$62 | \$78 | \$137 | \$155 | \$183 | \$199 | 9% |
| Number of prescriptions, millions | 1,144 | 1,406 | 2,119 | 2,329 | 2,537 | 2,638 | 7% |
| Share of aggregate spending | | | | | | | |
| Brand-name drugs and biologics | 79% | 76% | 76% | 77% | 79% | 80% | |
| Generic drugs | 21% | 24% | 24% | 23% | 21% | 20% | |
| Share of aggregate prescriptions | | | | | | | |
| Brand-name drugs and biologics | 39% | 26% | 13% | 11% | 10% | 10% | |
| Generic drugs | 61% | 74% | 87% | 89% | 90% | 90% | |
| Average gross spending per prescription | | | | | | | |
| Brand-name drugs and biologics | \$111 | \$161 | \$370 | \$468 | \$553 | \$619 | 14% |
| Generic drugs | 19 | 18 | 18 | 18 | 17 | 16 | -1% |
| Ratio: Average brand price to generic price | 5.8 | 8.8 | 20.3 | 26.7 | 32.9 | 37.7 | |

Note: POS (point of sale). "Gross spending" reflects payments from all payers, including beneficiaries (cost sharing), but does not include postsale rebates or discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. "Number of prescriptions" is standardized to a 30-day supply. Calculations are based on unrounded figures rather than the figures in the table.

*Figures based on preliminary Part D prescription drug event data.

Source: MedPAC analysis of Part D prescription drug event data.

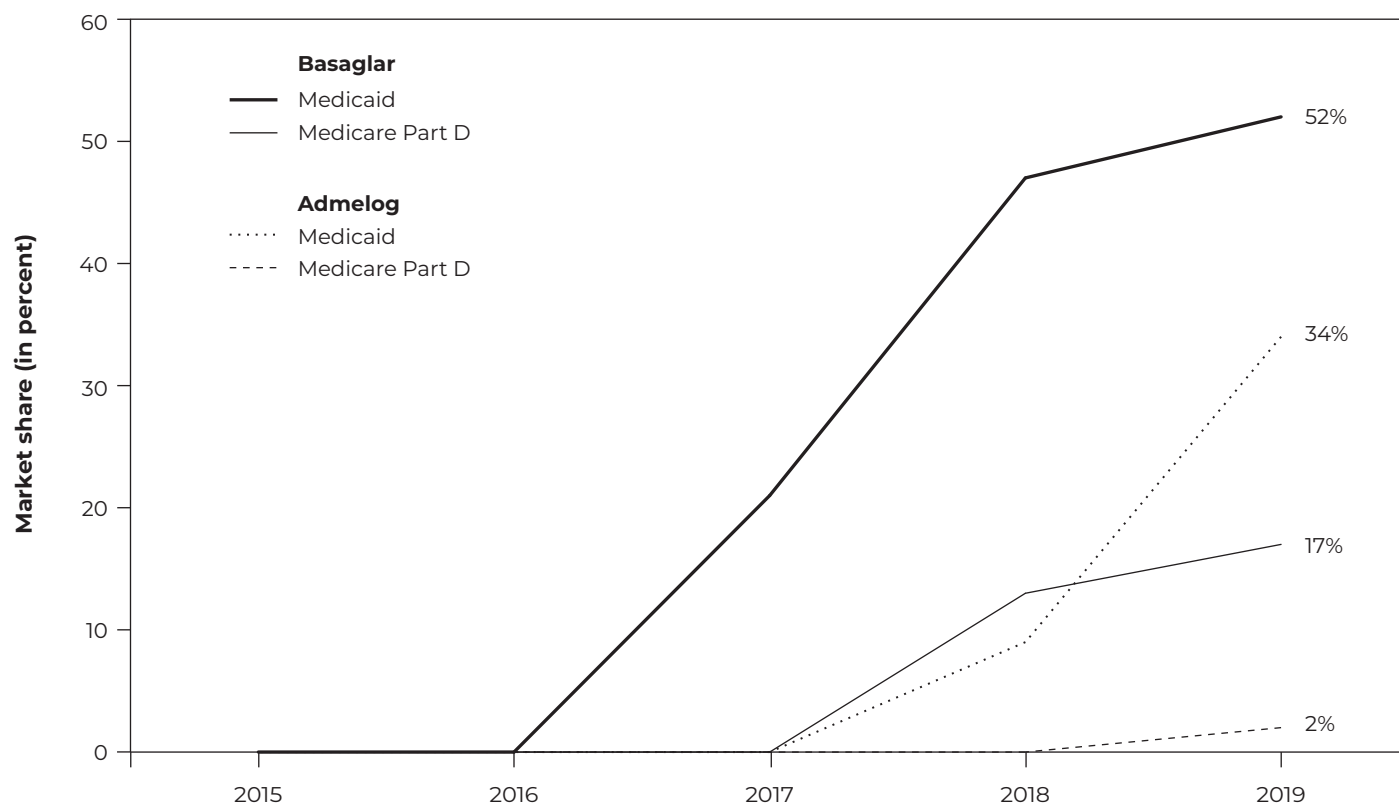
in 2019 and 2020, respectively (Table 13-3, p. 485). As a result, in 2020, our overall price index that takes generic substitution into account rose by 1.3 percent, a change from the 2.1 percent decline observed in 2019.²⁵

Low generic prices may be less effective at restraining future price and spending growth

Prices for generics are often a fraction of the prices for their brand-name counterparts (Government Accountability Office 2016, Schondelmeyer and Purvis 2019). Part D enrollees have embraced their use, with generic dispensing growing from just over 60 percent of all prescriptions in 2007 to nearly 90 percent by 2017 (Table 13-4). Broad acceptance of generic medicines

among prescribers and patients has provided significant savings to beneficiaries and the Medicare program.

However, generics' share of prescriptions has plateaued since 2017, and further opportunities for generic substitution may be limited. As the drug development pipeline has shifted, a significant portion are products for which generic or biosimilar versions are not available either because they are biologics (which are given longer periods of market exclusivity when they are licensed), specialty drugs with extensive patent protection, or both.

**FIGURE
13-2****Medicare Part D lags behind Medicaid in use of follow-on insulin products with lower list prices**

Note: "Market share" is defined as total number of dosage units for the follow-on biologic divided by the total number of dosage units for the same insulin product (insulin glargine for Basaglar and insulin lispro for Admelog) dispensed under the respective program (Medicaid or Medicare Part D) in a given year. The Food and Drug Administration approved follow-on biologics via a new drug application rather than the biosimilar pathway.

Source: MedPAC based on CMS Medicare Part D drug spending and data dashboard.

Meanwhile, rapid growth in prices of single-source brand-name drugs and biologics put upward pressure on Part D prices and program spending. Since 2010, manufacturer rebates received by Part D plan sponsors (excluding pharmacy DIR fees) have grown by nearly 20 percent per year on average. However, their effect on net prices has been modest. Between 2010 and 2019, Part D's spending per brand prescription, net of rebates, has grown by 13 percent per year on average (data not shown), compared with 14 percent per year on average on a gross basis (before rebates) (Table 13-4).

A number of factors have prevented biosimilar competition in Part D

The increasing role of biologics is a particular concern for program spending. Between 2006 and 2020, our price index for biologics grew by a cumulative 282 percent (data not shown).²⁶ As with generics, entry of biosimilar products could help moderate price increases for biologics. In turn, lower POS prices would help reduce the financial burden faced by beneficiaries who pay coinsurance and by Medicare's LIS, as it pays for nearly all of the cost sharing on behalf of beneficiaries with the LIS. However, our index that

takes such substitutions into account revealed almost no effect because biosimilar (including follow-on biologics) entry and use has thus far been very low. Tactics among manufacturers, regulatory hurdles, and the use of exclusionary contracting by payers have so far thwarted entry of and price competition from biosimilars in Part D (Cohen 2021a).

With only a small number of biosimilar products or follow-on biologics currently available in the retail pharmacy segment, it is difficult to know how biosimilar competition will affect prices and spending for biologics covered under the Part D program. Going forward, competitive pressure provided by biosimilar products would be crucial to restraining the prices of biological products, including net-of-rebate prices of reference products. However, Part D's experience with insulin's follow-on biologics and the expected entry of biosimilars for a leading biologic (Humira) highlight some of the potential hurdles.

Plans have been slow to cover follow-on biologic versions of insulin

Follow-on versions of two widely used insulins with lower list prices have entered the market in recent years—Basaglar (insulin glargine) and Admelog (insulin lispro). However, CMS data show that Medicare Part D has lagged behind Medicaid in the use of these products (Figure 13-2, p. 487). The slow adoption in Part D is concerning; it suggests that Basaglar and Admelog were either not covered by many Part D plans or were not the preferred insulin products on their formularies (Dusetzina et al. 2021b, Fein 2021d, Marsh 2021).

Basaglar was approved in 2014 as a follow-on biologic (via a new drug application rather than the biosimilar pathway) and has been available since December 2016.²⁷ Despite their higher list prices, Sanofi's Lantus and its newer high-concentration product, Toujeo, continued to dominate the insulin glargine market through 2019 (Centers for Medicare & Medicaid Services 2019a). In 2019, three years after launch, Basaglar's Part D market share had reached only 17 percent compared with 52 percent under Medicaid (Figure 13-2, p. 487).

A similar situation has occurred with Admelog, a follow-on biologic to Humalog. After its launch in April 2018, Admelog rapidly gained market share under Medicaid, accounting for over one-third of insulin lispro doses dispensed under Medicaid by 2019

(Figure 13-2, p. 487). In comparison, in 2019, Admelog accounted for just 2 percent of Part D's insulin lispro market. With a list price that is 65 percent below that of Humalog, Admelog could have provided significant savings for patients and Medicare even without any postsale rebates or discounts (Marsh 2021).

Medicaid's financial incentives differ from those under Part D in important ways, which may explain much of the difference in the experience of the two programs. First, states have strong incentives to manage Medicaid drug spending to ensure that they stay within their budgets. When states use managed care to deliver services, their payments to Medicaid managed care organizations (MCOs) are fully capitated, and as a result, there is a better alignment of incentives between the states and MCOs (Hinton et al. 2020). Most states also maintain a preferred drug list (PDL) as a way to drive utilization of lower-cost drugs, and an increasing number of states require their MCOs to follow their PDL (Gifford et al. 2020b).²⁸ Second, Medicaid's drug rebate program classifies biosimilar products (including follow-on biologics) as "single-source drugs," meaning that manufacturers of biosimilar products must pay rebates based on the formula for branded drug products, not based on the rebate formula for generic drugs (Centers for Medicare & Medicaid Services 2015).²⁹ This policy means that a biological product with a lower list price will also have a lower net price (net of rebates), which ensures that states and MCOs both prefer to use the lower-cost biosimilar product when clinically appropriate.

In contrast, under Part D, plan sponsors face limited financial risk and misaligned formulary incentives. Today, payments to plans consist mostly of cost-based reinsurance rather than capitated (direct subsidy) payments. In particular, plan sponsors bear little liability for benefit spending above the initial coverage limit. These unique features of the program undermine incentives for cost control and, in some cases, distort formulary incentives for plan sponsors to prefer higher-priced products with rebates over lower-priced products.³⁰

In 2021, the Food and Drug Administration (FDA) approved the first insulin biosimilar with an interchangeable designation. The designation is significant as it allows for automatic substitution at pharmacies, similar to the traditional generic drug

market (subject to state laws regarding interchangeable biosimilar substitution) (Cardinal Health 2021, National Conference of State Legislatures 2019).

Strategies used to limit the impact of the launch of Humira biosimilars

While the current biosimilars landscape is dominated by oncology therapies that primarily affect biologics covered under Part B, the next wave of biosimilars is expected to include those covered under Part D, including seven Humira biosimilars that already have FDA approval (Baldetti 2021, Hagen 2021c, McGowan 2021). Biosimilar competition has helped bring down prices of certain biologics, including the prices of reference biologics, covered under Part B (Medicare Payment Advisory Commission 2021a). However, the success of biosimilars likely varies across products, depending on factors that are unique to each therapeutic area, including provider acceptance, prevalence of “new start” patients, and competitive dynamics (Baldetti 2021, Frank et al. 2022).

Humira (adalimumab) is a biological product manufactured by AbbVie and is used to treat autoimmune diseases such as rheumatoid arthritis and ulcerative colitis. In 2020, gross Part D spending for Humira totaled more than \$4.1 billion (before rebates and discounts), making it one of the highest-selling products. Because of its substantial cost, Humira’s high price and annual price increases have been scrutinized by researchers and policymakers (House Committee on Oversight and Reform 2021, Rind et al. 2021). In 2021, Humira topped the GoodRx list of 10 most expensive brand-name drugs sold in the United States, with cash prices averaging more than \$9,000 per one-month supply (Wells 2021). Prices at the pharmacy typically track list prices set by the manufacturer. Between 2014 and 2021, Humira’s list price increased by 138 percent (Wells 2021). Of the \$16.1 billion in net U.S. revenue that AbbVie received for Humira in 2020, the Institute for Clinical and Economic Review estimated that \$1.4 billion was attributable to price increases taken between 2019 and 2020 that were not supported by new clinical evidence (Rind et al. 2021).

Humira’s extensive patent protection may have discouraged biosimilar manufacturers from challenging patents in court Humira was first launched in 2003. Although the patent for its active ingredient expired in 2016, AbbVie has extended its market protection in

part by amassing over 250 patents (Higgins-Dunn 2021, Ross 2018). The FDA approved the first of what are now seven biosimilars to Humira in 2016, with one product (Cyltezo) gaining interchangeable designation in late 2021.³¹ However, none of the seven has launched in the United States. Rather than challenge the patents in court, manufacturers of Humira biosimilars reached an agreement with AbbVie to delay their U.S. launches until 2023 (Hagen 2021c, Van de Wiele et al. 2021, Watral 2019).³²

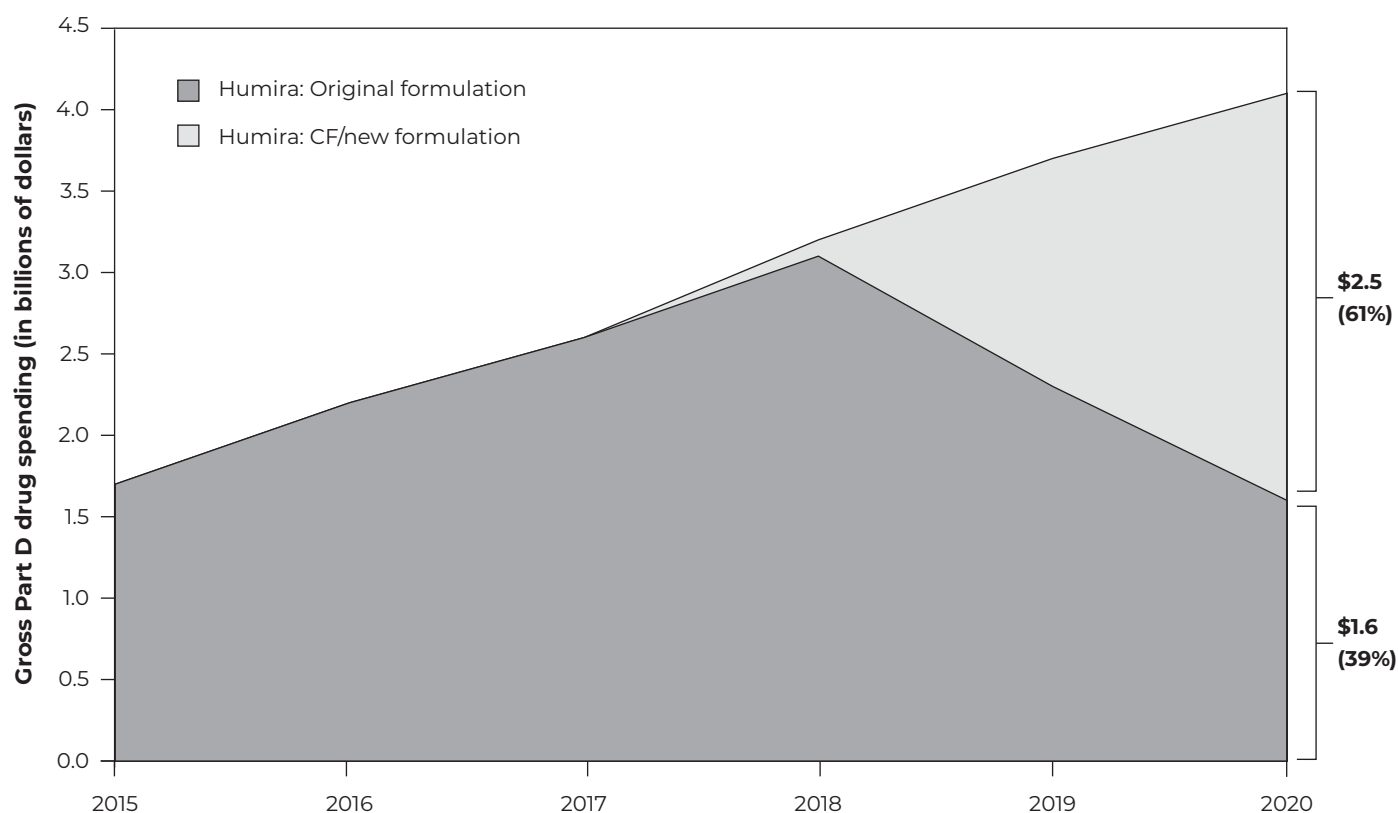
Biosimilars may face a diminishing market as more patients transition to a new high-concentration formulation (“product hopping”) “Product hopping” refers to a situation in which a biopharmaceutical company introduces a modified version of an original drug or a biological product and attempts to switch patients to the new version that is protected by additional patents (Rome et al. 2020). In July 2018, AbbVie launched a new citrate-free, higher-concentration formulation of Humira (Humira Citrate-free) while discontinuing two dosage forms of the original (lower) concentration versions (Hagen 2021a). One study (sponsored by AbbVie) found that the new formulation was “well tolerated and associated with less injection site-related pain” than the original formulation (Nash et al. 2016). In communications with patients and prescribers, AbbVie has referred to this study, which promotes transitioning patients from the original formulation to the new higher-concentration formulation (AbbVie 2021).

Humira’s new formulation has rapidly gained market share in Part D. Just two and a half years after launch, its share has grown from less than 5 percent of gross Part D spending for Humira products to 61 percent (Figure 13-3, p. 490).³³ Because all seven biosimilar products were approved in the original concentration, the continued transition of patients to products with higher concentration may add to any potential hesitancy prescribers or patients have about switching to a biosimilar product. That, in turn, may significantly limit biosimilar manufacturers’ ability to compete for adalimumab market share (Hagen 2021a).³⁴

The delay in the entry of Humira biosimilars has likely already cost Medicare billions of dollars. One study estimated that, between 2016 and 2019, Medicare could have saved nearly \$2.2 billion on Humira (and its biosimilars) had biosimilars entered the market in a

**FIGURE
13-3**

Humira biosimilars may face a diminishing market as more patients transition to the new higher-concentration formulation



Note: CF (citrate-free).

Source: MedPAC based on Acumen LLC analysis of Part D prescription drug event data.

timely manner (Lee et al. 2021). Humira biosimilars may face additional hurdles after their launch if Part D plan sponsors and their PBMs use exclusionary contracts with AbbVie. Such contracts would, in exchange for financial incentives (typically in the form of rebates or discounts), limit biosimilars' ability to "[gain] preferred access to the formulary, or any access at all" (Cohen 2021b).

Program costs

The costs of providing Part D benefits are shared by Medicare (taxpayers) and Part D enrollees. Medicare

pays plan sponsors two subsidies on behalf of each enrollee in their plans:

- **Direct subsidy**—A monthly prospective amount set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- **Reinsurance**—Reimbursement to plans for 80 percent of drug spending above an enrollee's annual OOP threshold (the catastrophic phase of the benefit). Plans receive prospective payments for reinsurance that are reconciled with actual spending (net of postsale rebates and discounts) for

**TABLE
13-5****Medicare's reimbursement amounts for Part D**

| | Calendar year | | | | | | | Average annual growth rate | | |
|--|---------------|-------------|-------------|-------------|-------------|-------------|-------------|----------------------------|-----------|-----------|
| | 2007 | 2010 | 2016 | 2017 | 2018 | 2019 | 2020 | 2007–2019 | 2019–2020 | 2007–2020 |
| Reimbursement amount (in billions): | | | | | | | | | | |
| Direct subsidy* | \$17.6 | \$19.6 | \$17.1 | \$14.6 | \$13.5 | \$11.8 | \$10.2 | –3.3% | –13.6% | –4.1% |
| Reinsurance | <u>8.0</u> | <u>11.2</u> | <u>35.5</u> | <u>37.6</u> | <u>40.6</u> | <u>46.1</u> | <u>47.8</u> | 15.7 | 3.7 | 14.7 |
| Subtotal, basic benefits | 25.6 | 30.8 | 52.6 | 52.2 | 54.1 | 57.9 | 58.0 | 7.0 | 0.2 | 6.5 |
| Low-income subsidy | 16.7 | 21.1 | 26.4 | 27.3 | 28.5 | 29.7 | 33.1 | 4.9 | 11.4 | 5.4 |
| Retiree drug subsidy | <u>3.9</u> | <u>3.9</u> | <u>1.0</u> | <u>0.8</u> | <u>0.7</u> | <u>0.6</u> | <u>0.6</u> | –14.4 | 0.0 | –13.4 |
| Total Part D | 46.2 | 55.8 | 80.0 | 80.3 | 83.3 | 88.2 | 91.7 | 5.5 | 4.0 | 5.4 |
| Enrollee premiums** | 4.1 | 6.7 | 12.7 | 14.0 | 14.2 | 13.8 | 13.6 | 10.6 | –1.4 | 9.7 |

Note: The numbers presented reflect reconciliation. Components may not sum to stated totals due to rounding.

*Net of risk-sharing payments resulting from Part D's risk corridors.

**For basic benefits, excluding low-income premium subsidies.

Source: MedPAC analysis based on Table IV.B10 of 2021 annual report of the Boards of Trustees of the Medicare trust funds.

each enrollee who reached the OOP threshold after the end of the benefit year.

Combined, the direct subsidy and expected reinsurance payments aim to cover 74.5 percent of the expected cost of basic benefits. Today, a much larger share of Medicare's payments takes the form of reinsurance (cost-based reimbursement) rather than the direct subsidy (capitated payments). To put this in perspective, in 2022, direct subsidy payments to plans average less than \$5 per member per month, compared with payments of nearly \$93 per member per month for expected levels of reinsurance.³⁵ In addition to reinsurance, Medicare shares financial risk with plan sponsors by risk adjusting direct subsidy payments to reflect the expected costliness of a plan's enrollees and by limiting each plan's overall losses or profits through risk corridors if actual benefit spending, excluding reinsurance, is much higher or lower than the plan sponsor anticipated in its bid.

Beneficiary premiums are designed to cover the remaining 25.5 percent of the expected cost of basic benefits. In addition to monthly premiums, Part D enrollees also pay any cost sharing required by plan sponsors or, in the case of LIS enrollees, cost-sharing amounts set in law.

Trends in program subsidies and costs

Between 2007 and 2020, program spending (including expenditures for the RDS) rose from \$46.2 billion to \$91.7 billion (Table 13-5), or an average 5.4 percent per year. In 2020, Medicare paid \$10.2 billion for direct subsidies, \$47.8 billion for individual reinsurance, \$33.1 billion for the LIS, and \$0.6 billion for the RDS. Medicare payments for individual reinsurance have grown faster than other components of Part D spending. Between 2007 and 2020, reinsurance payments rose by nearly 15 percent annually, compared with a decline of 4.1 percent for the capitated direct subsidy payments (see text box, p. 492).

Multiple factors have contributed to the decline in aggregate direct subsidy payments

Aggregate direct subsidy payments have declined consistently since 2012, reflecting moderate growth in gross plan liability (for basic benefits), in large part due to the increased use of generic drugs by Part D enrollees. In contrast, catastrophic spending, which is mostly paid by Medicare's reinsurance, has grown aggressively, driven by high and increasing prices of brand-name drugs and biologics. At the same time, postsale rebates and discounts, referred to collectively as direct and indirect remunerations (DIR), grew rapidly, quintupling between 2012 and 2020 to over \$50 billion. DIR is used to offset basic benefit costs paid by plans (plan liability) and Medicare (reinsurance). However, CMS's formula allocates

a disproportionate share of the DIR to offset plans' benefit liability (Centers for Medicare & Medicaid Services 2017, Medicare Payment Advisory Commission 2017b). For example, in 2020, plan liability accounted for less than half of total basic benefit costs (plan liability plus reinsurance costs), but CMS's formula allocated, on average, two-thirds of all DIR to plans to offset plans' benefit liability. Finally, because enrollee premiums are set by law at 25.5 percent of the expected average cost of basic benefits, those premiums have offset a growing share of plan liability net of DIR. In turn, Medicare's capitated direct subsidies have covered a diminishing share of basic benefit costs. ■

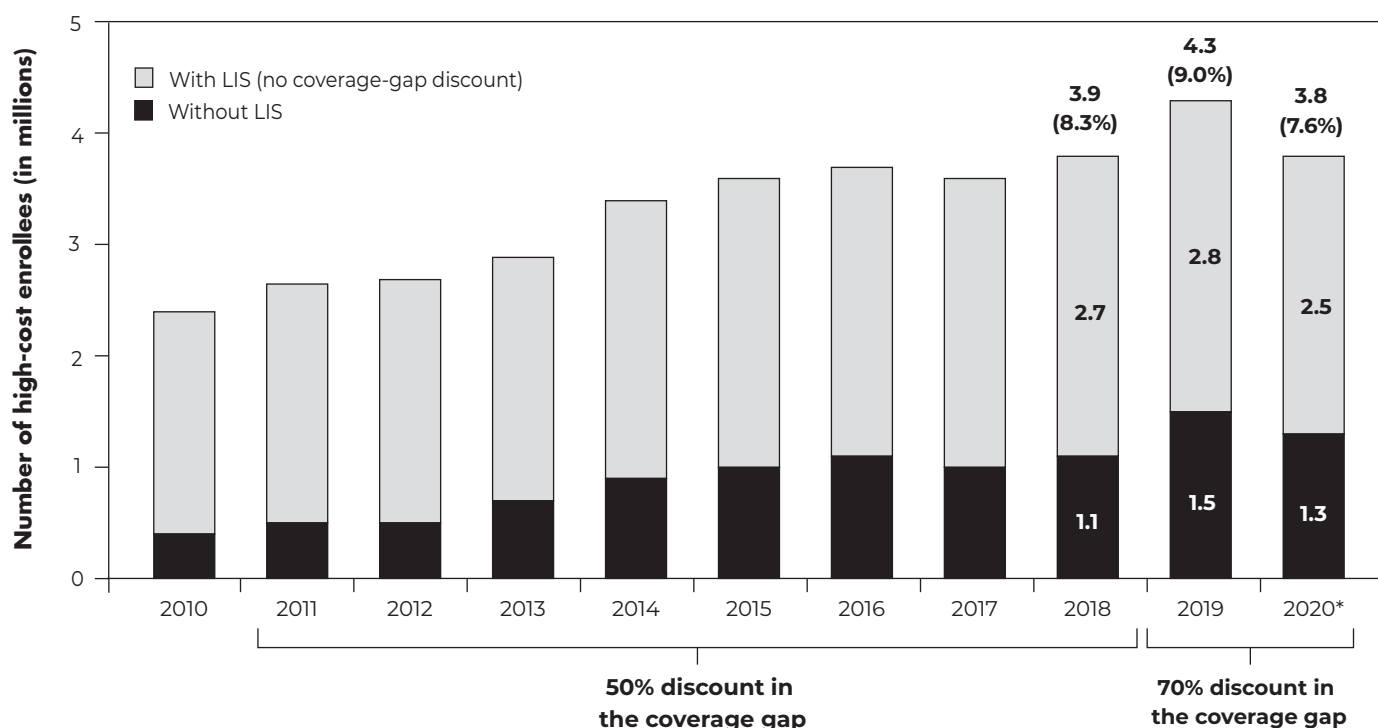
In 2020, aggregate premiums paid by Part D enrollees for basic benefits (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled \$13.6 billion, down 1.4 percent from payments in 2019. Before 2020, aggregate premiums paid by enrollees grew by an average of 10.6 percent per year, reflecting primarily growth in enrollment of beneficiaries without the LIS and some increase in benefit costs.³⁶

In 2020, as the OOP threshold rose by \$1,250, half a million fewer beneficiaries reached the catastrophic phase

In 2020, the number of Part D high-cost enrollees—those with spending high enough to reach the catastrophic phase of the benefit—fell by more than 11 percent from 4.3 million in 2019 (Figure 13-4). Much of the decline was likely driven by the 25 percent jump (\$1,250) in the OOP threshold between 2019 and 2020, from \$5,100 to \$6,350.³⁷ (As a point of comparison, the OOP threshold grew by just \$100 in 2019.) Although the large threshold increase made it much more difficult to reach the catastrophic phase, in 2020, the number of high-cost enrollees without the LIS (1.3 million) was nonetheless higher than in all years before 2019.

The financial implications of the higher OOP threshold differ for Part D enrollees with the LIS than for the other Part D enrollees. Because the LIS pays for nearly all costs in the coverage gap (above any nominal copayments required by law), the effects of the higher OOP threshold fall almost entirely on Medicare (see Figure 13-1, p. 472). In 2020, Medicare's payments for low-income cost-sharing subsidies rose by about \$3.4 billion, accounting for nearly all of the increase in LIS costs between 2019 and 2020 (Table 13-5, p. 491).

In contrast, for enrollees without the LIS, the financial impact of a higher OOP threshold differed depending on whether the prescription was for a generic or a brand-name drug. For brands, the manufacturer's coverage-gap discount is treated as though it were the enrollee's own OOP spending (see Figure 13-1, p. 472). For example, an enrollee who filled only brand-name drugs in the coverage gap was responsible for paying about a quarter of that increase—the rest was covered by manufacturer discounts. Meanwhile, beneficiaries who took only generic drugs were responsible for the full increase.

**FIGURE
13-4****Part D enrollees reaching the benefit's catastrophic phase, 2010–2020**

Note: LIS (low-income subsidy). Percentages shown are high-cost enrollees as a share of all Part D enrollees. Components may not sum to stated totals due to rounding.

*Figure is based on preliminary Part D prescription drug event data.

Source: Enrollee counts for 2010 to 2020 are based on MedPAC analysis of Part D prescription drug event data.

The rise in the annual OOP threshold meant that total (gross) spending at the OOP threshold would also be higher. CMS estimated an average increase of about \$1,400 to \$1,600, depending on the individual's LIS status (Centers for Medicare & Medicaid Services 2021c). Based on those higher spending levels, in 2020, roughly 443,000 enrollees (11.6 percent of high-cost enrollees) filled at least one prescription for a high-priced drug that was sufficient to meet the OOP threshold with a single claim. That figure is lower than the 483,000 with such claims in 2019 but still substantially higher than the 33,000 in 2010.

Continued aggregate growth in drug spending and use in 2020

The full extent to which 2020's higher OOP threshold affected beneficiaries' willingness to fill prescriptions

is unknown, especially in the midst of a pandemic. However, preliminary data for 2020 suggest that in the aggregate, enrollees' prescription use and spending continued to grow. Discounts paid by brand manufacturers in the coverage gap jumped by 25 percent—about \$2.5 billion higher than the \$10 billion paid in 2019. With the steep rise in Part D's OOP threshold, more enrollees remained in the coverage gap and yet, in the aggregate, continued to fill brand prescriptions, in part because brand prices were discounted. Among enrollees without the LIS, per capita use (measured by numbers of standardized 30-day prescriptions) and spending grew at rates comparable to those observed during the previous 5 years.

Taxpayers bear an increasing share of the risk for Part D spending

In 2020, the growth in Medicare's payments for reinsurance slowed to the lowest level since 2007, largely due to the increase in the OOP threshold discussed above. However, Medicare's reinsurance subsidies (for which taxpayers are at risk) were still the largest component of Part D spending, accounting for over 63 percent of payments to plans, up from 25 percent in 2007 (Figure 13-5).

Insurance risk provides an incentive for plan sponsors to offer attractive benefits while managing their enrollees' spending through formularies and other tools. However, data from the Boards of Trustees show that between 2007 and 2020, the portion of the average basic benefit paid to plans through Medicare's capitated direct subsidy fell from 54.7 percent to 13.5 percent (Figure 13-5). Correspondingly, in 2020, the portion for which plans are at risk (direct subsidy payments plus enrollee premiums) accounted for less than 37 percent of benefit costs (23 percent plus 13.5 percent), down from about 75 percent in 2007 (20.4 percent plus 54.7 percent). The Commission has been concerned that the shift of risk from plan sponsors to Medicare has eroded plans' incentives to manage spending.

Beneficiaries' access to prescription drugs

Formulary management is the most important tool used by plan sponsors. Greater flexibility to use formulary tools could help plan sponsors manage spending while ensuring that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some enrollees, those same tools could limit access to needed medications. To ensure access, CMS reviews each plan's formulary to check that it includes medicines in a wide range of therapeutic classes used by the Medicare population and applies utilization management tools in appropriate ways. Further, Part D law requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.³⁸

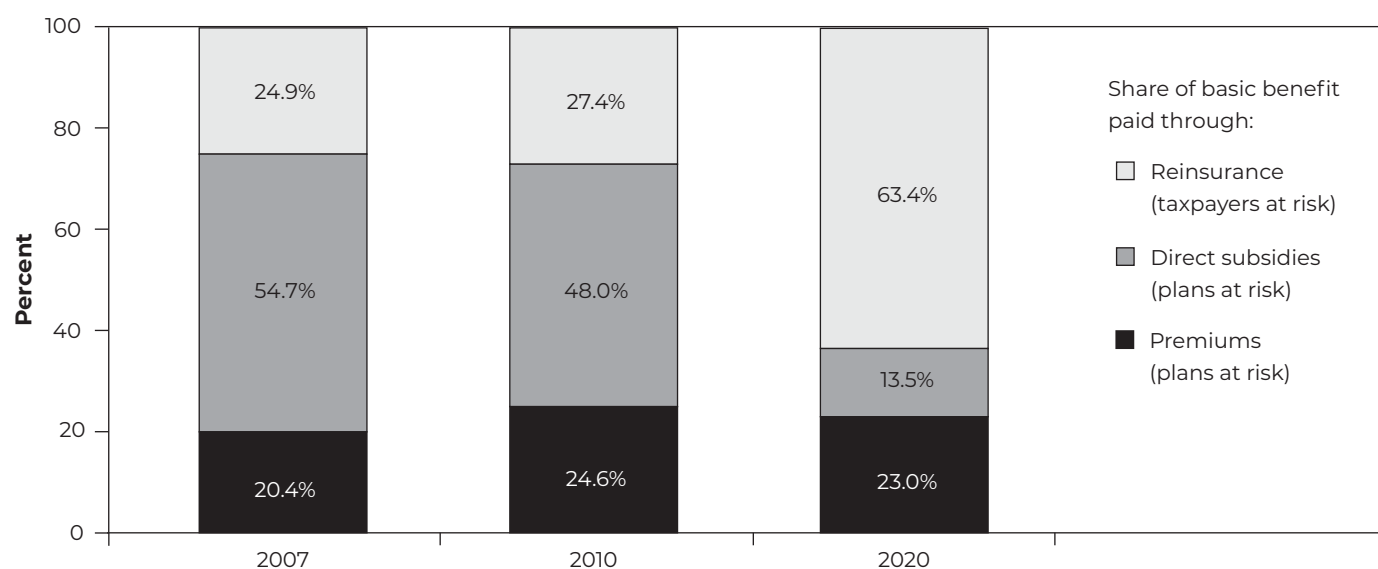
Medicare also requires plan sponsors to establish a process for coverage determination and appeals. Part D requires quicker adjudication times than for most medical benefits covered by MA plans.³⁹ If an enrollee is dissatisfied with plan's final coverage decision (redetermination), the enrollee may appeal the decision to an independent review entity and then to higher levels of appeal.

Measuring access is inherently complicated because clinical appropriateness can vary across patients. General program-wide indicators of access using data from CMS audits and Part D's appeals process suggest that beneficiaries may be less likely to encounter access issues resulting from inappropriate formulary administration or coverage determinations (Medicare Payment Advisory Commission 2021c). However, the slow adoption of electronic communications and tools by prescribers continues to be a concern. For some beneficiaries, high cost sharing can affect access.

Need to improve electronic communication between Part D plans and prescribers

A more constructive approach toward ensuring appropriate access would be to provide enrollees and prescribers with real-time information about formulary coverage and utilization management requirements in ways that fit into providers' workflow at the point of prescribing. Under this approach, questions about coverage could be resolved using electronic tools, such as real-time benefit tools (RTBTs) and electronic prior authorization (ePA).

If built into the prescriber's workflow, standardized approaches to ePA and automated coverage determinations could save patients and providers significant time and resources and speed up delivery of care (American Medical Association-convened workgroup of 17 state and specialty medical societies 2019). In 2019, CMS finalized a rule requiring Part D sponsors to implement one or more RTBTs capable of integrating with at least one prescriber's electronic health record system by January 1, 2021 (Centers for Medicare & Medicaid Services 2019b). However, the extent to which this requirement expands the use of RTBTs in Part D will depend on the degree to which clinicians—who face no requirements under this rule—adopt them when prescribing for their Medicare patients. In 2020, CMS issued a final rule

**FIGURE
13–5****Taxpayers bear increasing share of the risk for Part D benefit spending**

Note: Figures represent aggregate values for incurred basic benefits net of risk corridor payments. Figures for enrollee premiums include amounts paid to Part D plans by enrollees and by Medicare on behalf of enrollees who receive the low-income subsidy. Components may not sum to totals due to rounding.

Source: MedPAC analysis based on Table IV.B10 of 2021 annual report of the Boards of Trustees of the Medicare trust funds.

that requires Part D plan sponsors to implement real-time comparison tools for enrollees by January 1, 2023 (Centers for Medicare & Medicaid Services 2021e). Many details remain about how best to implement RTBTs so that the tools fit into the workflow at a relevant point in the prescribing process and contain accurate formulary and patient-specific information.

For some beneficiaries, high OOP costs may be a barrier to access

More than 80 percent of elderly Part D enrollees report that their Part D plans provide good value and that their OOP costs are reasonable (*Medicare Today* 2021). At the same time, in focus groups convened for the Commission, physicians and beneficiaries were acutely aware of high drug costs and reported having frequent discussions about ways to lower costs (Catterson et al. 2021). These seemingly conflicting results reflect the dichotomy between the majority of beneficiaries who

take generic drugs for common conditions and the relatively small number of beneficiaries who use many brand-name drugs or high-cost specialty drugs.

For an individual enrollee without the LIS, the cost-sharing burden for brand-name drugs and biologics can be substantial (see text box on reducing cost sharing for insulins, pp. 496–497). For high-cost specialty drugs, cost sharing can total thousands of dollars in the catastrophic phase of the benefit alone (Cubanski et al. 2019). (Most enrollees who receive Part D's LIS do not face a large financial hurdle because their cost sharing is limited to nominal copayments.)

For many reasons, beneficiaries have not always benefited from lower-priced alternatives (Dusetzina et al. 2020). For example, the list price differential between a generic and its brand counterpart may be relatively small. As a result, sponsors may continue to prefer the brand version that has lower costs for the

Reducing cost sharing for insulins may improve access, but high prices remain unaddressed

Prices of insulins have increased considerably over the years. A recent congressional report found that, in just five years (from 2014 to 2019), list prices of commonly used insulins rose by between 33 percent and 70 percent without any “significant advances in the efficacy of the drugs” (U.S. Senate Committee on Finance 2021). Another study found that, in 2018, insulin prices in the United States were always higher, and often 5 to 10 times higher, than those in other Organisation for Economic Co-operation and Development (OECD) countries (Mulcahy et al. 2020).⁴⁰

High prices of insulins can have significant financial as well as health implications for individuals with insulin-dependent diabetes. Even if the individual has health insurance, high cost sharing can make insulins unaffordable (Endocrine Society 2021). In Part D, between 2007 and 2017, average out-of-pocket (OOP) spending on insulin for individuals without Part D’s low-income subsidy (LIS) jumped from \$324 to \$580, or by an average increase of 6 percent per year, far exceeding the 1.6 percent average annual rate of inflation over this time period (Cubanski et al. 2020)

In 2020, over 3.3 million Part D enrollees took insulin. Of that total, about 2 million were LIS enrollees who paid nominal copayments or were enrolled in an employer group waiver plan, which may have offered more generous coverage. The remaining 1.3 million beneficiaries typically faced 25 percent coinsurance once they reached the coverage gap. For these beneficiaries, cost sharing in the coverage-gap phase typically exceeded \$100, a substantial increase from the \$47 copayment most plans charged in the initial coverage phase. Before 2021, virtually all plans used 25 percent coinsurance in the coverage gap because lowering cost sharing in this phase of the benefit would lower the amount of manufacturer discounts while raising plans’ benefit costs and enrollee premiums (Cubanski et al. 2020, Verma 2020).

Researchers and policymakers have raised concerns that high cost sharing in the coverage-gap phase makes insulins unaffordable for some beneficiaries (Endocrine Society 2021, Trish et al. 2021). While beneficiaries who use insulin typically fill 10 to 12 prescriptions for insulins in a given year, in 2020, about 22 percent of beneficiaries without the LIS filled fewer than seven prescriptions.⁴¹ That share

(continued next page)

plan owing to the coverage-gap discount or rebates paid by the manufacturer. Even when entries of multiple generic competitors result in substantially lower prices and plan sponsors adjust their formularies to prefer the generic version, beneficiaries can still pay relatively high OOP costs because the coverage-gap discount does not apply to generic drugs (Dusetzina et al. 2020).

High cost sharing can result in beneficiaries not initiating therapy or abandoning prescriptions at the

pharmacy (Doshi et al. 2018, Dusetzina et al. 2020).⁴² For drugs placed on specialty tiers, beneficiaries have little recourse because they may not request a tiering exception to obtain the specialty-tier drugs at lower (preferred) cost sharing.⁴³ It is not possible to measure the extent to which high prices are impeding access to needed medications. However, growth in the number of therapies that command very high prices is likely to raise the number of beneficiaries who face affordability issues (Dusetzina et al. 2020, Park and Look 2020).

Reducing cost sharing for insulins may improve access, but high prices remain unaddressed (cont.)

is higher than the 14 percent among beneficiaries with the LIS. Anecdotal evidence suggests that beneficiaries without the LIS may use a variety of strategies to avoid entering the coverage gap—for example, by obtaining insulins outside of the Part D program (such as cash purchases without using the Part D benefit) (Catterson et al. 2021, Wedell 2021). Part D plans, and therefore the program data, will not capture such prescriptions. However, it is also possible that some beneficiaries without the LIS are taking less than optimal doses of insulins because of high cost sharing (Trish et al. 2021).

In response to concerns about the high cost of insulins and potential access issues, in 2021, CMS's Center for Medicare & Medicaid Innovation began testing a new demonstration model, the Part D Senior Savings Model. The model allows participating enhanced drug plans to lower cost sharing for insulins to no more than \$35 per one-month supply without facing the financial disincentives that discourage plans from reducing cost sharing in the coverage gap (see the text box on the Part D Senior Savings Model for insulin in our March 2021 report to the Congress (Medicare Payment Advisory Commission 2021c)). While it is too soon to know

how this model has performed in improving access to insulins and providing better value for the Medicare program, plan offerings for 2022 suggest that the model is gaining popularity. In 2022, a total of 2,159 plans (33 percent of prescription drug plans and 38 percent of Medicare Advantage–Prescription Drug plans (MA–PDs)) are participating in this model, up from about 1,600 plans in 2021, largely driven by an increase in the number of participating MA–PDs (Cubanski and Damico 2021).

Although the Senior Savings Model may improve access to insulins, high OOP costs affect many other conditions and therapies (Medicare Payment Advisory Commission 2019). The model also will not address the underlying structural issues that may have contributed to the rapid growth in insulin prices (Medicare Payment Advisory Commission 2020a). Finally, focusing only on beneficiary cost sharing may worsen the pricing incentives faced by all participants in the drug supply chain, including manufacturers and pharmacy benefit managers. In turn, that could exacerbate the financial burden on Part D enrollees and taxpayers who finance the program. ■

Quality in Part D

Measuring the quality of enrollees' medication use is critical for assessing Part D's value, but it is a task that requires nuance. On the one hand, for many conditions, effective treatment may hinge primarily on access and adherence to prescription drugs. For this reason, Medicare evaluates how well Part D plans make medicines available through their formularies and network pharmacies. On the other hand, Medicare beneficiaries are likely to have multiple chronic conditions, take an average of nearly five prescription drugs daily, and are at higher risk for adverse drug

events associated with polypharmacy. Thus, the degree to which Part D plans help to manage enrollees' medication therapies is critically important as well.

CMS collects quality and performance data to monitor plan sponsors' operations and evaluate access to medicines, enrollee experience, and patient safety. A subset of these data form part of a 5-star rating system made available through Medicare's Plan Finder at [medicare.gov](https://www.medicare.gov) to help beneficiaries evaluate their plan options. The agency also uses star ratings that are based in part on prescription drug benefits to determine MA quality bonus payments. (Although both

MA-PDs and stand-alone PDPs are evaluated with star ratings, only MA-PDs are eligible for quality bonus payments in the Part C payment system.) The agency displays other Part D quality measures on cms.gov, including some metrics that are transitioning out of or are being evaluated for the star-rating system. In addition, by law, Part D plans are required to carry out medication therapy management (MTM) programs and programs to manage opioid use.

Part D star ratings

The star ratings are composed of metrics that are measured at the contract level and come from several sources—the Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information.⁴⁴ CMS flags the lowest-rated plans on Plan Finder to caution beneficiaries about choosing those plans. The highest-rated plans can enroll beneficiaries outside the annual open enrollment period.

For the 2022 ratings, MA-PDs were evaluated on up to 38 unique measures—26 that focus on Part C services, 10 that focus on Part D, and 2 that are common to both (Centers for Medicare & Medicaid Services 2021i). PDPs are evaluated only on scores for Part D measures. The 12 Part D measures fall under 4 domains: (1) drug plan customer service, (2) member complaints and changes in the drug plan's performance, (3) member experience with the drug plan, and (4) drug safety and accuracy of drug pricing. CMS aggregates individual scores for each measure such that a 5-star rating reflects excellent performance and 1 star reflects poor performance. Overall ratings are calculated as the weighted average of star ratings for each component measure.⁴⁵ Process measures (such as the accuracy of pricing data on the Medicare Plan Finder) receive a weight of 1, measures that capture access or member experience (such as complaints about the drug plan) receive a weight of 2, intermediate outcome measures (such as rates of medication adherence) receive a weight of 3, and drug plan quality improvement (a measure that reflects changes in performance from one year to the next) receives a weight of 5.

For 2022, average star ratings rose substantially, but much of that increase reflects changes CMS made in how it calculated the ratings to address the coronavirus pandemic.⁴⁶ Among PDPs, the average star rating

for 2022 (weighted by 2021 enrollment) increased to 3.70 from 3.58 a year earlier (Centers for Medicare & Medicaid Services 2021b). About 42 percent of PDP enrollees (based on 2021 enrollment) are in 2022 contracts with 4 or more stars, and another 53 percent are in contracts with 3.5 stars. Among MA-PDs offered for 2022, the average star rating jumped to 4.37 from 4.16. Based on 2021 enrollment, CMS estimated that 90 percent of MA-PD enrollees were in contracts rated 4 or more stars for 2022. While on the surface it appears that MA-PDs performed much better than PDPs, as we discuss in our chapter on the MA program, the current state of quality reporting in MA is such that we continue to question the reliability of MA-PD quality ratings. Further, PDP and MA-PD results are not entirely comparable because the latter reflect a much broader set of measures than the 12 metrics specific to Part D services. Among Part D measures only, average ratings of MA-PDs were higher than those of PDPs for 7 of the 12 metrics (Centers for Medicare & Medicaid Services 2021b).

As one window into plans' performance during the pandemic, CMS released nationwide averages of most Part D component measures for the 2022 ratings (collected during 2020 and 2021) without the adjustments made in response to the public health emergency. Compared with national averages from the 2021 ratings, the performance of both MA-PDs and PDPs improved significantly for measures of MTM services and for medication adherence to statin therapy and diabetes medications (Table 13-6). Higher measures of the metric for medication adherence (proportion of days covered (PDC)) may reflect enrollees' move toward 90-day prescription fills from 30-day fills during the pandemic lockdown.⁴⁷ After comparing changes in Part D adherence rates with other literature on average adherence rates for common conditions, some analysts argue that the long-term upward trend observed in Part D metrics may partly reflect improvements in PDC scores rather than true improvements in patient adherence (Farley and Urick 2021).

Programs to manage medication use

CMS expects Part D plan sponsors to ensure quality of medication care through internal programs and drug utilization reviews. In addition, by law, Part D plans are required to carry out medication therapy management

**TABLE
13-6****Changes in Part D measure scores from 2021 to 2022 star ratings**

| Part D measure | MA-PD contracts | | | PDP contracts | | |
|---|-----------------|--------------|-----------------------|---------------|--------------|-----------------------|
| | 2021 average | 2022 average | Change in performance | 2021 average | 2022 average | Change in performance |
| MTM program completion rate for comprehensive medication review | 76.89 | 83.35 | Better | 44.54 | 53.74 | Better |
| Medication adherence for cholesterol (statins) | 82.35 | 86.24 | Better | 84.32 | 87.08 | Better |
| Medication adherence for diabetes medications | 82.61 | 86.03 | Better | 84.65 | 86.68 | Better |
| Statin use in persons with diabetes | 80.25 | 82.86 | Better | 78.73 | 80.34 | Better |
| Medication adherence for hypertension (RAS antagonists) | 84.58 | 87.04 | Better | 86.62 | 88.45 | Better |
| Rating of drug plan | 85.05* | 86.43 | Better | 83.61* | 84.15 | Better |
| Getting needed prescriptions | 90.06* | 91.05 | Better | 89.97* | 90.56 | Better |
| Complaints about the plan | 0.19 | 0.21 | Worse | 0.04 | 0.06 | Worse |
| Call center—foreign language interpreter and TTY availability | 91.74 | 91.02 | Worse | 92.43 | 88.71 | Worse |
| Members choosing to leave the plan | 13.16 | 14.68 | Worse | 9.71 | 10.65 | Worse |

Note: MA-PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan), MTM (medication therapy management), RAS (renin angiotensin system), TTY (teletypewriter). Most measures are in percentages, except for complaints about the plan (number of complaints per 1,000 members). The measure “Medicare Plan Finder price accuracy” is not shown because it had substantive specification changes between the two years. The measure “drug plan quality improvement” is not shown.

*Measures from the Consumer Assessment of Healthcare Providers and Systems® used data from the 2020 star ratings (collected in 2019 and unaffected by the COVID-19 public health emergency).

Source: Centers for Medicare & Medicaid Services 2021b.

programs and drug management programs for enrollees at risk of opioid overuse.

Medication therapy management programs

Medicare requires each Part D plan sponsor to carry out MTM programs that focus on the quality of pharmaceutical care for high-risk beneficiaries by improving their therapeutic outcomes and reducing adverse drug events. CMS reviews and must approve a sponsor’s description of its MTM program as part of the annual Part D bidding process. The programs target two categories of beneficiaries: (1) those who have multiple chronic conditions, take multiple medications,

and are likely to have drug spending that exceeds an annual cost threshold (\$4,696 for 2022), and (2) those who are at risk for opioid misuse or abuse under a plan’s drug management program.

Plan sponsors are required to enroll, with opt-out provisions, all eligible enrollees in their MTM programs and report certain measures annually to CMS about all eligible beneficiaries. MTM programs must offer interventions for both beneficiaries and prescribers. At a minimum, the programs must provide enrolled beneficiaries with a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring

and follow-up of any medication-related issues.⁴⁸ CMS expects plan sponsors to have a process in place to measure and evaluate the outcomes of their interventions. Sponsors must also provide MTM program enrollees with information about the safe disposal of prescription drugs that are controlled substances.

Early in the Part D program, plan sponsors used a wide variety of eligibility criteria, types of interventions, and levels of effort (Medicare Payment Advisory Commission 2009). Sponsors had the flexibility to set eligibility criteria, and some sponsors targeted beneficiaries with more than three conditions or selected conditions that were somewhat less prevalent, resulting in limited participation (Gray et al. 2019). One reason for doing so may have been that plans must treat the cost of MTM programs as an administrative expense, which they reflect in their Part D bids. Over time, CMS has been more prescriptive with respect to eligibility criteria and MTM interventions to broaden participation and plan accountability.⁴⁹

For years, the Commission has had concerns about the effectiveness of MTM programs, particularly in stand-alone PDPs. Unlike MA-PDs, which bear financial risk for both the medical and drug spending of their enrollees, PDPs are accountable only for drug spending and may not have financial incentives to address medication-related issues or encourage adherence to high-value medications that can reduce medical spending. Past CMS analyses found lower rates of medication reviews among MTM enrollees in PDPs compared with those in MA-PDs. Today, the same pattern is still evident: In the 2022 star ratings (based on 2020 data), an average of 54 percent of enrollees in PDP MTM programs received a comprehensive medication review, compared with an average of 83 percent in MA-PD MTM programs (Table 13-6, p. 499).

In 2017, CMS began testing an Enhanced MTM model to see if new payment incentives and regulatory flexibilities would spur PDPs to improve their medication management interventions and reduce Medicare spending. Participating sponsors are allowed to set their own targeting criteria and tailor their MTM interventions to their enrollees.⁵⁰ CMS makes prospective payments per beneficiary per month and performance-based payments to the sponsors to cover estimated costs of their interventions. Six Part D sponsors operating 22 PDPs in 5 regions of the country

are participating over a 5-year period. In 2019, about 1.4 million PDP enrollees in those plans were targeted for enhanced MTM services and about 30 percent received services (Acumen LLC 2021). Although the entire five-year demonstration is not yet complete, over the first three years, CMS found no statistically significant effects on Medicare spending for Part A and Part B services, and plan payments under the model were larger than observable decreases in spending, resulting in net costs to Medicare (Centers for Medicare & Medicaid Services 2021h). Measures of use of diabetes medications showed modest improvement, but measures of potentially unsafe medication use in the elderly did not improve.

Drug management programs

Because of their higher burden of chronic conditions and disease, Medicare beneficiaries may be more likely to experience significant pain. In 2016, nearly a third of Part D enrollees filled at least one prescription for an opioid, mostly for pain not associated with treatment of cancer or terminal conditions (Medicare Payment Advisory Commission 2018). Among beneficiaries with the highest opioid use, nearly three-quarters used either benzodiazepines or gabapentin concurrently. Adverse events can be associated with opioid use, in part because individuals using opioids tend to take multiple drugs and because opioid use itself can cause serious harm, such as opioid use disorder, overdose, and death. Long-term use of opioids increases risk of falls or fractures, and side effects of opioids can interfere with treatment of comorbid conditions.

Part D plan sponsors have been required to operate drug utilization management, quality assurance, and MTM programs since the program's inception. However, as concern about the nation's opioid epidemic grew, CMS set additional requirements. The agency put in place the Overutilization Monitoring System (OMS) to identify, from claims, enrollees with high use of frequently abused drugs or patterns of obtaining prescriptions from multiple prescribers and pharmacies. In addition, CMS requires plan sponsors to administer safety alerts when high dosages of opioids are prescribed, and it posts display measures about opioid use on [cms.gov](https://www.cms.gov).

In 2019, plan sponsors were permitted to establish drug management programs (DMPs) that identify enrollees at risk of overuse and take steps to manage that

use. Beginning in 2022, all Part D plans are required to carry out DMPs, and enrollees with a history of opioid-related overdose must be included in them. CMS provides plan sponsors with information from the OMS about enrollees identified as potentially at risk. Sponsors must then conduct retrospective reviews of claims and case management—reaching out to the prescribers, making them aware if the patient has sought opioids from multiple prescribers, and determining whether the cumulative dosage was

intended. If the plan sponsor cannot determine that a beneficiary’s high opioid use is medically necessary or if prescribers verify misuse, the sponsor can apply “hard edits” to opioid claims so that the pharmacy will not fill the prescription or limits the quantity dispensed. Under certain circumstances, sponsors can limit access to frequently abused drugs through beneficiary-specific edits and restrictions on which prescribers or pharmacies the enrollee can use. ■

Endnotes

- 1 Even today, when the defined standard benefit has 25 percent coinsurance in both the initial coverage phase and coverage-gap phase, many Part D plans structure their cost sharing differently across the two phases, with copayments for generics and preferred drugs initially but 25 percent coinsurance in the coverage gap.
- 2 In 2022, individuals with the partial LIS pay a \$99 deductible and 15 percent coinsurance on prescriptions up to the OOP threshold. Above the OOP threshold, those LIS enrollees pay \$3.95 for each generic prescription and \$9.85 for brand prescriptions. For more on the magnitude of cost sharing for partial LIS enrollees, see Dusetzina et al. 2021a.
- 3 For example, in 2022, generic tiers cannot have copayments that exceed \$20 per prescription or charge coinsurance of more than 25 percent in the benefit phase between the deductible and the initial coverage limit. Plans may not use copayments of more than \$100 or coinsurance higher than 50 percent for drugs on nonpreferred tiers (Centers for Medicare & Medicaid Services 2021m).
- 4 CMS calculates benchmarks using a weighted average of both PDP and MA-PD premiums. For plans that offer enhanced coverage, CMS uses the portion of the plan's premium that reflects the cost of basic coverage. For MA-PDs, CMS uses plans' premiums for basic coverage before plan sponsors have applied any MA rebates (a portion of the difference between the MA payment rate and plans' bids to provide Part A and Part B services) to reduce or eliminate the premium. The weight for each plan equals its share of LIS enrollment.
- 5 The small share of LIS enrollees who receive a partial subsidy pay a portion of the premium for most PDPs, including those with premiums below the LIS benchmark.
- 6 Under CMS's de minimis policy, plan sponsors may voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is above the LIS benchmark for a subsidy-eligible individual, up to a de minimis amount. The de minimis amount for 2022 is \$2.
- 7 Instead of accepting the new assignment, LIS enrollees may choose a plan themselves. However, if their selected plan has a premium higher than the benchmark, the LIS enrollee must pay the difference between the plan's premium and the benchmark amount.
- 8 Beneficiaries who are current or former Part D enrollees can be auto-enrolled for a variety of reasons, such as losing and then regaining their LIS and Part D coverage, moving out of their plan's service area, asking to disenroll from their current plan without selecting a new plan, or failing to pay the premium for their current plan.
- 9 CMS allows Part D plan sponsors to use up to two specialty tiers that are exempt from its tiering exceptions process. For a drug to be placed on a specialty tier, average price must exceed a dollar-per-month threshold established by CMS. The threshold for 2022 is \$780 per month, an increase from the \$670 per month that was in place through 2021 (Centers for Medicare & Medicaid Services 2021j).
- 10 In 2020, the Congressional Budget Office estimated that the combined package would lead to one-year program savings of more than \$2 billion relative to baseline spending and savings of more than \$10 billion over five years.
- 11 EGWPs are sponsored by employers that contract directly with CMS or on a group basis with an insurer or pharmacy benefit manager to administer the Part D benefit. They differ from employer plans that receive the RDS in that Medicare Part D is the primary payer rather than the employer.
- 12 A portion of the difference between an MA plan's payment benchmark and its bid for providing Part A and Part B services is referred to as "MA rebate dollars." Plan sponsors can use MA rebate dollars to supplement benefits or lower Part D or MA premiums. In 2021, MA-PD sponsors applied on average \$40 per month (28 percent) of their Part C rebate dollars to Part D benefits. Of that amount, 47 percent was used to lower Part D premiums for basic benefits and the rest was used for supplemental drug benefits.
- 13 For 2020, actual aggregate reinsurance costs exceeded the plan sponsors' projections by \$5.4 billion (Liu 2021).
- 14 As with the income-related premium for Part B, higher Part D premiums apply to individuals with an annual adjusted gross income greater than \$91,000 and to couples with an adjusted gross income greater than \$182,000. A beneficiary whose income exceeds these levels pays a monthly adjustment amount in addition to their Part D plan premium. For 2022, adjustments range from \$12.40 to \$77.90 per month, depending on income (Centers for Medicare & Medicaid Services 2021a).
- 15 The LEP amount depends on the length of time an individual goes without coverage as generous as Part D and is calculated by multiplying 1 percent of the base beneficiary premium by the number of full, uncovered months an individual was eligible but was not enrolled in a Part D plan and went without other creditable coverage.

- 16 In 2018, CVS Health completed its acquisition of Aetna, and Cigna completed its acquisition of Express Scripts. To address antitrust concerns and obtain regulatory approval of the CVS Health–Aetna deal, Aetna sold its PDPs to WellCare. Subsequently, WellCare was acquired by Centene. Under CMS guidance, plan sponsors may offer no more than one basic and two enhanced PDPs per Part D region. Following a merger, CMS gives sponsors a transition period before they must comply. Cigna and Centene needed to consolidate their plans by 2022.
- 17 Most MA plans are MA–PDs, offering combined medical and outpatient drug benefits. However, a small share of MA plans (including Medicare Savings Account plans) do not offer prescription drug coverage.
- 18 Some pharmacies choose not to contract with certain plans because they do not like the terms and conditions the plans offer. Plan sponsors are not obligated to cover prescriptions at an out-of-network pharmacy, except under certain circumstances.
- 19 Plan sponsors cannot restrict access to a subset of network pharmacies unless dispensing a drug requires “extraordinary specialty handling, provider coordination, or patient education that cannot be met by a network pharmacy” (Centers for Medicare & Medicaid Services 2011). An exception is made if a manufacturer uses a limited distribution network. In this situation, the Part D enrollee would be able to fill that prescription only at one of the designated specialty pharmacies.
- 20 For example, independent specialty pharmacies have said they are evaluated on rates of statin dispensing—a drug class they typically do not dispense. Some community pharmacies are evaluated on rates of dispensing generics measured at the level of the pharmacy services administrative organization they use rather than that of their individual pharmacy.
- 21 The Department of Justice focused on the merger’s horizontal dimensions but did not challenge vertical aspects of the merger (Greaney 2019). As a condition of approval, Aetna divested its Medicare Part D prescription drug plan business to WellCare (now owned by Centene).
- 22 In interviews we conducted in 2017, we found that there is little transparency of transfer prices between PBMs and their pharmacies. CMS requires Part D plan sponsors to report PBM-negotiated rebates so that Medicare can appropriately pay the program’s share of net-of-rebate drug spending rather than list-price spending. However, postsale rebates and discounts received by PBM subsidiaries such as mail-order and specialty pharmacies are not reported (Medicare Payment Advisory Commission 2017a). In our interviews, PBM auditors and consultants voiced concerns that there is less visibility into the transfer prices PBMs pay to their mail-order and specialty pharmacies, which affects what payers are subsequently charged (Hargrave 2017). PBMs we spoke with noted that they have corporate firewalls to keep transactions between subsidiaries at arm’s length. However, information firewalls are difficult to enforce.
- 23 Total drug costs include spending for brand-name drugs as well as generics, on which manufacturers do not typically pay rebates.
- 24 An individual NDC uniquely identifies the drug’s labeler, drug, dosage form, strength, and package size.
- 25 For this index, Acumen groups NDCs that are pharmaceutically identical, aggregating prices across drug trade names, manufacturers, and package sizes. As a result, brand-name drugs are grouped with their generics if they exist, and this price index more closely reflects the degree to which market share has moved between the two.
- 26 Insulins account for a large share of biological products covered under Part D. Between 2006 and 2020, our price index for insulins grew by more than 300 percent, compared with just under 250 percent for other biological products (i.e., excluding insulins) during the same period.
- 27 Semglee is the first official biosimilar insulin glargine approved by the FDA, in July 2021. However, Basaglar has long been considered an unofficial biosimilar because it is considered to be highly similar to Lantus, its reference product (Hagen 2021b).
- 28 For a drug not on the PDL, a state may require prior authorization or attach a higher copayment, creating incentives for providers to prescribe a drug on the PDL when possible (Gifford et al. 2020a).
- 29 CMS encourages state Medicaid programs to “view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions . . . and to provide biologics that achieve desirable, cost-effective clinical outcomes for beneficiaries using the various drug utilization and cost management tools they have available (e.g., step therapy, prior authorization, preferred drug lists)” (Centers for Medicare & Medicaid Services 2015).
- 30 For some products, it is possible for the price net of rebates to be lower than an alternative product with lower list price. However, even for products with lower net prices, the financial benefit of postsale rebates disproportionately

- accrues to plans; patients who pay cost sharing on the higher price and Medicare's low-income cost-sharing subsidy do not benefit from lower net prices.
- 31 Biosimilar products may not be approved for all indications approved for the originator product. For example, Cyltezo is approved for six indications in adult patients compared with eight for Humira (Food and Drug Administration 2021). An interchangeable biosimilar product may be substituted for the reference product without the prescriber having to change the prescription, subject to state pharmacy laws, which vary by state.
 - 32 The Biologics Price Competition and Innovation Act (BPCIA) passed in 2010 created an abbreviated approval pathway for biosimilars that involves patent litigations. Based on a review of lawsuits related to the BPCIA, a study found that both "the complex litigation process established by the BPCIA and large numbers of patents enforced by originator manufacturers" have contributed to "frequent confidential settlements between originator and biosimilar manufacturers that have delayed the availability of biosimilars" (Stern et al. 2021).
 - 33 CMS dashboard data show that list prices for original and new formulations of Humira products (including the citrate-free version) are comparable on a per dosage basis (Centers for Medicare & Medicaid Services 2021k). For this reason, market shares measured by gross sales are likely to track very closely to market shares measured by volume.
 - 34 Boehringer Ingelheim, the manufacturer of Cyltezo, has filed a citizen petition with the FDA to change its interpretation of how the strength of a biosimilar is determined. The FDA has provided an interim response stating it has not yet resolved the issue (Stanton 2021).
 - 35 Calculated from information in CMS's announcement of the 2022 Part D national average monthly bid amount and base beneficiary premium (Centers for Medicare & Medicaid Services 2021d).
 - 36 Between 2007 and 2020, the number of Part D beneficiaries without the LIS grew, on average, by just over 7 percent annually.
 - 37 Changes in law required Medicare to temporarily apply slower growth rates to the OOP threshold over the period from 2014 through 2019. However, for 2020 and thereafter, the OOP threshold reverted to levels that would have been in place had the slower growth rates never applied.
 - 38 The transition fill is a temporary one-month supply provided within the first 90 days of coverage in a new plan or the new contract year for existing enrollees.
 - 39 Plan sponsors must make coverage determination and exception decisions within 72 hours of a request or within 24 hours for expedited requests. If the initial exceptions request does not include the necessary supporting statement, the plan has up to 14 calendar days to obtain the information. See our March 2020 report to the Congress for more details (Medicare Payment Advisory Commission 2020b).
 - 40 The study compared wholesale acquisition cost (WAC) to manufacturer prices in other OECD countries. The authors acknowledged that the net prices paid for insulins in the United States are likely to be lower than WAC but noted that U.S. insulin prices would still have been considerably higher (about four times higher) than in other OECD countries even if prices net of postsale rebates and discounts were used (Centers for Medicare & Medicaid Services 2013).
 - 41 We found similar results using the 2019 prescription drug event data (before the current public health emergency related to COVID-19).
 - 42 The relationship between higher cost sharing and adherence, treatment initiation, or the rate of prescription abandonment is likely to vary widely across therapeutic classes. For example, patients may be less sensitive to higher cost sharing for certain cancer treatments compared with therapies for chronic conditions such as rheumatoid arthritis (Medicare Payment Advisory Commission 2019).
 - 43 Part D enrollees can apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. However, recent enforcement actions regarding manufacturer donations to charities suggest that some PAPs are in violation of the anti-kickback statute (Office of Inspector General 2018, Sagonowsky 2017).
 - 44 Due to the COVID-19 public health emergency, CMS did not require sponsors to submit CAHPS survey data (or, for Part C measures, Healthcare Effectiveness Data and Information Set® (HEDIS®) data) for the 2021 star ratings. The components of 2021 Part D star ratings that were based on CAHPS data were replaced with earlier values from the 2020 star ratings (Centers for Medicare & Medicaid Services 2020). For 2022 ratings, CMS resumed use of the most recent CAHPS and HEDIS data (Centers for Medicare & Medicaid Services 2021i).
 - 45 For five clinically oriented Part D measures, CMS applies a categorical adjustment index to account for average within-contract differences between the performance of enrollees with the LIS or disabled status and other enrollees.

- 46 For example, CMS delayed implementation of bidirectional caps on the amount of allowable upward or downward movement in the cut points for star ratings in the event that national performance declined as a result of the pandemic. CMS also expanded a hold-harmless provision so that changes in a contract's quality improvement score could not cause the contract's summary star rating to decrease (Centers for Medicare & Medicaid Services 2021b).
- 47 Greater use of 90-day fills reduces the number of times uncovered days can be observed in the PDC measure.
- 48 CMRs must include a person-to-person or telehealth consultation performed by a pharmacist or other qualified provider and a written summary of the review that includes a medication list and action plan, if any, provided to beneficiaries in CMS's standardized format. A TMR is distinct from a CMR because it is focused on specific medication-related problems, actual or potential. A TMR can be conducted person to person or be system generated, and interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2021f).
- 49 Today, plan sponsors can no longer set eligibility criteria narrower than requiring beneficiaries to have more than three chronic conditions or use more than eight medications. If plan sponsors target beneficiaries with specific chronic conditions for their MTM programs, CMS requires them to include at least five out of nine core conditions: Alzheimer's disease, chronic heart failure, diabetes, dyslipidemia, end-stage renal disease, hypertension, respiratory disease, bone disease–arthritis, or mental health conditions.
- 50 For example, a sponsor might choose to provide more counseling services on medication adherence and devote fewer resources to comprehensive medication reviews.

References

- AbbVie. 2021. HUMIRA Citrate-free. <https://www.humiradermpro.com/citrate-free>.
- Acumen LLC. 2021. *Evaluation of the Part D Enhanced Medication Therapy Management (MTM) Model: Third evaluation report. Report prepared by Acumen for the Center for Medicare & Medicaid Innovation*. Burlingame, CA: Acumen.
- American Medical Association–convened workgroup of 17 state and specialty medical societies. 2019. Prior authorization and utilization management reform principles. <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-reform-initiatives>.
- Baldetti, J. 2021. What's next for the biosimilars market in the U.S.? *Managed Healthcare*, November 22.
- Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2021. *2021 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Washington, DC: Boards of Trustees.
- Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2015. *2015 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Washington, DC: Boards of Trustees.
- Cardinal Health. 2021. Biosimilar interchangeability laws by state. <https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf>.
- Catterson, R., A. Figueroa, M. Hertel, et al. 2021. *Beneficiary and clinician perspectives on Medicare and other issues: Findings from 2021 focus groups in select states*. Chicago, IL: NORC at the University of Chicago.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; contract year 2023 policy and technical changes to the Medicare Advantage and Medicare prescription drug benefit program. Proposed rule. *Federal Register* 87, no. 8 (January 12): 1842–1960.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021a. 2022 Medicare Parts A & B premiums and deductibles/2022 Medicare Part D income-related monthly adjustment amounts. <https://www.cms.gov/newsroom/fact-sheets/2022-medicare-parts-b-premiums-and-deductibles2022-medicare-part-d-income-related-monthly-adjustment>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021b. 2022 Part C and D star ratings fact sheet. <https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021c. Announcement of calendar year 2022 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies. January 15.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021d. Annual release of Part D national average bid amount and other Part C & D bid information. HPMS memo. July 29. <https://www.cms.gov/files/document/july-29-2021-parts-c-d-announcement.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021e. Contract year 2022 Medicare Advantage and Part D final rule (CMS-4190-F2). Fact sheet. <https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021f. Correction to contract year 2022 Part D Medication Therapy Management program guidance and submission instructions dated April 30, 2021. <https://www.cms.gov/files/document/memo-contract-year-2022-medication-therapy-management-mtm-program-submission-v-083121.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021g. COVID-19 experiences among the Medicare population: Winter 2021. <https://www.cms.gov/files/document/medicare-current-beneficiary-survey-covid-19-data-snapshot-infographic-winter-2021.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021h. Findings at a glance: Part D Enhanced Medication Therapy Management model. <https://innovation.cms.gov/data-and-reports/2021/mtm-thrdevalrept-fg>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021i. Medicare 2022 Part C & D star rating technical notes. October 4. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021j. Medicare and Medicaid Programs; Contract year 2022 policy and technical changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Final rule. *Federal Register* 86, no. 11 (January 19): 5864–6135.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021k. 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, Department of Health and Human Services. 2021l. Medicare Part D reporting requirements. Effective as of January 1, 2022. <https://www.cms.gov/files/document/cy2022part-d-reporting-requirements012022.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021m. Memo regarding contract year (CY) 2022 final Part D Bidding instructions. January 19.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2020. Medicare and Medicaid programs; policy and regulatory revisions in response to the COVID-19 public health emergency. Interim final rule. *Federal Register* 85, no. 66 (April 6): 19230–19292.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019a. Medicare Part D drug spending and data dashboard. <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019b. Modernizing Part D and Medicare Advantage and the Medicare prescription drug benefit programs to lower drug prices and reduce out-of-pocket expenses. Final rule. *Federal Register* 84, no. 100 (May 23): 23832–23884.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Modernizing Part D and Medicare Advantage to lower drug prices and reduce out-of-pocket expenses. Proposed rule. *Federal Register* 83, no. 231 (November 30): 62153–62201.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare Part D: Direct and indirect remuneration (DIR). Press release. January 19. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Medicaid Drug Rebate Program notice for participating drug manufacturers. Release no. 92. Baltimore, MD: CMS. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-092.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. Best practices and common findings memo #2 from 2012 program audits. Memo to all Medicare Advantage organizations and prescription drug plans from Gerard Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group. July 30.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011. *Prescription Drug Benefit Manual*. Chapter 5: Benefits and beneficiary protections. Baltimore, MD: CMS.

Cohen, J. 2021a. Approval of first interchangeable biosimilar, Semglee, is sign of an improving U.S. biosimilars market, despite challenges. *Forbes*, August 1. <https://www.forbes.com/sites/joshuacohen/2021/08/01/approval-of-first-interchangeable-biosimilar-semglee-is-sign-of-an-improving-us-biosimilars-market-despite-challenges/?sh=50ee816d7fa4>.

Cohen, J. 2021b. Rebate walls stifle prescription drug competition. *Forbes*, March 1. <https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=7825aeff66ae>.

Congressional Budget Office. 2021. *A comparison of brand-name drug prices among selected federal programs*. Washington, DC: CBO. <https://www.cbo.gov/publication/57007>.

Cubanski, J., and A. Damico. 2021. *Medicare Part D: A first look at prescription drug plans in 2022*. Issue brief. Washington, DC: Kaiser Family Foundation.

Cubanski, J., and A. Damico. 2020. *Medicare Part D: A first look at prescription drug plans in 2021*. Issue brief. Washington, DC: Kaiser Family Foundation.

Cubanski, J., W. Koma, and T. Neuman. 2019. *The out-of-pocket cost burden for specialty drugs in Medicare Part D in 2019*. Issue brief. Washington, DC: Kaiser Family Foundation.

Cubanski, J., T. Neuman, S. True, et al. 2020. *Insulin costs and coverage in Medicare Part D*. Issue brief. Washington, DC: Kaiser Family Foundation.

Doshi, J. A., P. Li, H. Huo, et al. 2018. Association of patient out-of-pocket costs with prescription abandonment and delay in fills of novel oral anticancer agents. *Journal of Clinical Oncology* 36, no. 5 (February 10): 476–482.

Dusetzina, S. B., W. Elkins, and J. Hoadley. 2021a. Extra help needs a hand: Partial subsidies in the Medicare Part D program. *Journal of General Internal Medicine* (May 23).

- Dusetzina, S. B., A. Sarpatwari, M. A. Carrier, et al. 2021b. Patient and payer incentives to use patented brand-name drugs vs authorized generic drugs in Medicare Part D. *JAMA Internal Medicine* 181, no. 12 (December 1): 1605–1611.
- Dusetzina, S. B., S. Jazowski, A. Cole, et al. 2019. Sending the wrong price signal: Why do some brand-name drugs cost Medicare beneficiaries less than generics? *Health Affairs* 38, no. 7 (July): 1188–1194.
- Dusetzina, S. B., B. Muluneh, N. L. Keating, et al. 2020. Broken promises: How Medicare Part D has failed to deliver savings to older adults. *New England Journal of Medicine* 383, no. 24 (December 10): 2299–2301.
- Endocrine Society. 2021. Addressing insulin access and affordability: An Endocrine Society Position Statement. *Journal of Clinical Endocrinology & Metabolism* 106, no. 4 (March 25): 935–941.
- Farley, J. F., and B. Y. Urick. 2021. Is it time to replace the star ratings adherence measures? *Journal of Managed Care & Specialty Pharmacy* 27, no. 3 (March): 399–404.
- Fein, A. 2021a. Consolidation and preferred pharmacy networks in 2022's Medicare Part D plans. *Drug Channels* blog. November 2. <https://www.drugchannels.net/2021/11/consolidation-and-preferred-pharmacy.html>.
- Fein, A. 2021b. DCT's top 15 specialty pharmacies of 2020: PBMs expand amid the shakeout—while Walgreens' outlook dims (rerun). *Drug Channels* blog. September 21. <https://www.drugchannels.net/2021/09/dcis-top-15-specialty-pharmacies-of.html>.
- Fein, A. 2021c. Small pharmacies continue to run away from Medicare Part D's preferred networks. *Drug Channels* blog. November 18. <https://www.drugchannels.net/2021/11/small-pharmacies-continue-to-run-away.html>.
- Fein, A. 2021d. Why PBMs and payers are embracing insulin biosimilars with higher prices—And what that means for Humira. *Drug Channels* blog. November 9. <https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html>.
- Fein, A. 2020a. PBM-owned specialty pharmacies expand their role in—and profits from—the 340B program. *Drug Channels* blog. July 21. <https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html>.
- Fein, A. 2020b. Why Part D plans prefer high list price drugs that raise costs for seniors. *Drug Channels* blog. January 22. <https://www.drugchannels.net/2020/01/why-part-d-plans-prefer-high-list-price.html>.
- Fein, A. 2018. Building a new drug wholesaler compensation model: What happens as brand inflation slows? *Drug Channels* blog. July 24. <https://www.drugchannels.net/2018/07/building-new-drug-wholesaler.html>.
- Fein, A. 2016. Behind Diplomat Pharmacy's plunge: A primer on DIR Fees in Medicare Part D. *Drug Channels* blog. November 8. <http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html>.
- Feldman, R. 2018. Perverse incentives: Why everyone prefers high drug prices—Except for those who pay the bills. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3162432.
- Food and Drug Administration. 2021. FDA approves Cyltezo, the first interchangeable biosimilar to Humira. Press release. October 18. <https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira>.
- Frank, R. G., M. Shahzad, A. Kesselheim, et al. 2022. Biosimilar competition: Early learning. *Health Economics*. Published online January 12. doi:10.1001/jamaoncol.2021.5433.
- Garthwaite, C. 2019. Testimony by Craig Garthwaite, Associate Professor of Strategy, Herman Smith Research Professor in Hospital and Health Services Management, Director of the Program on Healthcare at Kellogg (HCAK) at the Kellogg School of Management at Northwestern University before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy, and Consumer Rights. June 19. <https://www.judiciary.senate.gov/imo/media/doc/Garthwaite%20Testimony.pdf>.
- 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/>.
- Gifford, K., A. Lashbrook, S. Barth, et al. 2020a. *State Medicaid programs respond to meet COVID-19 challenges: Results from a 50-state Medicaid budget survey for state fiscal years 2020 and 2021*. Washington, DC: Kaiser Family Foundation.
- Gifford, K., A. Winter, and L. Wiant. 2020b. *How state Medicaid programs are managing prescription drug costs: Results from a state Medicaid pharmacy survey for state fiscal years 2019 and 2020*. Issue brief. Washington, DC: Kaiser Family Foundation.
- Government Accountability Office. 2016. *Generic drugs under Medicare: Part D generic drug prices declined overall, but some had extraordinary price increases*. GAO-16-706. Washington, DC: GAO.

- Gray, C., C. E. Cooke, and N. Brandt. 2019. Evolution of the Medicare Part D medication therapy management program from inception in 2006 to the present. *American Health and Drug Benefits* 12, no. 5 (September): 243–251.
- 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.
- Hagen, T. 2021a. Adalimumab biosimilars face product obsolescence before launch. *AJMC*. January 6. <https://www.centerforbiosimilars.com/view/adalimumab-biosimilars-face-product-obsolescence-before-launch>.
- Hagen, T. 2021b. Basaglar “biosimilar” had strong downward effect on insulin glargine prices. *AJMC*. October 19. <https://www.centerforbiosimilars.com/view/study-basaglar-biosimilar-had-strong-downward-effect-on-insulin-glargine-prices>.
- Hagen, T. 2021c. FDA approves Yusimry, the seventh adalimumab biosimilar. *AJMC*. December 20. <https://www.centerforbiosimilars.com/view/fda-approves-yusimry-the-seventh-adalimumab-biosimilar>.
- Hargrave, E. 2017. *Stakeholder perspectives about the roles of pharmacy benefit managers and specialty pharmacies in the specialty drug market*. Contractor report prepared for the Medicare Payment Advisory Commission. Washington, DC: MedPAC.
- Higgins-Dunn, N. 2021. AbbVie repeatedly hiked Humira, Imbruvica prices and abused patents to keep competitors at bay: Report. *Fierce Pharma*, May 18. <https://www.fiercepharma.com/pharma/abbvie-repeatedly-raised-prices-for-humira-imbruvica-and-abused-u-s-patent-system-to-extend>.
- Hinton, E., R. Rudowitz, L. Stolyar, et al. 2020. *10 things to know about Medicaid managed care*. Issue brief. Washington, DC: Kaiser Family Foundation.
- House Committee on Oversight and Reform. 2021. *Drug pricing investigation: AbbVie–Humira and Imbruvica*. A Committee on Oversight and Reform majority staff report. Washington, DC: Government Printing Office.
- Hwang, T. J., X. Qin, H. A. Huskamp, et al. 2021. Assessment of out-of-pocket costs with rebate pass-through for brand-name cancer drugs under Medicare Part D. *JAMA Oncology*. Published online November 11. doi:10.1001/jamaoncol.2021.5433.
- Johnson, N., C. Mills, and M. Kridgen. 2018. *Prescription drug rebates and Part D drug costs*. Milliman report prepared for America’s Health Insurance Plans. Seattle, WA: Milliman.
- Lee, C. C., M. Najafzadeh, A. S. Kesselheim, et al. 2021. Cost to Medicare of delayed adalimumab biosimilar availability. *Clinical Pharmacology & Therapeutics* 110, no. 4 (October): 1050–1056.
- Lieberman, S., M. Darling, and P. Ginsburg. 2017. A billion here, a billion there: Selectively disclosing actual generic drug prices would save real money. USC–Brookings Schaeffer Initiative for Health Policy blog post. September 12.
- Liu, D. L., Centers for Medicare & Medicaid Services, Office of the Actuary. 2021. Personal email communication with author, December 7.
- Long, D. 2021. U.S. specialty pharmaceutical trends, issues and outlooks for Asembia. Presentation to the Specialty Pharmacy 2021 Summit by Doug Long, VP, Industry Relations, IQVIA. October 27. <https://www.drugchannelsinstitute.com/files/Fein-Long-Asembia-27October2021.pdf>.
- Marsh, T. 2021. Can’t access generic humalog? There’s an even cheaper insulin option available. *GoodRx Health*, August. <https://www.goodrx.com/admelog/admelog-now-cheaper-than-generic-humalog>.
- McGowan, S. 2021. *Biosimilars pipeline report: A guide for understanding the growing market*. Conshohocken, PA: AmerisourceBergen.
- Medicare Payment Advisory Commission. 2021a. *A data book: Health care spending and the Medicare program*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2021b. *Payment basics: Part D payment system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2021c. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2020a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2020b. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2017a. Background on pharmacy benefit managers and specialty pharmacies. Presentation at the Commission's September public meeting. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/pbms-and-specialty-pharmacies---final.pdf.

Medicare Payment Advisory Commission. 2017b. Payment and plan incentives in Part D. Presentation at the Commission's April public meeting. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/payment-and-plan-incentives-in-part-d-april-2017-for-public.pdf.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Today. 2021. Senior satisfaction survey. <https://medicaretoday.org/resources/senior-satisfaction-survey/>.

Mulcahy, A., D. Schwam, and N. Edenfield. 2020. *Comparing insulin prices in the United States to other countries: Results from a price index analysis*. Santa Monica, CA: RAND Corporation. https://www.rand.org/pubs/research_reports/RRA788-1.html.

Nash, P., J. Vanhoof, S. Hall, et al. 2016. Randomized crossover comparison of injection site pain with 40 mg/0.4 or 0.8 mL formulations of adalimumab in patients with rheumatoid arthritis. *Rheumatology and Therapy* 3, no. 2 (December): 257-270.

National Conference of State Legislatures. 2019. State laws and legislation related to biologic medications and substitution of biosimilars. <https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx#:~:text=Authorizes%20a%20pharmacist%20to%20select,is%20not%20to%20be%20made>.

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.

Office of Inspector General, Department of Health and Human Services. 2018. Letter from Gregory E. Demske, Chief Counsel of HHS OIG to James C. Stansel, Executive VP and Chief Counsel of PhRMA. <https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf>.

Park, J., and K. A. Look. 2020. Part D coverage gap reform: Trends in drug use and expenditures. *American Journal of Managed Care* 26, no. 8 (August): 349-356.

Rind, D., F. Agboola, D. Nikitin, et al. 2021. *Unsupported price increase report: Unsupported price increases occurring in 2020; Interim report*. Boston, MA: Institute for Clinical and Economic Review.

Rome, B. N., F. A. Tessema, and A. S. Kesselheim. 2020. US spending associated with transition from daily to 3-times-weekly glatiramer acetate. *JAMA Internal Medicine* 180, no. 9 (September 1): 1165-1172.

Ross, C. 2018. Extraordinary tactics, perverse incentives: Makers of top-selling drugs hike prices in lockstep, and patients bear the cost. *Stat News*, November 14. <https://www.statnews.com/2018/11/14/humira-abbvie-amgen-enbrel-price-hikes-biosimilars/>.

Sagonowsky, E. 2017. IRS investigates patient charity as a possible 'conduit' for Big Pharma sales. *Fierce Pharma*, June 29. <https://www.fiercepharma.com/pharma/irs-probes-whether-patient-charity-acted-as-a-conduit-for-big-pharma>.

Schondelmeyer, S., and L. Purvis. 2019. *Trends in retail prices of generic prescription drugs widely used by older Americans: 2017 year-end update*. Washington, DC: AARP.

Schwartz, K., M. Rae, and T. Neuman. 2020. *What we know about provider consolidation*. Washington, DC: Kaiser Family Foundation.

Scott Morton, F., and L. Boller. 2017. *Enabling competition in pharmaceutical markets*. Working paper #30. Washington, DC: Center for Health Policy at Brookings.

Sood, N., K. Mulligan, and K. Zhong. 2021. Do companies in the pharmaceutical supply chain earn excess returns? *International Journal of Health Economics and Management* 21, no. 1 (March): 99-114.

Sood, N., M. Ribero, M. Ryan, et al. 2020. *The association between drug rebates and list prices*. Los Angeles, CA: USC Schaeffer, Leonard D. Schaeffer Initiative for Innovation in Health Policy & Economics.

Stanton, D. 2021. Boehringer's adalimumab becomes first interchangeable mAb biosimilar. *BioProcess International*, October 20. <https://bioprocessintl.com/bioprocess-insider/regulations/boehringers-adalimumab-becomes-first-interchangeable-mab-biosimilar/>.

Starc, A., and A. Swanson. 2021a. Preferred pharmacy networks and drug costs. *American Economic Journal: Economic Policy* 13, no. 3 (August): 406-446.

Starc, A., and A. Swanson. 2021b. Promoting preferred pharmacy networks. 1% steps for health care reform. <https://onepercentsteps.com/wp-content/uploads/brief-pppn-210208-1700.pdf>.

Stern, A. D., J. L. Chen, M. Ouellet, et al. 2021. Biosimilars and follow-on products in the United States: Adoption, prices, and users. *Health Affairs* 40, no. 6 (June): 989–999.

Trish, E., K. Kaiser, and G. Joyce. 2021. Association of out-of-pocket spending with insulin adherence in Medicare Part D. *JAMA Network Open* 4, no. 1 (January 4): e2033988.

U.S. Senate Committee on Finance. 2021. *Insulin: Examining the factors driving the rising cost of a century old drug*. A Senate Finance Committee staff report. Washington, DC: Government Printing Office.

Van de Wiele, V. L., A. S. Kesselheim, and A. Sarpatwari. 2021. Barriers to US biosimilar market growth: Lessons from biosimilar patent litigation. *Health Affairs* 40, no. 8 (August): 1198–1205.

Verma, S. 2020. The Part D Senior Savings Model: Reducing out-of-pocket costs for insulin in Medicare Part D. *Health Affairs* blog. March 11. <https://www.healthaffairs.org/doi/10.1377/hblog20200311.582575/full/>.

Watral, D. 2019. AbbVie says Humira's many patents is no antitrust violation. *Law 360*, October 15. <https://www.kirkland.com/news/in-the-news/2019/10/abbvie-says-humiras-many-patents-is-no-antitrust-v>.

Wedell, K. 2021. 'It is legal extortion.' Diabetics pay steep price for insulin as rebates drive up costs. *USA Today*, December 13. <https://www.usatoday.com/story/money/2021/12/13/diabetes-insulin-cost-prices-rebates/8821585002/?gnt-cfr=1>.

Wells, A. 2021. The top 10 most expensive popular brand-name drugs in the U.S. (and how to save). *GoodRx Health*, July 14. <https://www.goodrx.com/healthcare-access/drug-cost-and-savings/top-10-most-expensive-popular-brand-name-drugs-us-how-to-save>.

