Research Report

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Prescription Drug Prices, Rebates, and Insurance Premiums

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About This Report

Section 204 (of Title II, Division BB) of the Consolidated Appropriations Act, 2021, requires insurance companies and employment-based health plans to submit information to the government annually on top drugs by volume, cost, and negotiated discounts; total negotiated discounts by therapeutic class; and enrollment, premiums, and other information. As required by the law, the U.S. Department of Health and Human Services (HHS), on behalf of the Department of Labor and the Department of the Treasury, will prepare biannual public reports describing the newly collected data and addressing the extent to which the data can help describe payment for drugs by private health insurance plans and issuers, trends in drug prices, and links between drug spending and premiums. The HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) has contracted with RAND to assist in the preparation of an initial report analyzing trends in drug spending, other health care costs, and premiums in commercial markets to provide a framework for later analyses related to the series of public reports.

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Summary

Section 204 (of Title II, Division BB) of the Consolidated Appropriations Act (CAA), 2021,[1] requires private health insurance plans and issuers[2] (with "plan sponsors and issuers" reporting information) to report information on enrollment, premiums, health care spending, and prescription drug utilization and spending to the federal government. The data collected under this requirement, known as Prescription Drug Data Collection (RxDC for short), will broaden policymakers' understanding of prescription drug markets under commercial coverage at the same time state and federal governments implement and debate major policies to address drug prices and spending.

Under the CAA, the government must release public reports describing these new data and addressing specific research questions, including discussion of potential links between drug spending and premium growth. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services (HHS) will develop these public reports on behalf of the Department of Labor, the Department of the Treasury, and the Office of Personnel Management. To help inform ASPE's report, a RAND team

- examined U.S. trends in prescription drug coverage, prices, and spending
- summarized extant evidence on associations between drug spending and premiums
- to the extent feasible, conducted illustrative analyses using 2020 and 2021 RxDC data.

In this report, the authors share their findings from their analysis and recommendations to the government to address limitations of the RxDC data.

[1] Section 204 falls under Title II of Division BB, "Transparency." Title I of Division BB is the No Surprises Act.

[2] In this report, the term *private health insurance plans and issuers* will be used to refer to all group health plans (both self-insured and fully insured) sponsored by employers (including state and local governments) and all group and individual health insurance coverage. These terms do not include plans operated by private companies for beneficiaries of public insurance programs, such as Medicare or Medicaid. However, the Office of Personnel Management joined the U.S. Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the "Departments") to require the submission of prescription drug and health care spending data from Federal Employees Health Benefits (FEHB) plans in the same manner that private health insurance plans and issuers must provide such data under Section 204 of Title II, Division BB, of the CAA (Office of Personnel Management, Department of the Treasury, Department of Labor, and Department of Health and Human Services, 2021). Accordingly, for the purposes of this report, the term *private health insurance plans and issuers* should be considered to include FEHB plans.

Market Dynamics for Retail-Dispensed Brand-Name Drugs

The market for prescription drugs is complex, with many stakeholders (e.g., drug companies, distributors, pharmacies, and health care providers) and detailed, typically bilateral contractual arrangements guiding the transfer of products, payments, and information between these stakeholders. The specific details of these relationships vary across categories of drugs, distribution channels, and payers. *On-patent* brand-name drugs are a key prescription drug category from a policy perspective: These drugs account for a small share of total prescription fills and a much larger share of total drug spending.[3] In contrast, roughly nine of every ten fills in the United States are with generic drugs that tend to be much less expensive than their brand-name counterparts.

For some on-patent, brand-name drugs dispensed through retail and mail-order distribution channels, rebates paid by drug companies to pharmacy benefit managers (PBMs) in exchange for favorable formulary placement lead to an important distinction between the cost of drugs to insurers and their PBMs at *gross* prices versus lower *net* prices. In the typical case, drug companies initially sell drugs to distributors, pharmacies, and other intermediaries at a *manufacturer gross* or *list* price (for example, $100).[4] These initial buyers sell drugs with markups on top of the manufacturer's gross price (for example, a $120 pharmacy price). For drugs dispensed via retail channels, this total amount is paid to the pharmacy by some combination of the patient (through cost sharing—for example, $30) and, if applicable, the patient's drug coverage (for example, $90 from the insurer). Then, later, the drug company sends a payment in the form of a rebate to the PBM such that the ultimate net price paid by insurers is less than their initial outlay (for example, with a rebate of $70, the net price paid for the drug is $50, with $30 paid by the patient and $20 by the insurer). Rebates tend to be higher when there are close substitutes to the drug in question, such as drugs in the same therapeutic class, and when insurers and PBMs have leverage to shift patients and prescribers to one manufacturer's preferred drug over another through tiered formulary benefit structures[5] and utilization management (for example, prior authorization, step therapy requirements, and quantity limits).

PBMs, which have more specialized expertise in designing and maintaining drug benefits than commercial insurers and plan sponsors, typically negotiate rebates for brand-name drugs

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[3] More specifically, these on-patent brand-name drugs are protected from direct competition by some combination of patents and regulatory exclusivity granted by the U.S. Food and Drug Administration (FDA) that run in parallel. *Off-patent* drugs can be sold in the United States under a brand name but account for a small share of total spending (Mulcahy et al., 2021b).

[4] The actual transactional prices at this stage often involve modest discounts off of list prices—for example, for prompt payment.

[5] Tier formularies require lower cost sharing for therapeutic alternatives where a plan sponsor or its PBM faces a lower cost and higher cost sharing for other alternatives where the PBM faces a higher cost. Many tiered formularies place inexpensive generic drugs on the most preferred tier with no or low cost sharing, followed by preferred brand-name drugs where PBMs negotiate the lowest net price, then other, non-preferred brand-name drugs, and finally very expensive specialty drugs.

and implement tools to steer patients and prescribers to preferred brand-name drugs (typically those that are more highly rebated) instead of others. When rebates are paid by drug companies to PBMs, the PBM may in some cases retain a portion of the negotiated rebate as its own margin (either a share or flat margin depending on contractual arrangements).[6]

Most PBMs also receive administrative and service fees from plan sponsors. These fees may be considerably larger in magnitude than amounts retained from rebates from brand-name drugs, if any. PBMs also play an important broader role in cost control—for example, by steering patients to inexpensive generic drugs and generally less-expensive (to PBMs and payers) mail-order distribution compared to retail pharmacy distribution. Supply chains and financial incentives differ for generics and mail-order drugs, as well as for physician-administered drugs and drugs administered or dispensed as part of an inpatient facility stay, compared with the market dynamics for retail-dispensed brand-name drugs summarized above. Other stakeholders, including group purchasing organizations and separate pharmacies specializing in high-cost "specialty" drugs, can play important roles in these other scenarios, although specific arrangements vary and increasing vertical consolidation is gradually blurring some historical divisions between stakeholder types.

The Importance of RxDC

Relatively little is known about the business arrangements between PBMs and their clients for retail-dispensed, brand name drugs. This is particularly the case for their commercial clients, despite the importance of these contractual relationships in determining the net prices paid by plans and issuers for drug coverage and the implications for patients. While there is some evidence that PBMs generally pass most of negotiated rebates to payers (Sood et al., 2017), less is known about specific PBM practices, including whether the negotiation process determining net prices for many brand-name drugs may inflate list prices and the extent of PBMs' revenue from clients through channels other than retained rebates. If PBMs do effectively lower spending for their clients in net terms, plan sponsors and issuers could, conceptually and where applicable, lower premiums, provide additional benefits to enrollees, increase their own profit, or return amounts to beneficiaries under medical loss ratio (MLR) policies.

RxDC aims to address the lack of a comprehensive, reliable source of information on enrollment, premiums, and drug and non-drug health care spending among enrollees in commercial health plans. In particular, RxDC fills an important gap in policymakers' understanding of the net drug prices faced by the private payers, which account for the majority of Americans with health coverage (Keisler-Starkey, Bunch, and Lindstrom, 2023), and their

[6] In Medicare Part D, PBMs pass 99 percent of rebates on to plan sponsors (U.S. Government Accountability Office, 2019). Contractual arrangements between PBMs and plan sponsors may vary in commercial coverage.

PBMs.[7] The federal government already receives information on the magnitude of rebates from sponsors of Medicare Part D outpatient retail drug plans and from state Medicaid programs. Furthermore, the government has access to negotiated net prices from certain public health programs, such as the Veterans Health Administration.

Analysis of the implications of the net price negotiation for consumers, including premiums paid by all enrollees and cost sharing paid by patients receiving prescription drugs, has historically been challenging to conduct because of the lack of data on net prices paid by private health insurance plans and issuers. The Section 204 reporting requirements are intended to result in broad, generalizable data useful to inform analyses of this type. The Section 204 data and the research that the data will enable are particularly timely given the ongoing debate on the merits of PBM drug price negotiation and rebates as opposed to other policy approaches to address high U.S. drug prices.

Research Questions and Approach

This report addresses a set of specific research questions developed by ASPE in three main areas: trends in prescription drug spending at gross and net prices; trends in coverage for prescription drugs, including benefit design; and implications of rebates for consumers (Table S.1). More broadly, this background report aims to lay a foundation for future biannual ASPE reports to Congress which, per the CAA, must address the following topics:

1. payment for drugs under commercial plans
2. prescription drug price and spending trends
3. the relationship between drug spending and premiums.

To address both the scope of CAA biannual reports and ASPE's broader research questions, we conducted a series of environmental scans (one on each broad topic), and, for trends in drug spending and coverage, we analyzed several publicly available data sources. Our efforts and findings were informed by interaction with a technical expert panel (TEP) and conversations with a separate, small set of key informants. As a final step, we conducted a set of illustrative analyses using 2020 and 2021 RxDC data.

[7] This report uses *coverage* and *insurance* as synonyms for clarity and consistency across sources, some of which use one, the other, or both terms. Technically, coverage under self-insured plans is not considered insurance. under the Public Health Service Act, the Employee Retirement Income Security Act (ERISA), and elsewhere in statute and regulation.

Table S.1. Research Questions

Drug Spending and Price Trends	Drug Coverage and Premium Trends	Implications of Rebates for Patients
• What are the trends in gross drug spending and drug spending by group and individual market plans? • What are the trends in prescription drug spending net of rebates in these plans? • How do the trends vary by market segment and therapeutic class?	• What are trends in the number of people with prescription drug coverage in group and individual market plans? • What proportion of individuals with prescription drug coverage are subject to the essential health benefits (EHB) standards under the Affordable Care Act? • What are the trends in premiums for group and individual market health coverage? • What are the trends in employer and employee contributions toward group premiums? • What are the trends in overall deductibles and out-of-pocket limits? • What are the trends in separate prescription drug deductibles and out-of-pocket limits? • What are the trends in prescription drug benefit design and cost sharing, including use of copayments versus coinsurance? • What are the trends in plan use of formularies? • How have plans handled COVID-19 therapeutics available under Emergency Use Authorization?	• How have the following contributed to premium changes over time, and how have these impacts varied by market segment? (a) prescription drug costs, net of rebates; (b) hospital services; (c) physician services; (d) other spending categories • How does the use and impact of prescription drug rebates in commercial drug coverage compare with the use and impact of rebates in Medicaid and in Medicare Part D? • What is the quality of the evidence in regard to data sources, empirical methods, and ability to compare estimates across studies and payers?

Statutory Charge: Overview of Section 204 Reporting Requirements

HHS, the Department of Labor, and the Department of the Treasury (the "Departments") promulgated regulations to implement Section 204 of the CAA in November 2021 (Office of Personnel Management, Department of the Treasury, Department of Labor, and Department of Health and Human Services, 2021). Section 204 and the regulations lay out a list of specific data elements that are reported annually aggregated to each combination of plan sponsor or issuer employer identification number (EIN) level,[8] market segment (student market, individual market, fully insured small group plans, fully insured large group plans, self-insured small group plans, self-insured large group plans, and Federal Employees Health Benefits [FEHB] Program plans), and state.

The following box summarizes the specific information included, with information reported separately for each drug in several "top drug" lists. For information reported at the drug and

[8] The initial RxDC instructions required aggregation at the plan sponsor, issuer, or third-party administrator (TPA) employer identification number (EIN) level, with the further requirement that submissions may not be more aggregated than the level of aggregation for one of the submitted templates (D2, "spending by category," described elsewhere). This restriction was later waived, allowing aggregation at higher levels (specifically, at the PBM level). The report addresses this issue in later chapters.

therapeutic class levels, the Centers for Medicare & Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight (CCIIO) developed a crosswalk linking National Drug Codes (NDCs), which are identifiers for specific drug products, to standardized definitions of RxDC "drug" and "therapeutic class" for reporting purposes. In addition to the listed data elements, private health insurance plans and issuers must report whether there were reductions in premiums and out-of-pocket costs associated with rebates and other discounts. Submitters can meet this last requirement with narrative statements rather than empirical estimates.

RxDC Data Elements

Private health insurance plans and issuers, on behalf of their plans subject to RxDC reporting, must report the following annual information aggregated by submitter, market segment, and state across a set of "plan templates" and eight "data templates" labeled D1 through D8:

- plan characteristics (including enrollment, market segment [e.g., fully insured large employer versus individual market], and states in which the plan is offered)
- total spending on drugs and categories of medical services (for example, hospital care)
- premiums paid monthly
- total out-of-pocket costs for drugs
- claim volume for the top 50 brand-name drugs by volume (separately by drug for this and other "top drug" lists)
- payments for the top 50 drugs by payments (at net prices)
- payment increases from the prior plan year for the top 50 drugs by magnitude of increase
- rebate and other remuneration amount for the top 25 drugs by this amount
- total rebates and other remuneration by therapeutic class.

In addition, private health insurance plans and issuers must submit plan-level information (including plan ID numbers; market segment; covered lives; and PBM, third-party administrator [TPA], carrier, and other employer identification numbers [EINs], as relevant) in one of three "P" templates.

The reporting requirement applies to plans and issuers. However, in some cases, an entity other than a plan sponsor (reporting on behalf of its plans) or issuer, such as a TPA or a PBM, might submit information on behalf of a plan or issuers, either as a service or because these other organizations are the only entities with access to the required information. For example, while plan sponsors might have information on total annual prescription drug spending across all applicable beneficiaries, they may need to rely on their PBMs for lists of rank-ordered individual drugs by magnitude of spending or rebates. The regulations allow TPAs and PBMs to submit information on behalf of plans as "reporting entities."

Although private health insurance plans and issuers were required to submit 2020 data by December 27, 2021, in response to requests from the reporting entities, the Departments allowed later submission of both 2020 and 2021 data.[9] ASPE within HHS is the lead for development of a series of biannual reports to Congress describing and analyzing the collected data on behalf of the three departments and the Office of Personnel Management.

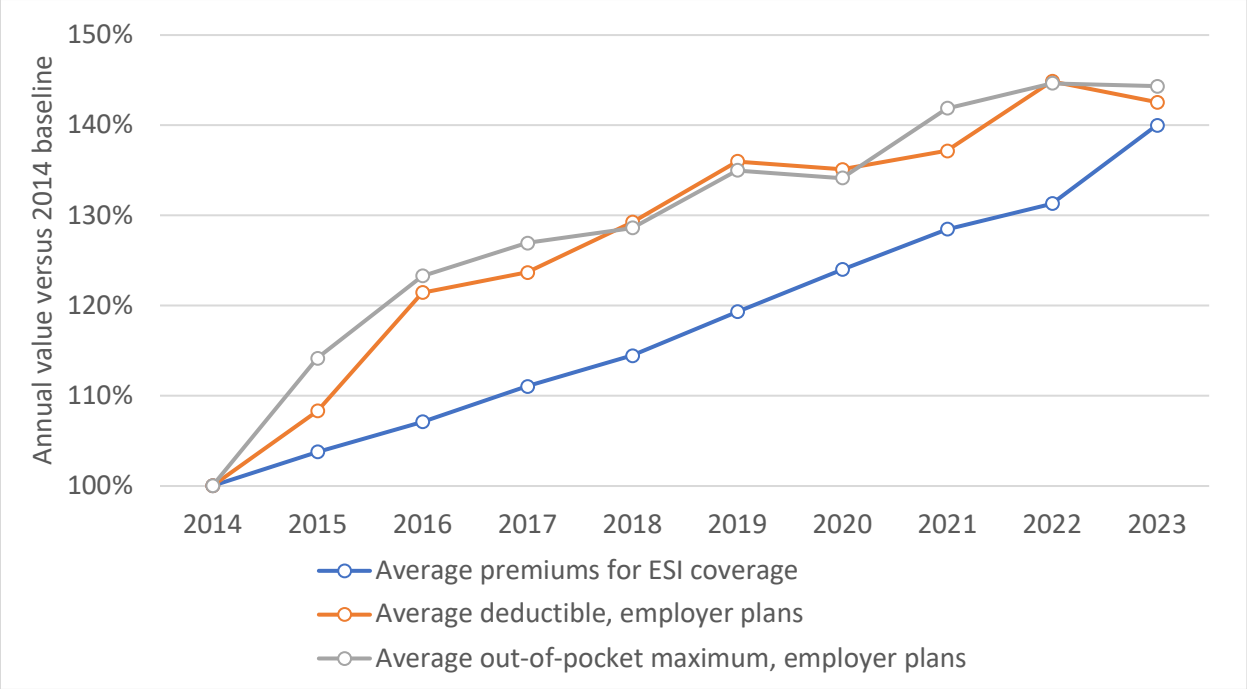
[9] The Departments allowed submissions covering both 2020 and 2021 through December 27, 2022, with a later extension through January 31, 2023.

Findings

Insurance Coverage for Drugs, Insurance Benefit Design, and Premium Trends

In terms of drug coverage, we found that nearly all enrollees[10] in large group health plans have prescription drug coverage through the same plan that provides their broader health insurance. The share of enrollees with drug coverage through their non-group health plans is likely to be lower, as not all off-Marketplace non-group health plans are required to meet EHB requirements (which include drug coverage). Premiums, deductibles, and out-of-pocket maximums have grown over time overall and across different plan types (see Figure S.1 for illustrative trends in employer coverage and Chapter 2 for full details across plan types). Formularies, which are the lists of drugs covered under a drug benefit and are often paired with lower cost sharing for drugs with higher negotiated rebates, are becoming "deeper" (that is, with a greater number of tiers to differentiate drugs at different cost sharing levels) over time.

Figure S.1. Selected Premium, Deductible, and Out-of-Pocket Maximum Trends, 2014–2022



SOURCE: Authors' analysis of 2014–2022 Kaiser Family Foundation (KFF) Employer Health Benefit Survey data, 2014–2023 KFF Marketplace Cost-Sharing Summaries.
NOTE: For plans with combined medical and drug deductibles, this figure summarizes that deductible. For plans with separate medical and drug deductibles, this figure summarizes the medical deductible. Data are enrollment-weighted.

[10] For brevity, we use "enrollees" to refer collectively to participants and beneficiaries (as applicable to group health plans) as well as enrollees in non-group health plans.

Relatedly, we found that the use of coinsurance (that is, where patients are responsible for a share of list prices) rather than copayments (that is, where patients are responsible for a fixed amount) is increasingly common for more expensive drugs, particularly in Marketplace plans. For example, in 2014, 28 percent of Marketplace plans used coinsurance and 50 percent used copays for non-preferred brand drugs; by 2022, 52 percent used coinsurance and 19 percent used copays. Because coinsurance is based on quickly growing list prices, coinsurance amounts also increase quickly despite relatively slower growth in the net amounts paid by PBMs. Patients with coverage may also be exposed to higher list prices during the deductible phase of their benefit. Deductibles increased on average by 5 percent annually between 2014 and 2022 among employer plans and by 8 percent annually between 2014 and 2023 among Marketplace plans with combined medical and prescription drug deductibles.

Drug Spending and Price Trends

In our literature reviews and analysis of secondary data, we found some evidence that the average list prices set by drug companies are increasing at a faster rate over time compared with the net amount retained by drug companies or the net prices paid by insurers and their PBMs (that is, after rebates). One recent report estimated year-on-year growth of 6.9 percent for spending on drugs at gross prices from 2011 to 2022, compared with a lower 4.7 percent growth rate for payer spending at net prices over the same period (IQVIA, 2023). This suggests that a growing "wedge" between list and net prices, driven mostly by increases in list prices, yields increasingly larger margins for PBMs. However, there is scant evidence on the actual margins retained by PBMs, with a few studies suggesting a shift away from PBMs retaining a share of gross-to-net negotiated discounts and instead receiving service-based and other fees from their clients.

Patient out-of-pocket spending as a share of total drug spending was relatively constant for those with group and marketplace coverage and decreased by roughly 50 percent for those with off-market individual coverage. For retail-dispensed prescription drugs, average annual cost sharing for large group plan enrollees was relatively stable, decreasing from $125 in 2014 to $109 in 2019.[11] Despite this modest relative decline overall, we found that aggregate out-of-pocket spending in dollar terms increased dramatically for some therapeutic classes from 2014 to 2020, including a near-doubling of out-of-pocket spending for oncology drugs.

Empirical Evidence on Links Between Rebates, Spending, and Premiums

Relatively little existing empirical research links drug spending directly to premiums, changes in benefit design, or other specific impacts on consumers. Conceptually, this linkage is

[11] Annual spending figures are not adjusted for inflation. For comparison, adjusting for the Consumer Price Index, All Urban Consumers (CPI-U), a $125 annual out-of-pocket amount in 2014 would have been 10 percent higher in 2019 ($137).

likely complex; premiums are only one of many levers that insurers can adjust when prescription drug spending changes. For example, there is some anecdotal evidence suggesting that insurers prefer to keep premiums low and adjust other plan features, such as cost sharing and other aspects of plan generosity, when drug spending increases because of the outsized influence that premium levels have on enrollment decisions.

There is broad consensus that price negotiation and rebates result in net prices that are substantially lower than gross prices. For some therapeutic classes—for example, insulins—the gross-to-net discount may approach 80 percent for commercial payers (Mulcahy et al., 2021a). However, the status quo of drug company and PBM negotiation does introduce some concerning incentives, including potential upward pressure on list prices that are the basis for consumer cost sharing.

Higher and increasing list prices, even if negotiated net prices are lower, raise important policy and equity concerns. For example, patients filling expensive prescriptions may pay a disproportionate total share of the cost of drugs through cost sharing, particularly when enrolled in a plan offering relatively lower premiums and relatively larger patient liability for drug spending. Untethering cost sharing from list prices or restricting cost sharing in other ways may lead to a less skewed distribution of drug costs across all plan enrollees. Ultimately, the net effects of rebates on patients through premiums, cost sharing, and generosity of coverage are difficult to assess.

RxDC Data Limitations and Considerations

In our initial experience working with 2020 and 2021 RxDC data, we found that plan sponsors, insurers, other reporting entities used inconsistent and varying approaches to aggregating and attaching identifiers to their submissions. While PBMs often reported prescription drug spending, utilization, and rebate information, plan sponsors, issuers, and TPAs for medical coverage often reported the premium, enrollment, and medical spending information. Some PBMs submitted data aggregated at the PBM level rather than at the plan sponsor or issuer level—in other words, making one submission covering all of their clients' offerings in a given market segment and state. Submitters inconsistently reported plan sponsor, issuer, TPA, PBM, and other employer identification numbers (EINs) in the separate lists of plans submitted along with the eight main RxDC data templates, leaving unanswered questions regarding the extent of compliance with RxDC reporting requirements for plans and issuers. Overall, we found that only one in ten submitters defined by plan sponsor, market segment, and state had a full set of eight RxDC data templates.

As a result of inconsistent aggregation across submitters, we generally could not combine data submitted at different levels of aggregation, which is necessary to address several of the research questions posed by Section 204. To avoid the need to link across submissions and data templates, the analyses described in this report are limited to those using information only from

one of the eight RxDC data templates at a time. We also focused on relative comparisons rather than estimating absolute magnitudes. This helped address the very different level of data aggregation used by different submitters. While these restrictions mitigate several limitations and concerns regarding the underlying RxDC data, the narrower set of illustrative analyses does not address key research questions where links between submissions are required—for example, investigation of associations between drug and other health care spending and premiums.

A further limitation is that much of the drug spending and price information reported in the RxDC templates appears to be from the PBM perspective rather than the plan sponsor/issuer perspective, with important and potentially large payments from plan sponsors/issuers to PBMs (e.g., service fees or other contractual payments) excluded from the scope of RxDC data collection.

Illustrative Analyses of 2020 and 2021 RxDC Data

When analyzing RxDC drug spending information, we found ratios of net to gross drug prices of roughly 0.8, with modest differences across market segments and geography. In other words, for every $100 initially spent on drugs at gross prices, $20 is later returned to payers in the form of rebates and other discounts, for net spending of $80. This 0.8 ratio is higher than similar estimates from other studies, although, unlike RxDC data and our analysis, those studies focus on net-to-gross ratios from the manufacturer perspective, cover noncommercial markets, and use proprietary modeling to approximate both rebates and plan-sponsor-paid amounts. We also found results for specific therapeutic classes that aligned with expectations from prior studies, with relatively lower net prices for insulins, oral anticoagulants, and some other classes. These analyses, however, do not address whether these lower ratios are driven by relatively high gross prices, relatively low net prices, or both. Relatedly, we found generally small (albeit not necessarily statistically significant) decreases in net-to-gross ratios for individual therapeutic classes and across all drugs from 2020 to 2021—for example, from spending at net prices at 53 percent of spending at gross prices in 2020 versus 51 percent in 2021.

Inconsistencies in the submission of data in this first reporting cycle prevented us from analyzing the relationship between drug prices, spending, and premiums or other costs to consumers. In one narrow analysis using available RxDC data, we found some evidence of slight increases in the share of spending at net prices paid directly by patients out of pocket for a few drug classes from 2020 to 2021. For example, among kinase inhibitors, a class of expensive specialty drugs used primarily to treat cancers, out-of-pocket spending increased from 2.1 percent in 2020 to 2.9 percent in 2021.Despite the modest initial share, this is a large relative increase that may have important financial implications to patients given the high cost of these drugs.

Conclusions and Next Steps

Going forward, the data collected under Section 204 will likely serve as a helpful new input to policy development around commercial drug spending, premiums, benefit design, and related topics. However, given data limitations, there are limits to what analytic questions the already collected 2020 and 2021 data can answer, and these limitations also may apply to 2022 RxDC data that were submitted June 1, 2023. We propose a set of seven recommendations, including five technical and RxDC instruction clarifications and two implementation process recommendations. These recommendations do not necessarily reflect the views of ASPE. The five technical and RxDC instruction clarification recommendations are as follows:

1. Require reporting at a standardized, plan sponsor/segment/state level. (This includes rescinding a suspended "aggregation restriction" provision that allowed PBMs to report RxDC data at a more aggregated level than their plan sponsor clients.)
2. Broaden and standardize how submitter IDs are reported and linked so that the government is able to assess whether "plans and issuers" actually submit RxDC data.
3. Clarify and require that amounts come from the plan sponsor perspective.
4. Include enrollment, spending at net and gross prices, and out-of-pocket spending consistently across all templates.
5. Add high-level breakdowns for single-source brand, other brand, and unbranded generic drugs.

The final two recommendations deal with the implementation and processes surrounding RxDC:

6. Update documentation and instructions annually.
7. Provide technical assistance and organize listening sessions with PBMs and plan sponsors/issuers on an ongoing basis.

These and other potential changes and refinements to RxDC and the Section 204 reporting requirements would help to ensure that future analyses can address the government's interest in payment for drugs, trends in drug spending and prices, and associations between drug spending and premiums, as well as broader, related topics related to commercial drug coverage and impacts on consumers.

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Chapter 1. Introduction

Background

According to the Centers for Medicare & Medicaid Services (CMS) National Health Expenditure Accounts (NHEA) data, U.S. spending on retail-dispensed prescription drugs alone accounted for $405.9 billion, or approximately 9 percent of total U.S. health care spending, in 2022 (Hartman et al., 2023; CMS, 2023d). This amount reflects NHEA's estimates of after-the-fact discounts for certain drugs that, as we describe in this report, are an important determinant of drug spending. Per capita spending on retail prescription drugs increased by about 50 percent from 2012 through 2022, slightly lower than the 54 percent growth in per capita U.S. health care spending over the same period (Hartman et al., 2023; CMS, 2023d). In 2022, out-of-pocket spending for retail prescription drugs increased about 12 percent, the largest annual increase since 2002 (CMS, 2023d). The NHEA projects growth of approximately 57 percent in retail drug spending over the next decade (2022 through 2031) (CMS, 2023d). Other studies combine the NHEA retail prescription drug data and other data to estimate *total* U.S. spending on prescription drugs, expanding beyond NHEA's focus on retail-dispensed drugs to include those distributed and dispensed via physician offices, hospitals, and elsewhere in the health care delivery system.[12] One recent study estimated total U.S. prescription drug spending of roughly $600 billion in 2022 (IQVIA, 2023).[13]

Growing prescription drug spending for patients and taxpayers, as well as high drug prices, remain an important and perennial concern to policymakers, consumers, and providers alike (Hamel et al., 2022; U.S. House of Representatives, 2021; Chiaravalloti, 2018; Landon, Reschovsky, and Blumenthal, 2004). The most direct concerns link high drug prices, which correspond to higher out-of-pocket spending, to suboptimal use of prescription drugs, with important downstream implications for both health and health care spending (Khera et al., 2019; Iuga and McGuire, 2014). However, the magnitudes of drug spending and prices also raise a host of broader policy concerns related to the financing of the U.S. health care system, including the costs of drug and medical health insurance coverage, the tax financing and solvency of Medicare and other federal health care programs, and the contribution of Medicaid spending to strained state budgets.

[12] A report from the Altarum Institute estimated that spending on nonretail drugs (that is, drugs dispensed via hospital or other facility-based pharmacies) was about 40 percent of spending on retail drugs (Roehrig, 2018). The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) combined these estimates and reported that total spending on retail and nonretail drugs was 18 percent of U.S. health spending from 2016 to 2021 (Parasrampuria and Murphy, 2022).

[13] This estimate reflects spending by payers at net prices and across all distribution channels.

While the social and policy relevance of prescription drug spending is clear, there remain critical gaps in our understanding of how prescription drug markets function. For example, the prices ultimately paid by patients, health plans and issuers, and their pharmacy benefit managers (PBMs) for drugs are often unclear, particularly for expensive brand-name drugs, despite the importance of understanding the net amounts paid for drugs. This ambiguity stems in large part from complex and opaque contractual arrangements among several stakeholders. As we describe below, the most important of these arrangements reflects bargaining between manufacturers offering after-the-fact discounts and payers shifting utilization toward the manufacturer's products in exchange. Relatedly, and as a second example, the individual drug- and transaction-level margins retained by actors involved in the manufacture, distribution, dispensing, and coverage of prescription drugs are typically unknown, again despite the importance of understanding these margins and corresponding economic incentives when developing policy in this area.

Section 204 Reporting Requirements

To help address these gaps in information, the Consolidated Appropriations Act (CAA), 2021, created a new data collection requirement for private health insurance plans and issuers. Division BB, Section 204, of the CAA requires plan sponsors and issuers to report information on aggregate spending on drugs and non-drug health care; spending at gross prices (that is, initial prices, rather than net prices after rebates and other discounts) and rebate amounts by therapeutic class; and the top drugs by spending, volume, and rebates plus other renumeration. Section 204 also requires private health insurance plans and issuers to report on plan characteristics, premiums, enrollment, and other information. Finally, Section 204 requires collection of information on the impacts of rebates, fees, and other remuneration on premiums and out-of-pocket costs, which addresses the key policy questions described above.

While some of the prescription drug-related information required to be reported according to Section 204 is already available to policymakers and researchers for government programs, the already available data are rarely packaged together and are generally not available across such a broad range of commercial group and individual plans. The U.S. Department of Health and Human Services (HHS) already requires reporting of rebates and other remuneration for Medicare Part D plan sponsors. Separately, HHS or other parts of the federal government have access to information on amounts paid under the Medicaid Prescription Drug Rebate program and by public programs, such as the Veterans Health Administration and the Department of Defense TRICARE program. However, the government generally does not have information on the net prices paid by commercial payers for specific drugs.

RxDC Data Collection

To satisfy the data reporting requirements laid out in Section 204, HHS, along with the Department of Labor and the Department of the Treasury (the "Departments"), developed and implemented a new Prescription Drug Data Collection (RxDC) system, including templates, instructions, and submission mechanisms. Importantly, the first years of RxDC data collection apply only to drugs dispensed via the retail channel. Physician-administered drugs may be added in later years. See the box below for an overview of the information collected via RxDC.

The same section of the CAA requires the Departments to prepare biannual public reports describing payment for drugs under commercial plans, prescription drug pricing trends, and an assessment of the extent to which drug costs relate to premiums. The Departments and the Office of Personnel Management (which is applying the reporting requirements to Federal Employees Health Benefits [FEHB] Program plans) agreed that ASPE will lead the development of the reports. The first biannual report was due in 2023.

RxDC Data Elements

- Plan characteristics (for example, enrollment, plan year start and end dates)
- Premiums
- Total spending on drugs and categories of medical services (for example, hospital care)
- Total out-of-pocket costs for drugs
- Claim volume for the top 50 brand-name drugs by volume (separately by drug for this and other "top drug" lists)
- Payments for the top 50 drugs by payments (at net prices)
- Payment increases from prior plan year for the top 50 drugs by magnitude of increase
- Rebate and other remuneration amount for the top 25 drugs by rebate and other remuneration dollar amount
- Total rebates and other remuneration aggregated by therapeutic class (for all classes)
- The impact of rebates, fees, and other remuneration on premium and out-of-pocket costs (narrative response)

As of December 2023, plan sponsors and issuers (and other reporting entities submitting information on their behalf) had reported three years of data. Although private health insurance plans and issuers were required to submit 2020 data by December 27, 2021, in response to requests from the reporting entities, the Departments allowed later submission of both 2020 and 2021 data.[14] Data for 2022 were generally submitted by June 1, 2023, as per the statutory timeline.

The Departments initially required RxDC submissions to be aggregated to no more than the plan sponsor, issuer, or third-party administrator (TPA) EIN; market segment (for example, large and small self-insured and fully insured employment-based group health plans); and state level. There was also an initial limit of one submission of each of the eight RxDC reporting templates at this level (CMS, 2023a). Both of these limitations (on aggregation and the number of submissions) were later relaxed via updated reporting instructions.

[14] The Departments allowed submissions covering both 2020 and 2021 through December 27, 2022, with a later extension through January 31, 2023.

This ability of submitters to submit data at different levels of aggregation without coordinating with each other, coupled with variation in how submitters interpreted RxDC reporting instructions, led to differences in how submitters aggregated and reported information. In many cases, plan sponsors and issuers reported required information related to enrollment, non-drug medical spending, and premiums while their PBMs separately submitted information related to drug utilization and spending. While plan sponsors reported information only on their own plans, PBMs often aggregated information more broadly across all of their plan sponsor clients. As a result, at least in some cases, it is not possible to combine RxDC submissions containing enrollment, premium, and non-drug medical spending data with those containing drug utilization and spending data. This limitation narrows the range of analyses that is feasible with the initial years of RxDC data. Later sections of this report include further discussion of RxDC data limitations and considerations and findings from an initial set of analyses that was feasible using the first two years of RxDC data.

Key Policy Questions

The scope of the biannual Section 204 reports focuses on

1. payment for drugs under commercial plans
2. prescription drug price and spending trends
3. the extent to which drug spending relates to premiums.

The newly collected RxDC data can directly address the first two topics identified by Section 204. The main contribution of RxDC data is in quantifying the *rebates* received by private health insurance plans and issuers and their *spending at the resulting net prices*. While the RxDC data will also reflect payer spending at initial, gross prices, this information is already captured to a large extent for commercial insurers via third-party claims aggregators.[15] Information on the magnitude of rebates and the resulting net prices to private insurers and their PBMs is primarily relevant to certain on-patent, brand-name drugs where rebates are common and substantial in magnitude. Relatedly, RxDC collects relatively little information specific to generic drugs. However, generic drugs do contribute to total drug spending reported via RxDC.

On the third topic, one RxDC question asks submitters directly to describe in narrative form how drug spending relates to premiums and asks for a quantitative estimate only "if possible." Many responses to this question were, as described later in this report, high-level narratives. While drug spending is conceptually related to premiums, so are benefit design (for example, formulary structure and cost sharing), non-drug medical spending, and a host of other factors.

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[15] The Health Care Cost Institute, Marketscan (from Merative, formerly Truven/IBM), Fair Health, and other vendors capture broad convenience samples of commercial pharmacy claims from large group health plans. Other vendors, such as IQVIA and Symphony Health, along with state all-payer claims databases, capture broader prescription claims activity. Each of these sources includes initial gross spending and prices for specific pharmacy claims but does not include spending at net prices.

While data collected via RxDC covers several of these interconnected impacts on consumers, it does not cover all of them.

Net Spending Dynamics for Certain Brand-Name Drugs

One of the least-understood aspects of the U.S. prescription drug market is the process by which companies selling brand-name drugs and PBMs negotiate the final, "net" price paid by a health plan and, therefore, net spending on a given drug. PBMs, which are the entities managing drug benefits and negotiating prices with drug companies on behalf of plan sponsors and issuers, provide a range of services to their clients.[16] However, their most important function is to negotiate discounts from drug companies in exchange for shifting patients and prescribers to the drug company's products through formularies, cost sharing, utilization management, and other tools. PBMs receive these negotiated discounts via rebates paid by drug companies. In most cases, PBMs pass a share of the rebates back to their clients and that amount, after addressing other fees and payments from plan sponsors and issuers to PBMs, determines the ultimate (or net) cost of a drug from the plan sponsor or issuer perspective.

Bargaining between drug companies and PBMs—and the resulting differences between spending at gross versus net prices—applies mainly to a small number of brand-name drugs that

1. are single source—that is, not available from multiple manufacturers as a generic or biosimilar
2. compete with other close substitute drugs in the same therapeutic area
3. are used in a clinical area where PBMs can effectively shift patients and prescribers to one of the multiple competing drugs.

The following paragraphs describe each of these three typical conditions in detail. See Appendix A for additional details on the stakeholders and flows of products, payments, and information related to prescription drug markets related to these three conditions.

Condition 1: Single-Source Drug

Single-source, brand-name drugs collectively account for only one in ten prescriptions filled in the United States (Association for Accessible Medicines, 2021; Buttorff, Xu, and Joyce, 2020). The remaining 90 percent of prescriptions are filled with multi-source generic drugs. Generic versions of the same drug compete with one another and with the original brand-name version of the drug on price directly. This and other factors—for example, incentives favoring

[16] The specific business relationships between a PBM and plan sponsor or issuer vary. In many cases, a commercial health plan sponsor or issuer contracts with a large, national PBM to manage its drug benefit and negotiate rebates from drug companies on behalf of the payer. In other cases, the insurer and PBM are part of the same company but are operated somewhat separately. Some broad health systems and public programs, such as the Veterans Health Administration, have a more integrated PBM function within a source of coverage or a government program. We describe PBMs and plan sponsors and issuers as separate entities in this report to emphasize their different functions while noting cases where incentives or outcomes may differ for more vertically integrated payer-PBM relationships.

pharmacy substitution of generics when available—drive prices for generic drugs downward and generic utilization rates up.

Condition 2: Competitive Drug Market

Importantly, negotiation between drug companies and insurers (and PBMs) applies only when there are one or more close substitute drugs. Otherwise, drug companies retain substantial leverage in negotiations, and discounts from list to net prices are modest, if they exist at all. Insulins are the archetypal example of the former case, with three large manufacturers selling broadly substitutable insulin products. PBMs leverage this competition to secure substantial reductions off list prices (roughly 80 percent) paid as rebates (Mulcahy et al., 2021a) in exchange for placing insulins from only one manufacturer on preferred formulary tiers. Many oncology drugs fall in the latter case, with no or few direct substitutes and few PBM and insurer tools to meaningfully steer patient and prescriber decisionmaking. There are likely few differences between list and net prices in this scenario because PBMs have little or no bargaining leverage.

Condition 3: PBM Leverage to Shift Prescribing Volume

The magnitude of the rebate negotiated between PBMs and drug companies hinges on how insurers and their PBMs steer patients and prescribers—and, therefore, volume—to a drug company's product rather than to a competitor's substitute product. Insurers and their PBMs use two main approaches to steer volume to a preferred brand-name drug on which the negotiated rebate is large. The first approach—tiered formularies paired with differential cost sharing—primarily targets patients, while the second approach—utilization management tools such as prior authorization requirements—primarily targets prescribers.

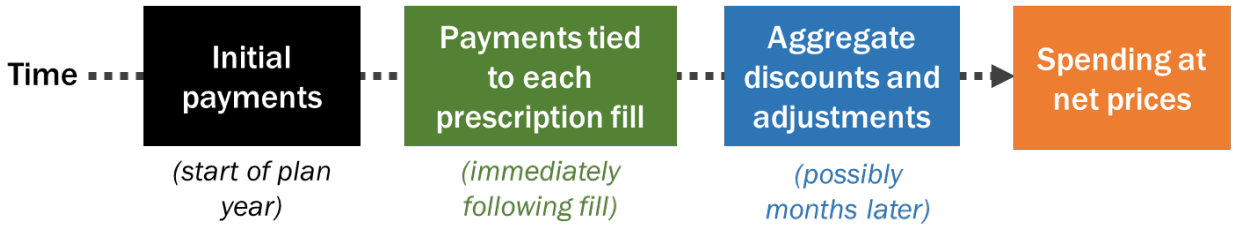
In sum, only a subset of single-source brand-name drugs are in therapeutic classes with close substitutes and where PBMs can effectively shift prescribing volume in exchange for price concessions from manufacturers. While plan sponsors, issuers, and their PBMs can recover some initial spending at gross price levels for other types of drugs—for example, contractual "claw back" payments from pharmacies to PBMs for even generic drugs—most of the aggregate rebates and other discounts stem from rebates paid on this narrow set of brand-name drugs.

Typical Payment Flows for Brand-Name Drugs with Large Gross-to-Net Discounts

Payment for brand-name drugs dispensed through retail pharmacies typically involve transactions at several points in time (Figure 1.1):

1. initial payments at the start of a coverage period
2. transactions at the time and immediately after a prescription is filled
3. after-the-fact rebates and adjustments that may happen months after a fill.

Figure 1.1. Typical Transaction Time Frames for Retail-Pharmacy-Dispensed Brand-Name Drugs



All of these transactions must occur before the exact net price and spending at net prices can be calculated. Because the calculation of rebates, discounts, and other adjustments typically occurs annually, the time between an initial payment to pharmacies (at an initial gross price) and the ultimate resolution of net price (for example, after rebates) may span several months.

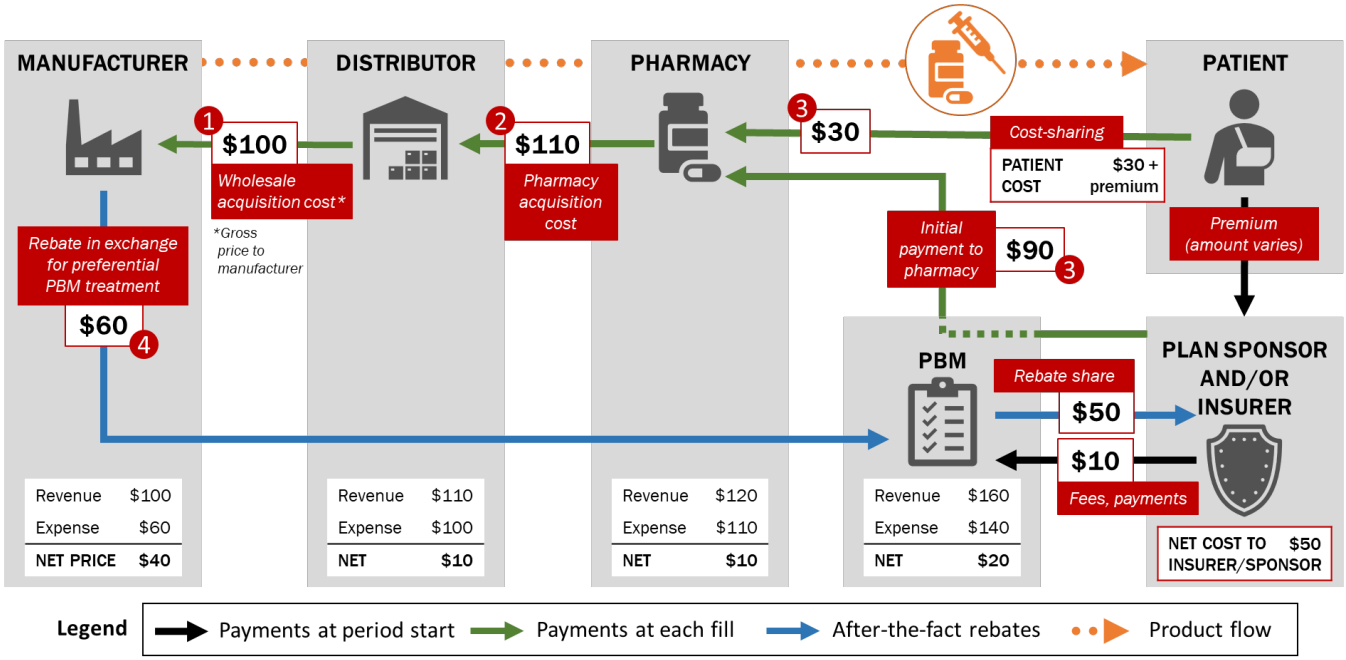
Figure 1.2 illustrates the multistep process with an example brand-name, retail-dispensed drug dispensed to an enrollee in a private health insurance plan. The amounts shown in the example are strictly hypothetical and may or may not resemble the typical relative sizes of the transactions in reality (which, in many cases, are not visible to researchers or policymakers). For brevity and tractability, Figure 1.2 does not illustrate payments that apply in some cases—for example, payments from pharmacies to PBMs (pharmacy direct and indirect remuneration [DIR]) or payments from manufacturer fees paid to distributors or retailers.

For a typical brand-name drug dispensed through a retail pharmacy, drug companies sell drugs to distributors and other buyers at a list price determined by the company (for example, $100 per pill for a hypothetical drug; see step 1 in Figure 1.2). The distributor and, later, a pharmacy mark up the price in turn (for example, to $110 and then to $120; step 2 in Figure 1.2). A covered patient filling a prescription for the drug at a preferred pharmacy that is part of a network built by their PBM typically pays some portion of this amount out of pocket (for example, $30); out-of-pocket costs are higher at out-of-network pharmacies. The plan sponsor or PBM pays the pharmacy the balance of the pharmacy's price (for example, a balance of $90, which, in addition to the $30 already paid by the patient, equals the $120 total price negotiated between the pharmacy and PBM; collectively, step 3 in Figure 1.2).

Then, based on terms negotiated in advance and potentially several months or longer after a given prescription is filled, drug companies pay PBMs a rebate (for example, $60), yielding a net (that is, net of rebate) manufacturer price of $40 (step 4 in Figure 1.2).[17] PBMs pass most, but not all, of the rebate amount back to plan sponsors (for example, $50 out of $60) and are often paid other fees (for example, $10), retaining in this example a total of $20. The net cost to the plan sponsor in this example is $50 (that is, $90 initial outlay minus $50 from rebates, plus $10 payment to PBMs), and the total paid between the plan sponsor and patient is $80 (the $50 net cost to the plan sponsor plus the $30 paid out of pocket by the patient).

[17] The final rebate amount paid to the PBM may not be known immediately, particularly in cases where the discount hinges on meeting prescription volume targets.

Figure 1.2. Illustrative Flows of Product and Payments for Retail-Pharmacy-Dispensed Brand-Name Drugs



NOTE: Numbers in red circles indicate the typical sequence of fill-specific events. The amounts shown in the example are strictly hypothetical and may or may not resemble the typical relative sizes of the transactions in reality (which, in many cases, are not visible to researchers or policymakers). For brevity and tractability, the figure does not illustrate relatively modest payments that apply in some cases, such as payments from pharmacies to PBMs (pharmacy DIR) or payments from manufacturer fees paid to distributors or retailers.

It is crucial to differentiate between net prices from different stakeholder perspectives. The net prices to *manufacturers* after rebates—which are described above—are different, and smaller, than the net amounts paid collectively by *plan sponsors and issuers and their enrollees*. These differences stem from markups along the prescription drug supply chain, separate negotiations between PBMs and pharmacies, and another set of separate negotiations between PBMs and their clients.

While gross prices and spending by plan sponsors and issuers are well-studied and easily measured, **rebates, shares of rebates retained by PBMs and not passed back to their clients**, and other **fees and payments to PBMs from their clients** are, as mentioned earlier, difficult to assess on a prescription-by-prescription basis, or even in aggregate. These amounts are crucial to understanding the net amounts paid by plan sponsors and issuers for drugs.

There are several possible—and potentially complementary—explanations for how this system of high list prices offset by rebates[18] may have evolved. First, because rebate amounts are

[18] Prior to the settlement of a class action lawsuit brought by a group of pharmacies in 1994, drug manufacturers offered up-front discounts to health plans and other purchasers (but not to pharmacies) for the same drugs, amounting to illegal price discrimination. The settlement allowed for retrospective payment of rebates if the purchasers meet certain requirements. Although the rebates are technically offered to all purchasers, pharmacies are not able to meet the market share threshold (Gudiksen, 2018).

confidential, this system allows for price discrimination, where drug companies charge some insurers more than others. Second, intermediaries earning a percentage of transaction prices (including distributors, pharmacies, and PBMs under some arrangements) make a larger dollar amount with higher list prices, leading to upward pressure on list prices over time (Sood et al., 2020). Third, a higher price in the United States, which is the only high-income country where list prices are set unilaterally by drug companies, may result in higher prices in other countries (Comanor, 2022). While several countries previously referenced U.S. prices explicitly in drug price regulation, as of January 2024 only Japan still does so. Implicitly, U.S. prices for new drugs in particular may be the de facto starting point for price negotiations or regulation in other countries.

Differing Perspectives on the Brand-Name Drug Net Spending Status Quo

While negotiated rebates to get to lower net prices are the norm for brand-name drugs facing some degree of competition, there is ongoing debate over whether the current system benefits consumers relative to potential alternative approaches to pricing. Proponents of negotiated rebates, including most insurers and PBMs, point to the resulting lower net prices (#OnYourRxSide, undated; Johnson, Mills, and Kridgen, 2018). Most drug companies point to PBMs as the main driver of high U.S. drug prices but prefer the status quo over broader government price regulation or negotiation that would apply across many or all insurers (PhRMA, undated).

In contrast, groups representing patients and some providers and policymakers point to five main concerns:

1. Patients pay a relatively large share of drug spending out-of-pocket when cost sharing is based on list prices and rebates are large (HHS, 2020).
2. Incentives under the status quo may put upward pressure on list prices, further increasing patient cost-sharing burden and resulting in important health and financial implications for those with inadequate or no drug coverage (HHS, 2020).
3. The fragmented nature of bilateral negotiations between each insurer and drug company leads to differences in preferred drugs, coverage, and cost sharing for patients that may disrupt care for patients (Rood et al., 2012; Ridley and Axelsen, 2006).
4. Because the magnitude of negotiated rebates is proprietary, it is difficult to assess the extent to which consumers and patients, rather than manufacturers and the health care industry, benefit from these savings (Marsa and AARP, 2019).
5. The trade-offs in terms of patient and health care system costs and narrower coverage and access to care to achieve lower net prices are not well understood or described.

Broader Policy Questions That RxDC Data Could Help Address

These conflicting perspectives on the advantages and disadvantages of negotiated net prices lead to several policy questions, each of which has historically been difficult to address:

- **What share of negotiated rebates—in other words, reductions in spending on prescription drugs—ultimately benefits consumers and through which channels?** Proprietary rebate amounts, complex contractual arrangements between plan sponsors or issuers and their PBMs, and fragmented data across stakeholders each complicate analyses of the margins retained by PBMs. More importantly, the close relationships between net spending on drugs, premiums, and benefit design—including coverage and cost sharing—make it difficult to understand how changes in net spending on drugs and the magnitude of rebates for a given private health insurance plan or issuer affect patients in subsequent years.
- **What alternatives exist to the current system, and what are their advantages and disadvantages relative to the status quo?** The current system of price negotiation implemented through rebates evolved as business practices over time. Policymakers have proposed changes (U.S. House of Representatives, 2023; U.S. Senate, 2023) with uncertain effects. However, savings and benefits to consumers under the status quo are also uncertain, making it difficult to establish a baseline for comparison.

Scope and Outline of This Report

This report distills key trends, findings, and questions related to a set of specific research questions from ASPE and, more broadly, to the initial biannual report to Congress. Given the compressed time frame for analysis of the 2020 and 2021 data, this initial report focuses largely on findings from a literature review and analysis of data from sources other than those collected under Section 204. In addition to this introduction (Chapter 1), these initial report sections include

- findings from a literature review and analyses of secondary data related to trends in prescription drug coverage, premiums, and other plan benefit design parameters (Chapter 2)
- findings from a separate literature review and analyses of other data related to drug price and spending trends, including an exploration of what is already known about the magnitude of rebates and other discounts relative to payments at gross prices (Chapter 3)
- a summary of conceptual linkages and empirical evidence on relationships among rebates, spending, premiums, and other impacts on consumers (e.g., cost sharing and coverage) (Chapter 4).

The report includes one chapter (Chapter 5) describing a set of initial analyses using 2020 and 2021 RxDC data with a focus on how the analyses relate to certain research questions posed by ASPE and the scope of the report to Congress. While these analyses are limited in scope because of 2020 and 2021 RxDC data limitations, the intent is to illustrate the potential for later rounds of RxDC data to fully address questions posed in the CAA. The final chapter (Chapter 6) closes by summarizing key conclusions and proposing recommended changes for future years of RxDC data collection and analysis. Our recommendations focus on addressing limitations of the already collected 2020 and 2021 RxDC data so that future years of collected data can more directly address questions posed in the law. Both our conclusions and recommendations are informed by

our initial analysis of 2020 and 2021 RxDC data, our literature reviews and secondary analyses of other data, and informal discussions with a small number of key informants, including academic researchers with expertise in prescription drug policy and actuaries. Appendix A provides an overview of the prescription drug market, Appendix B includes additional details of the methods we used in Chapters 2 and 3, and Appendix C includes a table describing the rates at which RxDC submissions were submitted to CMS at the same level of aggregation.

Chapter 2. Coverage and Premium Trends

Since the inception of the Affordable Care Act's (ACA's) health insurance marketplaces in 2014, there have been changes in prescription drug coverage, health insurance premiums, and many aspects of plan benefit design, both for medical coverage overall and for prescription drug coverage specifically. In considering the link between prescription drug rebates, drug spending, and premiums and other consumer health insurance costs, it is important to understand the underlying trends in these parameters. In this chapter, we describe trends in health insurance premiums, prescription drug coverage, and other plan benefit design parameters since 2014.

Research Questions

- Coverage:
  - What are trends in the number of people with prescription drug coverage in group and individual market plans?
  - What proportion of individuals with prescription drug coverage are subject to the essential health benefits (EHB) standards under the ACA?
- Premiums
  - What are the trends in premiums for group and individual market health coverage?
  - What are the trends in employer and employee contributions toward group premiums?
- Benefit design
  - What are the trends in overall deductibles and out-of-pocket limits?
  - What are the trends in separate prescription drug deductibles and out-of-pocket limits?
  - What are the trends in prescription drug benefit design and cost sharing, including use of copayments versus coinsurance?
  - What are the trends in plan use of formularies?
- How have plans handled COVID-19 therapeutics available under Emergency Use Authorization (EUA)?

Approach

We performed targeted literature searches and analyses of several datasets to address the research questions described in the box. We briefly describe our approach below and provide more detail on the data sources and analysis in Appendix A.

Literature Review

We used a multistep process to identify peer-reviewed and gray literature. After developing search terms for each of the research questions, we implemented searches in the PubMed database (search terms are included in Appendix B). We limited the searches to studies of the U.S. market that were focused on primary or secondary research. We then supplemented the PubMed results with gray literature from Google Scholar by using the "Related Articles" function for articles we determined to be the most relevant to each research question.

Data Sources and Analysis

Kaiser Family Foundation Employer Health Benefit Survey 2014–2022

The Kaiser Family Foundation (KFF) conducts an annual survey of employers to understand trends in employer-sponsored health coverage (Claxton et al., 2021). The survey includes detailed questions on health insurance offer rates and plan benefit design details of offered plans, such as premiums, employee contributions, and employee cost sharing. We used both the raw data from the survey for years 2014–2023 and the data summarized in the annual Employer Health Benefits report produced by KFF to summarize prescription drug coverage, premiums, and other plan benefit design details for employer-sponsored health insurance.

Medical Expenditure Panel Survey Data

The Medical Expenditure Panel Survey (MEPS) is a set of surveys of individuals and families that includes information on use of health services, costs of services, and sources of payment (including detailed insurance types), among other things (Agency for Healthcare Research and Quality [AHRQ], 2019). For the purposes of the analyses described in this chapter, we used MEPS Household Component Full-Year Consolidated Files from 2014 to 2020 to summarize sources of health insurance coverage and sources of prescription drug coverage.

CCIIO Health Insurance Exchange Public Use Files

The CMS CCIIO publishes a set of public use files (PUFs) that include information on benefits, cost sharing, and premiums for Marketplace plans sold through the federally facilitated exchanges (FFEs), as well as for plans sold on state-based exchanges (SBEs) in states that rely on the federal information technology platform for certain functions (CMS, 2023b). The exchange PUFs are available from 2014 to 2023, and we used all years of available data for our analyses. In particular, we used the Plan Attributes PUF and Benefits and Cost Sharing PUF to understand trends in prescription drug cost sharing in Marketplace plans.

Trends in Prescription Drug Coverage

Sources of Prescription Drug Coverage

Key Findings

- Private group coverage is the primary source of prescription drug coverage in the United States.
- ACA-compliant individual market and small group plans are required to offer prescription drug coverage. In addition, the majority of employer-sponsored insurance (ESI) plans offer prescription drug coverage as well.
- Average premiums for ESI have increased at a steady rate over time, while average benchmark premiums for marketplace plans jumped in 2018 due to a policy change by the federal government.
- Deductibles and out-of-pocket maximums have generally increased over time and are higher for marketplace plans than for ESI plans.
- Plans have increasingly used more complex formularies over time, generally to steer enrollees toward lower-cost drugs.
- Copays are the most common form of cost-sharing for tier-1 drugs, while coinsurance is more common for higher-cost tier 4 drugs.
- Many insurers waived cost-sharing for COVID-19 therapeutics, at least in the first year of the pandemic.

Health plans often include prescription drug coverage as a benefit, although this is not always the case. Medicare plans did not cover prescription drugs until the introduction of Medicare Part D in 2006. Now, individuals covered by Medicare may be in a Medicare Advantage plan that incorporates the Part D prescription drug coverage benefit, or they may separately purchase a stand-alone Part D plan. While some drugs (particularly those that must be administered in a physician's office) may be covered under the medical benefit, in this chapter, we discuss coverage of pharmaceuticals that would be covered under the prescription drug benefit.

In Table 2.1, we summarize the number of individuals with prescription drug coverage via Medicare, Medicaid, private group plans, private individual market plans, and other public sources, as well as the number of uninsured individuals in the United States, based on our analyses of the MEPS data from 2014 to 2020. Since individuals can report multiple sources of coverage across a year (for example, when an individual switches coverage or has two simultaneous sources of coverage), we implemented the following hierarchy to create mutually exclusive categories:

1. uninsured for full year
2. Medicare Part D
3. Medicaid
4. private group
5. private individual market (both on- and off-Marketplace)
6. other public insurance.

We note that we did not include coverage by the Indian Health Service (IHS) in any of the above categories, because the National Health Interview Survey and other federal surveys do not classify individuals who have coverage only through the IHS as being insured (Finegold et al., 2021).

Private group coverage is the primary source of prescription drug coverage (and health insurance coverage more generally) in the United States, followed by Medicaid and Medicare

Part D. We note that in 2020, there was a decrease of more than 10 million individuals (6 percent) reporting prescription drug coverage via a private group health plan and a concurrent increase of over 5 million individuals (9 percent) reporting Medicaid coverage. This is likely due to changes in employment status and income during the coronavirus disease 2019 (COVID-19) pandemic, as well as more liberal Medicaid continuous coverage policies during the pandemic. Private individual market insurance covers a smaller number of individuals. In this chapter, we primarily report on aspects of prescription drug coverage provided by private group health plans and private individual market plans.

Table 2.1. Prescription Drug Coverage by Specific Sources of Coverage (in millions), 2014–2020

	2014	%	2015	%	2016	%	2017	%	2018	%	2019	%	2020	%
Private group	149.2	53	151	53	152.8	53	156	54	154.6	54	152.4	53	143.1	49
Private individual market	9.4	3	11.5	4	10	3	9.4	3	10.1	3	10.5	4	10.8	4
Medicare Part D	30.9	11	32.4	11	34.4	12	36	12	36.9	13	37.2	13	40.8	14
Medicaid	59.4	21	61.8	22	62.3	22	63.7	22	63.5	22	63.7	22	69.3	24
Other public	2.3	1	2.8	1	2.4	1	2.2	1	2.4	1	2.5	1	2.5	1
Uninsured	31.3	11	26.1	9	24.6	9	21.5	7	21.2	7	20.6	7	22.8	8
Total	282.5		285.6		286.5		288.8		288.7		286.9		289.3	

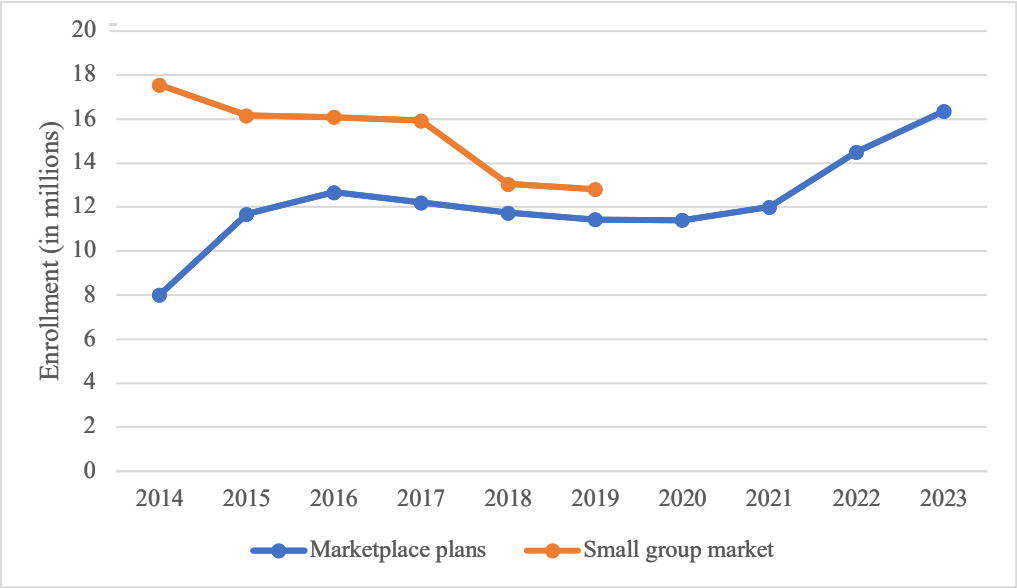
SOURCE: Authors' analysis of MEPS data.
NOTE: (1) Not all sources of prescription drug coverage are included in this table. Prescription drug coverage provided by the IHS and separate private prescription drug coverage (not provided by the health plan) are not included in this table. (2) Those dually enrolled in Medicaid and Medicare Part D are included under Medicare Part D only. (3) "Uninsured" are those who are uninsured for all of the given year.

Essential Health Benefit Standards

The ACA requires that new ("non-grandfathered") individual market and small group market health plans cover a set of ten categories of health care services, referred to as EHB. EHB includes coverage of prescription drugs, meaning that all on-Marketplace plans, as well as all non-grandfathered ACA-compliant off-Marketplace and small group plans, include coverage for prescription drugs (CCIIO, 2023b).[19] Figure 2.1 shows Marketplace enrollment between 2014 and 2023 (KFF, undated-b) and small group market enrollment for the three largest insurers per state between 2014 and 2019 (KFF, 2019).

[19] A health insurance plan is considered to be ACA compliant if it meets the various regulations set forth in the ACA.

Figure 2.1. Marketplace and Small Group Market Enrollment, 2014–2023



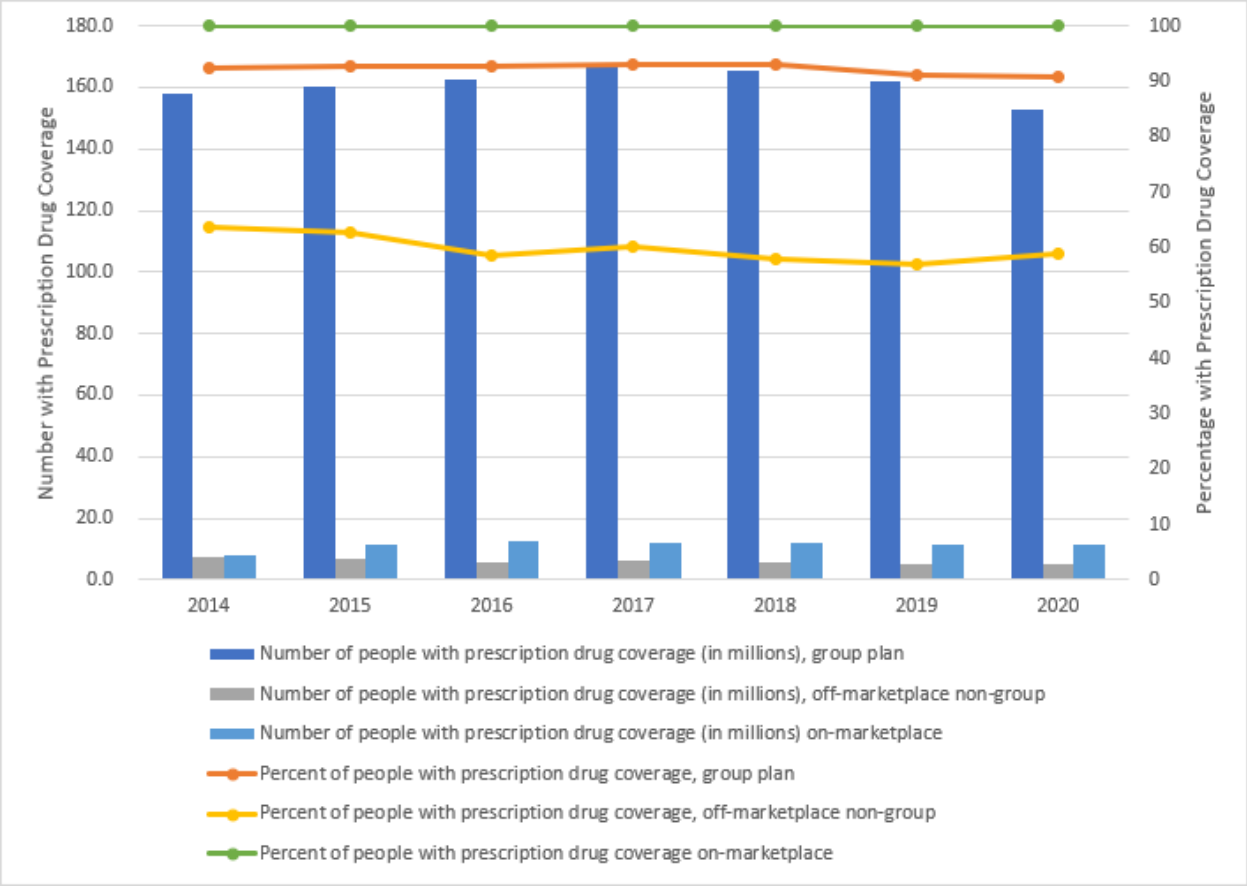
SOURCE: Authors' summary of KFF enrollment data.
NOTE: The orange small group market line represents the top three insurers in each state only, for which data are only available through 2019.

Trends in Prescription Drug Coverage Among Plans Not Required to Meet Essential Health Benefit Standards

Large group plans are not subject to the same EHB standards as non-group and small group market plans (CMS, 2011). However, the majority of group health plans do offer prescription drug coverage. Based on analyses of the MEPS data, we determined that among those enrolled in group health plans (including ESI as well as other group coverage), over 90 percent had prescription drug coverage included as part of their health plan (Figure 2.2). This is consistent with a finding from the KFF 2023 Employer Health Benefit Survey that, in 2023, 99 percent of covered workers were at a firm that included prescription drug coverage in its largest health plan (Claxton et al., 2023). However, we found that for individuals enrolled in off-Marketplace non-group plans,[20] prescription drug coverage was less common, with less than two-thirds of survey respondents who reported having off-Marketplace individual market plans noting that they had prescription drug coverage through that plan (Figure 2.2). We note, however, that ACA-compliant individual market plans (on- or off-Marketplace) are required to include prescription drug coverage as an EHB. Therefore, there may be some underreporting of prescription drug coverage by individuals covered by off-Marketplace plans in the MEPS.

[20] Off-Marketplace non-group plans are not subject to the same ACA requirements as those sold on the Marketplaces, although they may choose to conform to certain requirements to be considered ACA-compliant.

Figure 2.2. Number and Percentage of Group and Off-Marketplace Non-Group Plan Enrollees Reporting Having Prescription Drug Coverage Under Their Health Plan, 2014–2020



SOURCE: Authors' analysis of MEPS data.

Plan Benefit Design

Health insurance copayments, coinsurance, and deductibles are examples of plan benefit design parameters. The actuarial value of a plan is the percentage of patient health care costs that the plan pays, on average. The actuarial value is determined by the various plan benefit design parameters: A plan with lower copays and deductibles has higher actuarial value, and vice versa. The ACA implemented various regulations related to actuarial value, particularly for the individual and small group markets. In the individual market, plans are categorized by metal tiers (bronze, silver, gold, and platinum), which correspond to actuarial values of 60 percent, 70 percent, 80 percent, and 90 percent. The ACA requires that ACA-compliant plans (including employer-sponsored and other group plans) offer minimum value, meaning an actuarial value of at least 60 percent. In general, the higher the upfront premium, the lower the key elements of consumer cost sharing (that is, the deductible, copayment, and coinsurance amounts) will be. Essentially, by agreeing to pay higher guaranteed costs upfront (the premium), consumers can

lower their potential cost sharing as they use health care throughout the plan year (and vice versa).

Setting Health Insurance Premiums

Premiums are an important indicator of overall health insurance plan costs, but not the only indicator. In this subsection, we explain how health insurance premiums are set and recent trends in health insurance premiums. In the following subsection, we describe trends in other plan benefit design parameters.

ACA Premium Regulations

The ACA was enacted in 2010 and included a comprehensive set of reforms related to health insurance. One of the primary goals of the ACA was improving health insurance affordability (HHS, 2022a), and, to that end, the law included reforms and regulations related to premium setting by health insurers. In the individual and small group health insurance markets (CCIIO, 2023a), insurers are only permitted to vary premiums based on age, smoking status, family size, and geography of the enrollee, as well as plan actuarial value. Importantly, insurers are not permitted to vary premiums based on health status (Tolbert, 2015).

The ACA further imposes restrictions on premium setting based on the medical loss ratio (MLR) for all insurers (including fully funded group health insurance coverage). The MLR is the percentage of premium dollars spent on health care as opposed to administrative costs. The ACA requires plans sold on the individual and small group markets to have an MLR of at least 80 percent, while large group plans are required to have an MLR of at least 85 percent (CCIIO, 2011). If insurers charge a premium that results in an MLR that is lower than the threshold, they are required to pay back a rebate to consumers (or, in the case of ESI, to the employer and employee).

The ACA premium regulations act as the basis for the requirements that insurers must meet, but states are free to set stronger requirements if they wish. For example, some states do not permit premium rating by smoking status, while others have implemented narrower age or smoking status rating ratios than those set by the ACA. States may also, for example, establish an age rating curve, establish requirements related to billing consumers for premiums, or expand the definition of small employer to include firms larger than 50 employees (CCIIO, 2023a). However, any state regulations must minimally meet the broadly established ACA requirements.

Typical Actuarial and Insurance Company Practices

Insurers set health insurance premiums based on actuarial projections of spending in the year, which stem from models accounting for changes in enrollment, risk (that is, the case mix of relatively healthier and sicker enrollees), health care utilization, and prices negotiated with providers (American Academy of Actuaries, 2019). Plans offering both health and drug benefits

often separately model expenses under the drug benefit using prior-year information even though they ultimately set a single premium. While the insurer's prior experience is the main driver of these projections, actuarial models can also account for specific anticipated shocks (such as the approval of new drugs or implementation of a new law or regulation).

As noted above, premiums are only one of many parameters set by insurers when designing insurance products. Higher deductibles and cost sharing by patients actually using care will, all else equal, lead to lower premiums paid by all enrollees. Relatedly, narrower choice of providers and services and greater use of barriers to lower-value or inappropriate care, such as prior authorization, can lower utilization and prices, which again could lead to lower premiums.

In general, insurers have an incentive to develop products that, through a combination of premiums and plan design features, will maximize revenue relative to costs. Insurers bear some administrative expenses ("loading"), which are factored into premiums. Insurers initially earn any difference between collected premiums and expenses, although the amount they ultimately retain is limited by MLR requirements, which require insurers to provide rebates to consumers for premiums that are not spent on medical claims, allowable quality improvement activities, or a defined administrative loading amount. The amount due back to plan enrollees at the end of the plan year may be reduced by increasing spending on benefits prior to the end of the plan year or by reducing premium rates midyear. Despite these restrictions on insurer margins, some studies have found that market competition also plays an important role in premium calculations (Gabel et al., 2018; Guardado, Emmons, and Kane, 2013), suggesting that insurers may, all else equal, be able to set higher premiums in markets without adequate competitive pressure (Liu et al., 2022).

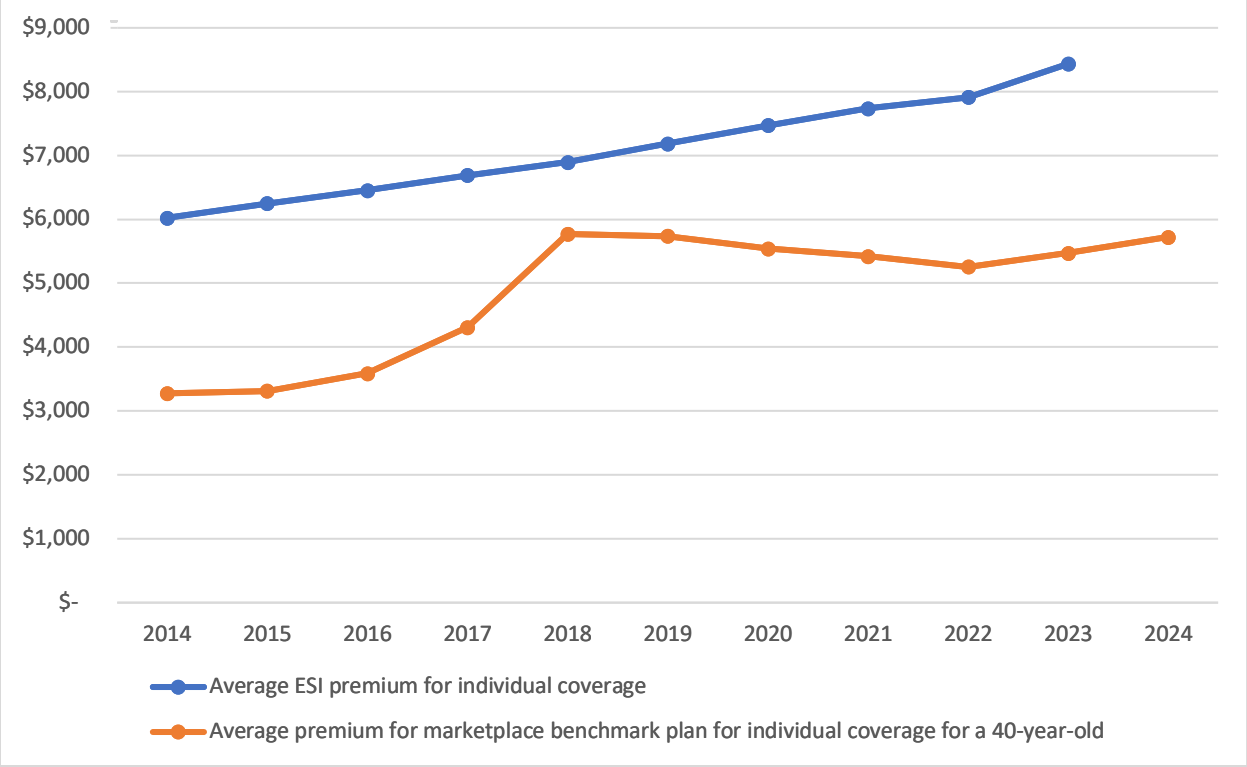
Trends in Health Insurance Premiums for Employer and Marketplace Plans

For employer-sponsored health insurance coverage, which generally has an actuarial value of 80–90 percent (Actuarial Research Corporation, 2017; Moehrle, 2015), the average premium for self-only coverage increased at a rate of 2 to 7 percent per year between 2014 and 2023, ranging from $6,000 in 2014 to $8,400 in 2023 (Figure 2.3) (Claxton et al., 2014–2023). The employer share of the premium remained steady at 82–83 percent per year across 2014–2023 (Claxton et al., 2014–2023).

There has been more volatility in Marketplace premiums, particularly in the early years of the Marketplace. This was caused, for example, by lack of competition and a greater ratio of sick to healthy enrollees than expected (CCIIO, 2023a). The unsubsidized premium for individual coverage for a 40-year-old on the benchmark silver plan (actuarial value of 70 percent) ranged from $3,300 in 2014 to $5,700 in 2023. 2024. The year-to-year percentage change in premiums ranged from –3 percent (between 2021 and 2022) to +34 percent (between 2017 and 2018) (KFF,undated-a). The large jump in benchmark premiums between 2017 and 2018, however, was a direct result of a change in federal policy, rather than market volatility alone.

In 2017, the Trump administration announced that the federal government would no longer reimburse Marketplace plans for the cost of providing cost-sharing reduction (CSR) subsidies to income-eligible enrollees enrolled on silver plans. However, insurers were still required to provide such subsidies. Therefore, in 45 states (as of 2019), insurers "silver loaded" the cost of CSRs onto silver premiums, a strategy in which CSR costs were loaded onto the premium for silver plans, thereby drawing higher federal premium tax credits (Gaba et al., undated). While this practice led to a jump in silver premiums, those higher premiums drew more federal premium subsidy dollars, thereby not adversely impacting subsidized enrollees (while unsubsidized enrollees can still enroll in un-loaded plans on other tiers). In fact, research has found that silver loading has generally led to higher subsidies and higher enrollment in Marketplace plans (Aron-Dine, 2019).

Figure 2.3. Average Premiums for ESI and Marketplace Coverage, 2014–2024



SOURCE: Authors' analysis of KFF Employer Survey Data, 2014–2023, and KFF Marketplace benchmark premium data, 2014–2024.
NOTE: Average age and plan actuarial values differ between ESI and the Marketplace benchmark plan; therefore, these premiums should not be directly compared to one another. ESI premium averages are enrollment weighted.

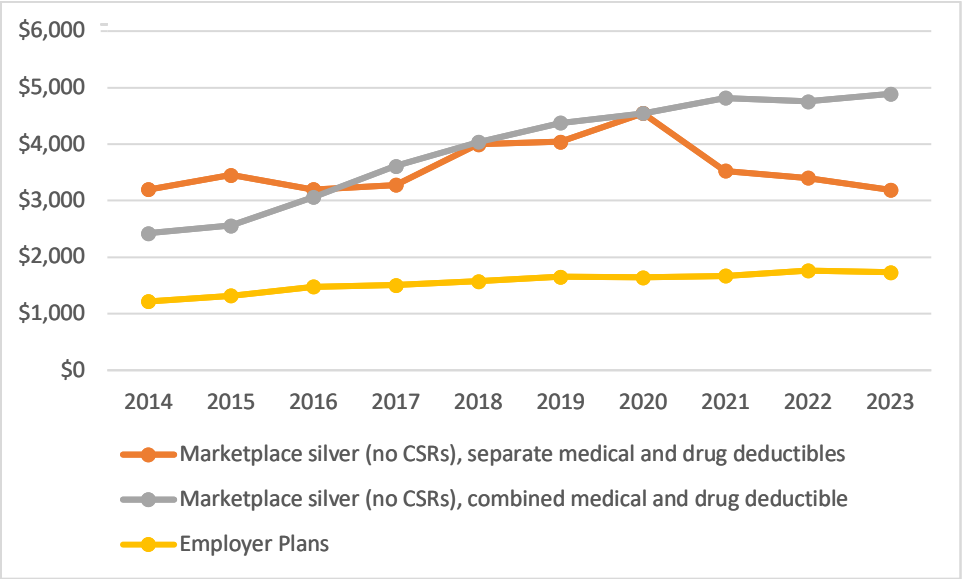
Trends in Other Plan Benefit Design Parameters for Employer and Marketplace Plans

Trends in Medical Deductibles

Based on analysis of the KFF Employer Health Benefit Survey from 2014 to 2023, we found that the average single-coverage deductible among workers covered by an employer-sponsored plan increased steadily over time, from approximately $1,200 in 2014 to over $1,700 in 2023 (Figure 2.4). This is slightly lower than the average deductibles for single coverage via employer plans as calculated using the MEPS data between 2014 and 2021. Average deductibles in the KFF data were about 10–20 percent lower than those in the MEPS data (Keenan and Miller, 2022; Collins, Radley, and Baumgartner, 2022).

For Marketplace plans with a combined medical and prescription drug deductible, this trend generally holds, although the baseline medical deductibles are substantially higher relative to ESI (for those who do not receive CSR subsidies), likely due to the higher actuarial value of ESI plans. The average medical deductible for silver Marketplace plans (prior to any CSR subsidies) followed an increasing trend over time, but at a higher rate than employer plans, ranging from $2,400 in 2014 to $4,900 in 2023 (KFF, 2023). Conversely, trends in medical deductibles for silver Marketplace plans with separate medical and drug deductibles were less consistent over time (Figure 2.4). They ranged from $3,200 in 2014 to $4,500 in 2020 before falling to $3,200 in 2023. The baseline deductibles for Marketplace plans are consistent with those reported by an ASPE report summarizing Marketplace deductibles for Healthcare.gov states from 2017 to 2021 (Branham et al., 2022). It should be noted, however, that CSR subsidies for Marketplace plans mean that the actual annual deductible for enrollees receiving the highest subsidies can be less than $100.

Figure 2.4. Trends in Health Insurance Deductibles, 2014–2023



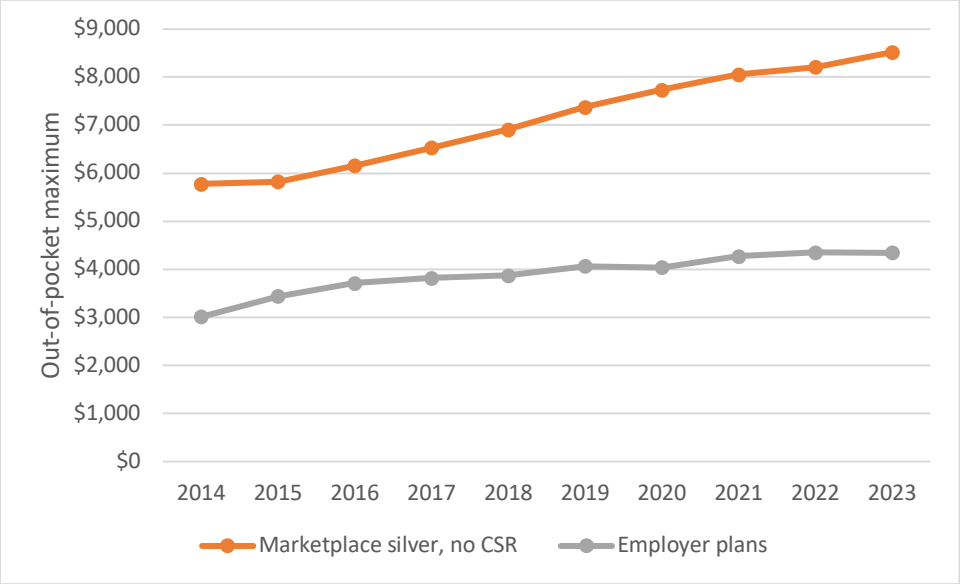
SOURCE: Author analysis of 2014–2023 KFF Employer Health Benefit Survey and authors' summary of KFF Marketplace Cost-Sharing Summaries, 2014–2023.
NOTE: For plans with combined medical and drug deductibles, this figure summarizes that deductible. For plans with separate medical and drug deductibles, this figure summarizes the medical deductible. KFF Employer Health Benefit data are enrollment-weighted.

Trends in Medical Out-of-Pocket Limits

Prior to the enactment of the ACA, it was common for health care plans to impose annual and lifetime maximums on the coverage provided, so that enrollees whose spending exceeded either limit bore the full cost of their utilization of prescription drugs or other health services. The ACA prohibits annual and lifetime dollar limits on EHB and requires that all non-grandfathered plans set annual out-of-pocket limits on enrollee spending. In 2014, the maximum out-of-pocket limit was $6,350 for individual plans (Tolbert, 2015); this increased to $9,450 for the 2024 plan year (CMS, undated).

Based on analysis of the KFF Employer Health Benefit Survey (Claxton et al., 2014–2023), we found that the average out-of-pocket maximum for single coverage among covered workers ranged from $3,000 in 2014 to $4,300 in 2023, a moderate increase over time (Figure 2.5). For silver Marketplace plans, prior to any CSR subsidies, average out-of-pocket maximums for single plans were higher (again, likely due to differences in actuarial value) but followed a similar trend, ranging from $5,800 in 2014 to $8,500 in 2023 (KFF, 2023). These averages were roughly $500 below the annual maximum out-of-pocket limit allowed by the ACA.

Figure 2.5. Trends in Health Insurance Out-of-Pocket Maximums, 2014–2023



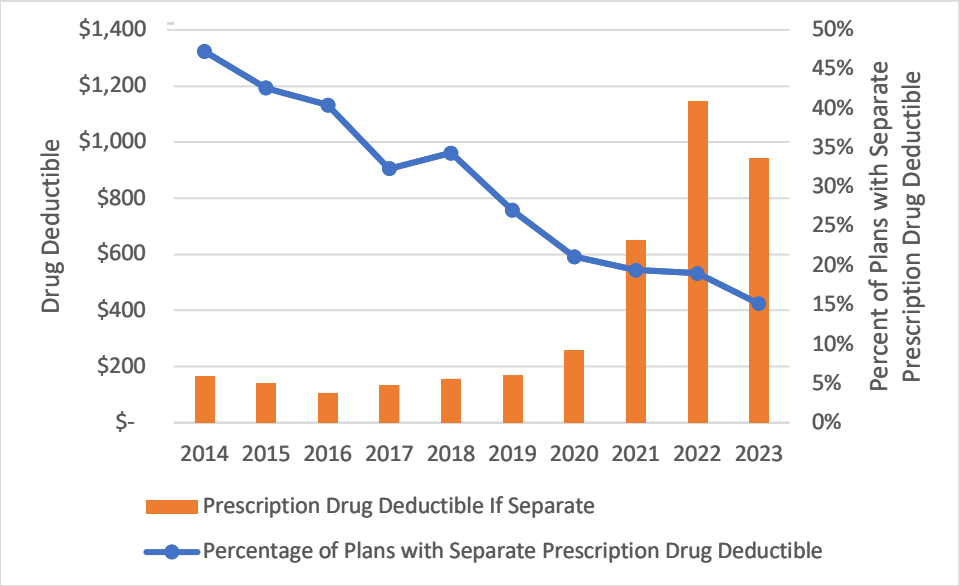
SOURCE: Author analysis of 2014–2023 KFF Employer Health Benefit Survey and authors' summary of KFF Marketplace Cost-Sharing Summaries, 2014–2023.
NOTE: KFF Employer Health Benefit Survey data are enrollment-weighted.

Trends in Separate Prescription Drug Deductibles

Among ESI plans, there has been little variation in the percentage of covered workers in a plan with prescription drug coverage that had a separate prescription drug deductible; this percentage ranged from 12 to 15 percent across 2014–2019. Among covered workers with a separate prescription drug deductible, the average deductible was $230 in 2015, $150 in 2017, and $190 in 2019 (the only years for which those data were collected since 2014) (Claxton et al., 2014–2023; Trish and Herring, 2015).

Among Marketplace plans sold on the federally facilitated marketplace, the percentage with separate prescription drug deductibles has declined over time, from 47 percent in 2014 to 15 percent in 2023 (Figure 2.6). This is due, in part, to the fact that higher-tier plans (gold and platinum) are more likely to have separate prescription drug deductibles than lower-tier plans (KFF, 2014), and these higher-tier plans make up a smaller share of the total number of plans over time. As the percentage of plans with separate prescription drug deductibles declined over time, the deductible increased from under $200 annually in 2014–2019 to over $1,000 by 2022 before falling slightly in 2023 (among plans with a separate prescription drug deductible).

Figure 2.6. Trends in Prescription Drug Deductibles in Federally Facilitated Marketplace Plans, 2014–2023

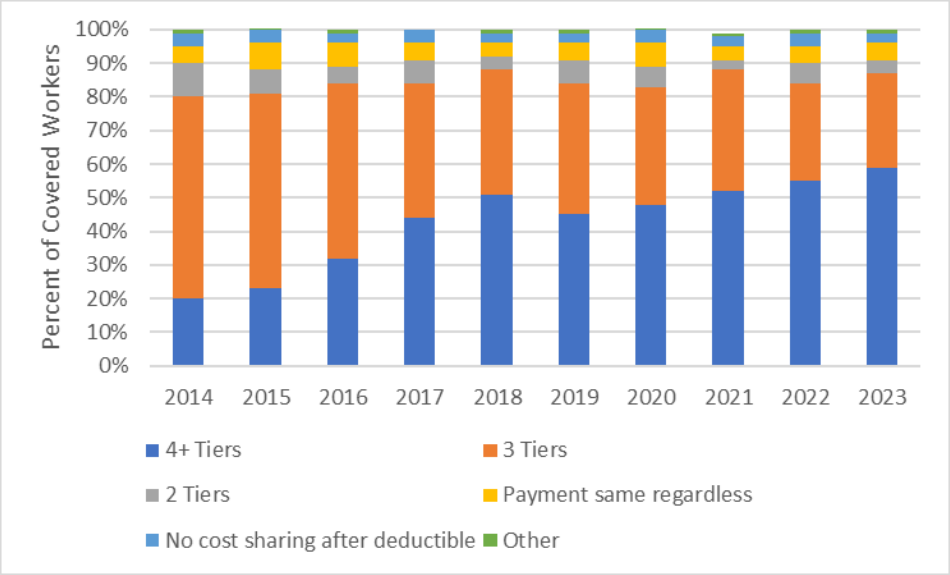


SOURCE: Authors' analysis of CCIIO Marketplace PUF data files, 2014–2023.

Trends in Plan Use of Tiered Formularies

The list of prescription drugs covered by a plan is referred to as a *formulary*. Plans may also set tiered cost sharing within the formulary, where enrollee cost sharing is generally lower for lower-cost, and therefore lower-tier, drugs. Among workers covered by employer-sponsored health insurance plans, the vast majority (80–88 percent across 2014–2023) faced three or more tiers of cost sharing for prescription drugs (Figure 2.7). Across this time period, the percentage of covered workers facing four or more tiers increased from 20 percent in 2014 to 59 percent in 2023, while the percentage facing three tiers decreased from 60 percent in 2014 to 28 percent in 2023, indicating that employer-sponsored plans are increasingly relying on the use of more-detailed formularies. Changes in formulary structure may impact prescription drug usage among plan enrollees (Nair et al., 2003) and are generally used by insurers to guide enrollees toward the use of less expensive generic drugs or preferred-brand drugs.

Figure 2.7. Trends in Use of Formularies Among Employer Plans, 2014–2023

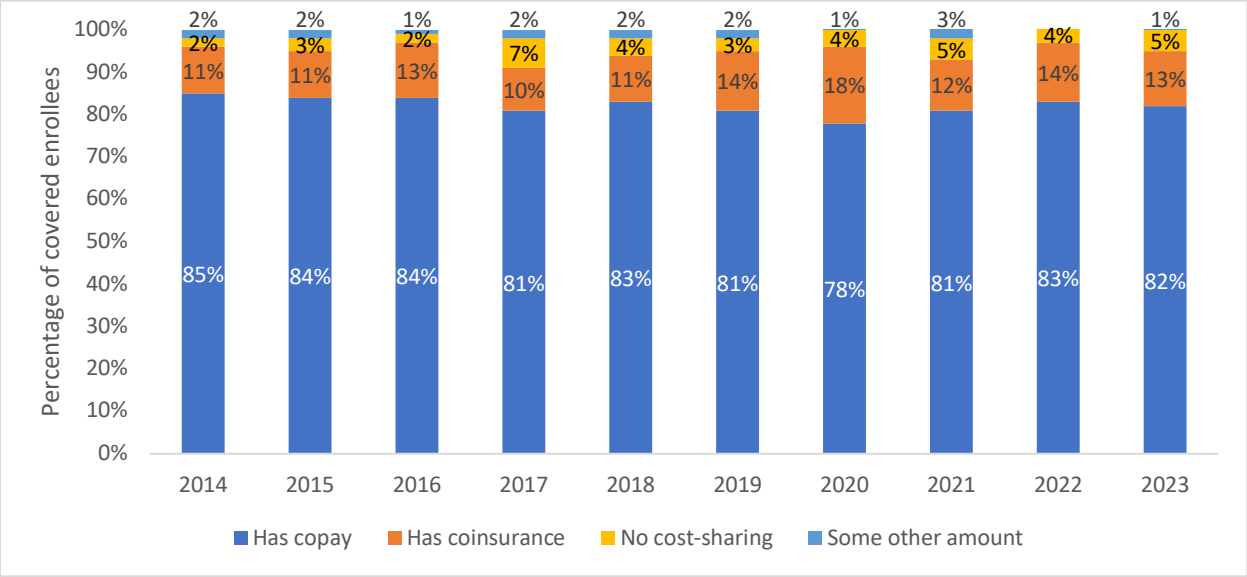


SOURCE: Authors' summary of KFF Employer Health Benefit Survey, 2014–2023.
NOTE: The data on the number of prescription drug tiers for 2017 and beyond are not directly comparable to the data from 2014 to 2016 due to a change in the way the KFF Employer Health Benefit Survey asked employers about prescription drug coverage. Beginning in 2017, the survey asked separately about cost sharing for prescription drug tiers that do not exclusively cover specialty drugs and those that do. Therefore, while we present results from 2014 to 2023, please consider the changes to the survey beginning in 2017 when interpreting the results. The number of tiers presented in this figure is inclusive of specialty-only tiers.

Trends in Use of Copayments and Coinsurance for Prescription Drug Coverage

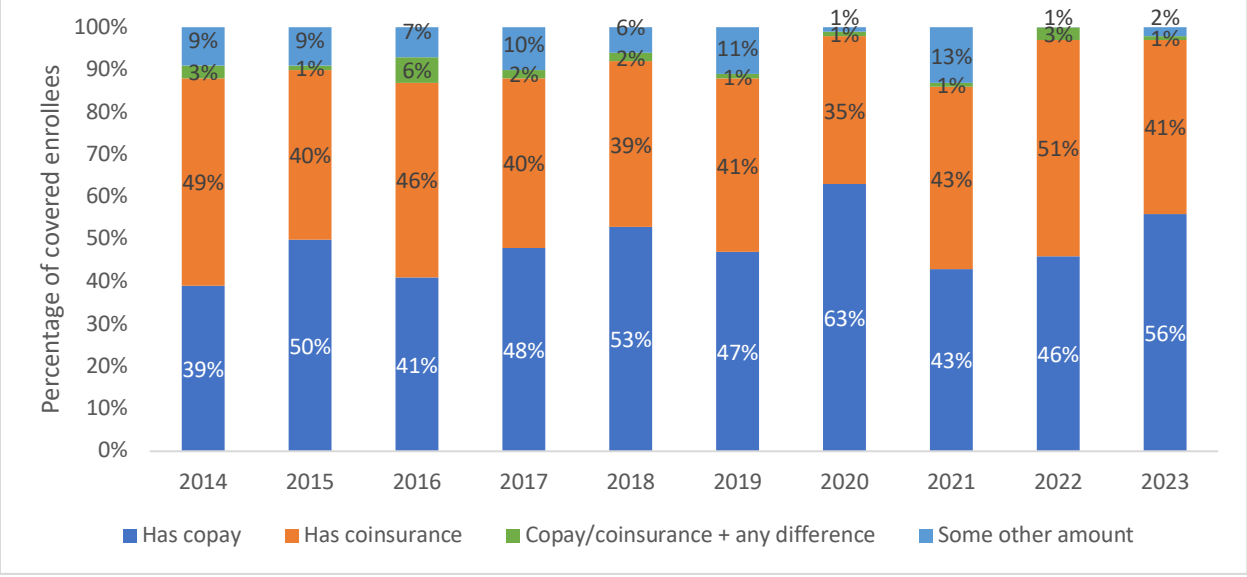
Among workers covered under employer-sponsored plans, 78–85 percent had a copay for tier 1 drugs (generally low-cost, generic drugs) over 2014 to 2020, with a slight declining trend over time. Far fewer workers faced coinsurance for tier 1 drugs, ranging from 10–14 percent in most years, with a dip in 2020 (Figure 2.8). A substantially smaller percentage of workers faced copays for tier 4 drugs (generally higher-cost, branded drugs) during this time period (ranging from 39–63 percent), but they were more likely to face coinsurance for tier 4 drugs (ranging from 35–51 percent) (Figure 2.9). Typically, as drugs become more expensive, insurers seek to increase consumers' exposure to the cost of the medication. A similar trend was observed for Marketplace plans for generic versus non-preferred-brand drugs (Figures 2.10 and 2.11).

Figure 2.8. Trends in Use of Copay Versus Coinsurance for Tier 1 Drugs in Employer Plans, 2014–2023



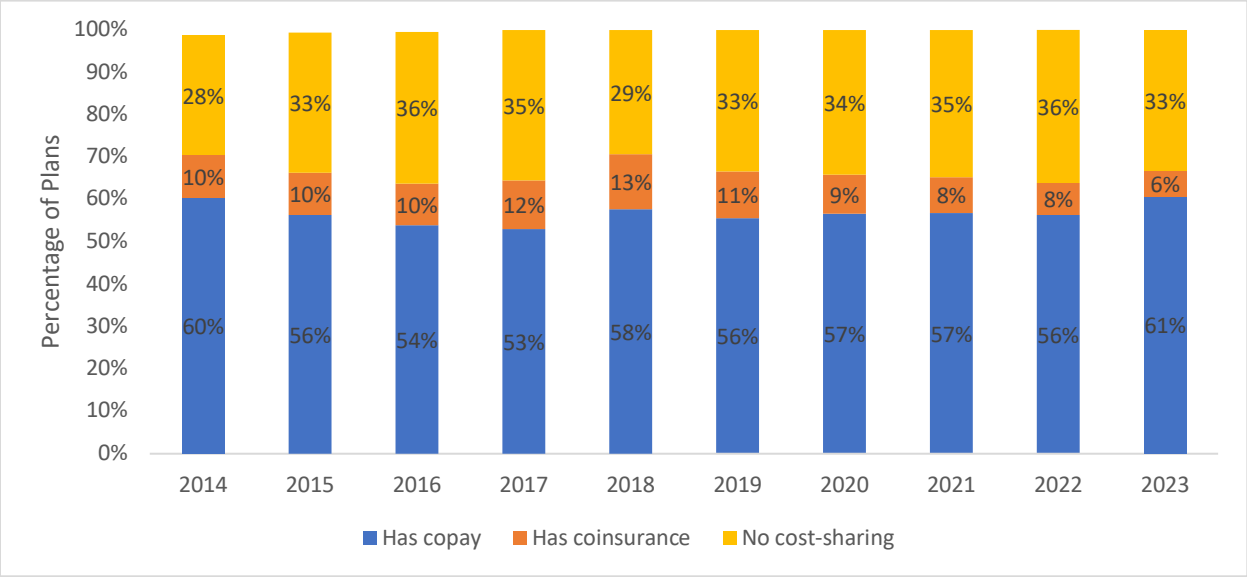
SOURCE: Authors' summary of KFF Employer Health Benefit Survey, 2014–2023.

Figure 2.9. Trends in Use of Copay Versus Coinsurance for Tier 4 Drugs in Employer Plans, 2014–2023



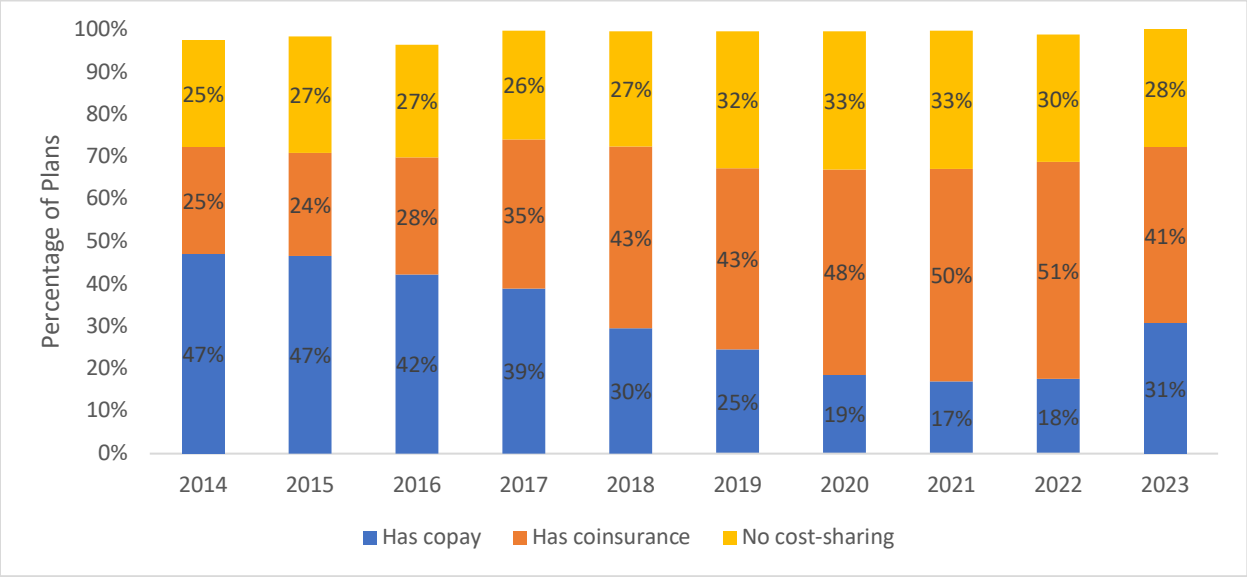
SOURCE: Authors' summary of KFF Employer Health Benefit Survey, 2014–2023.
NOTE: "Copay/coinsurance + any difference" means that the employee pays a copay or coinsurance plus the difference between the cost of the prescription and the cost of a comparable generic drug.

Figure 2.10. Trends in Use of Copay Versus Coinsurance for Generic Drugs in Marketplace Plans, 2014–2023



SOURCE: Authors' summary of CCIIO Marketplace PUFs, 2014–2023.
NOTE: The fourth possible category (has coinsurance and copay) is omitted from this figure, because it represents less than 1 percent of plans in most years.

Figure 2.11. Trends in Use of Copay Versus Coinsurance for Non-Preferred-Brand Drugs in Marketplace Plans, 2014–2023



SOURCE: Authors' summary of CCIIO Marketplace PUFs, 2014–2023.
NOTE: The fourth possible category (has coinsurance and copay) is omitted from this figure, because it represents less than 1 percent of plans in most years.

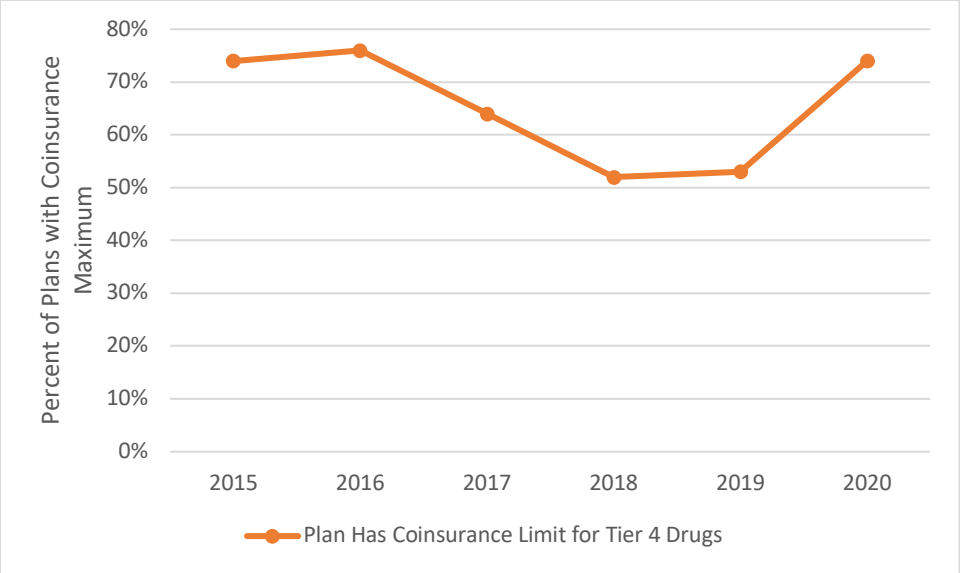
Trends in Separate Prescription Drug Out-of-Pocket Limits

Out-of-pocket limits constrain the overall financial exposure of enrollees to drug costs during a plan year. Among Marketplace plans, the percentage with a separate out-of-pocket limit for prescription drugs has historically been very low and has declined over time. In 2014, 5 percent of Marketplace plans on the FFE had separate out-of-pocket limits for prescription drugs; by 2023, this had dropped to nearly 0 percent (four of more than 30,000 plans). The out-of-pocket limit for prescription drugs, among plans that had a separate limit, ranged from $1,100 to $2,100 across 2014–2023, but patterns were not discernible, particularly given the very small number of plans that had such limits in place.

Trends in Coinsurance Maximums

Although the KFF Employer Health Benefit Survey reports do not directly report on separate out-of-pocket limits for prescription drugs, they do report on coinsurance maximums for prescription drugs, which are limits to the dollar amount paid by enrollees out of pocket on a given claim. These maximums may vary by formulary tier. Outside of formulary tiers that cover only specialty drugs, the majority of covered workers (83 percent in 2021) are in a plan with three or more cost-sharing tiers for drugs. Among covered workers with prescription drug coinsurance in plans with three or more tiers of prescription drug cost sharing, 74 percent had a maximum coinsurance for tier 4 drugs (high-cost, usually brand-name drugs) in 2015. There was some variation over time, and, by 2020, 74 percent had a maximum for tier 4 drugs (Figure 2.12).

Figure 2.12. Trends in Percentage of Employer Plans with Coinsurance Maximums, 2015–2020



SOURCE: Authors' summary of KFF Employer Health Benefit Survey, 2015–2020.

Coverage of COVID-19 Therapeutics

During the Public Health Emergency, private insurers' approaches to cost sharing varied for COVID-19 treatments. While there was no federal mandate waiving out-of-pocket COVID-19 treatment costs, a handful of states, such as Massachusetts, New Mexico, and Rhode Island, required that private insurers waive cost sharing, while a few other states (Idaho, Michigan, and Minnesota) made agreements with many of the insurers to do the same (KFF, undated-c; Hall, 2021). There were no cost-sharing regulations for private insurers in other states.

Even in the absence of federal or state mandates, many insurers still opted to waive cost sharing of COVID-19 treatments, at least in the short term. In the first year of the pandemic, the vast majority of privately insured enrollees (88 percent) were exempt from cost sharing for COVID-19 treatment (McDermott and Cox, 2020). For many patients, this exemption was temporary, as 72 percent of the two largest health plans in each state were no longer waiving cost sharing for COVID-19 treatments by August 2021 (Ortaliza et al., 2021). Likewise, by November 2021, only 36 percent of firms with 50 or more workers offered plans that waived cost sharing for COVID-19 treatments, according to a survey by KFF. Larger firms (that is, those with at least 1,000 employees) were more likely to offer plans that waived cost sharing than were smaller firms (Claxton et al., 2021). These statistics, however, do not distinguish between COVID-19 pharmaceutical treatments and health care services that were used to treat COVID-19 patients.

In the case of COVID-19 pharmaceuticals, the federal government funded most of the research and development and the subsequent purchasing of these products through the Biomedical Advanced Research and Development Authority (BARDA) (HHS, 2022b). Thus, these products, which include monoclonal antibody therapeutics such as bebtelovimab[21] and antivirals such as nirmatrelvir/ritonavir (Paxlovid) and molnupiravir (Lagevrio) were available to pharmacies at no cost (Beleche et al., 2022). While payers therefore did not need to pay for the drug itself, pharmacies could still charge dispensing fees per contractual arrangements with insurers. Public payers, such as Medicare and Medicaid, waived the dispensing fees to patients, while private insurers varied in passing this cost to consumers. Some insurers, such as Humana, waived all cost sharing for antivirals during the EUA period (Humana, 2022). Others, such as Cigna, passed on some of the dispensing fees, which they limited to $6 out of pocket, to their enrollees at the point of sale (Cigna, undated).

Following the end of COVID-19 Public Health Emergency on May 11, 2023, COVID-19 treatments such as nirmatrelvir/ritonavir and molnupiravir remained available without cost sharing for supplies provided by the U.S. government. However, once the government stops purchasing and distributing COVID-19 treatments, coverage and cost sharing for COVID-19 therapeutics might change accordingly (HHS, 2023).

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[21] Bebtelovimab was never marketed under a U.S. brand name. The product was available in the United States only via an EUA and was withdrawn when the EUA was withdrawn.

Key Takeaways

Since 2014, there has been a general trend of increasing health care and prescription drug costs to enrollees, including premiums but also deductibles and other cost sharing. However, this increase has generally been in line with growth in income in recent years, with people under 65 years of age spending approximately 5 percent of income on health care between 2014 and 2022 (U.S. Bureau of Labor Statistics, undated). While prescription drug rebates could reduce enrollee costs in theory, the relationship between rebates and the various parameters of enrollee spending described in this chapter are not obvious. The data collected under Section 204 may allow us to better understand the extent to which prescription drug rebates have shaped the trends described in this chapter.

Chapter 3. Drug Spending Trends

The goal of this chapter is to characterize the drivers of changes in prescription drug spending over the past decade. We summarize trends in prescription drug spending at different prices, both overall and for groups of drugs and prescription fills defined by distribution channel (that is, retail versus provider-dispensed drugs), therapeutic classes, and other characteristics. The specific research questions addressed in this chapter are listed in the box.

Research Questions

- What are the trends in gross drug spending and drug spending by group and individual market plans?
- What are the trends in prescription drug spending net of rebates in these plans?
- How do the trends vary by market segment and therapeutic class?

Conceptual Underpinnings of Prescription Drug Spending Trends

Prescription drug spending measured over any interval is a function of three components:

- the **volume** of drugs purchased
- the **mix** of drugs purchased (the relative contributions or shares of different drugs to total volume)
- **prices** for individual drugs.

Changes in any or all of these three components can drive spending higher or lower from one period to the next. Some analyses hold the volume and mix of drugs constant over time, thereby focusing only on average changes in price across all drugs. Studies taking this "price index" approach sometimes further decompose price changes into two components—the first a broader inflationary component and the second a change in "real" prices. Other studies focus on changes in volume and price among certain groups of drugs, where they disaggregate these measures by therapeutic classes, distribution channels (retail versus provider), brand-name versus generics, and biologics versus small-molecule drugs. In this report, we explore trends in spending across these drug groups in order to determine the role of each of these three components in contributing to changes in drug spending.

The Scope of Spending Estimates and Their Methods

The most important difference between spending trends we analyzed or cite from the literature is the perspective of the drug price across these sources (for example, drug companies, insurers and their PBMs, or the broader societal perspective). The net price paid by PBMs, which includes distributor and pharmacy markups, is greater than the net price paid to manufacturers,

which does not include those markups. As noted in earlier chapters, comprehensive information on commercial PBM and payer net prices, and therefore spending, for individual drugs or even overall across all drugs is not available from any source. The RxDC data will therefore allow for new analyses.

When describing spending trends in this chapter, we use the terms *manufacturer* and *payer* to describe the amounts received by manufacturers and paid by PBMs and their plan sponsor and issuer clients, respectively. We also use *gross* versus *net* to differentiate between estimates that do and do not reflect rebates and other remuneration offsetting manufacturers' initial revenue and payers' initial outlays. See the box for an overview of price (and, relatedly, spending) definitions.

Key Price Definitions

- The **manufacturer gross price** is the amount received by the manufacturer when it sells a drug to an initial buyer (often a distributor). Sales at manufacturer gross prices are available from data sources auditing invoices in the distribution chain (for example, IQVIA National Sales Perspectives [NSP] data).
- The **manufacturer net price** is the amount that manufacturers retain *after* paying rebates to PBMs. These adjustments may not be final for months (or even years) after the initial sale at gross prices. Manufacturer net prices for brand-name drugs sold by drug companies that are publicly traded in the United States can be *estimated* using invoice data (for example, from IQVIA) and product-level net revenue (for example, from SSR Health).
- The **gross price to payers** is the total amount paid to the pharmacy by a PBM or payer, usually by a combination of patient cost sharing and a plan-paid amount, and sometimes with other sources of payment, such as coupons or sources of secondary coverage. Gross prices to payers include dispensing fees paid to pharmacies and reflect markups along the prescription drug supply chain. These amounts are available in many different sources of claims data.
- The **net price to payers** reflects discounts paid by drug companies (often through rebates) and pharmacies. It is not always clear whether the payer net price is measured from the PBM or payer/plan sponsor perspective. In the latter case, the PBM's margin, including allocated fees and other payments from the plan sponsor or issuer to the PBM, should be reflected in the net price. Medicare Part D plan sponsors report prices in these terms to the government: they are, however, not publicly available. There is no comprehensive source of net prices to commercial payers.

No existing source of data describes spending across all prescription drugs at net prices paid by payers. The different datasets available for monitoring changes in drug spending over time cover different sets of drugs, reflect prices from different points in the drug supply chain, and vary in their handling of rebates and other discounts. These differences have important implications for the resulting spending estimates. Details on these data sources are expanded on in Table 3.1.

Table 3.1. Data Sources for Gross and/or Net Drug Spending

Source	Description and Limitations	Perspective
IQVIA's NSP	IQVIA NSP data is a U.S. market-wide estimate of volume and payments from the manufacturer perspective. Prices calculated from IQVIA NSP data represent manufacturer gross prices. While they might reflect some on-invoice discounts (e.g., prompt pay discounts), they do not include off-invoice rebates.	Manufacturer
SSR Health's net revenue estimates	SSR Heath's net price data reports the net amount received by drug companies after rebates and other concessions. These data are limited to those products for which net revenue information is listed in U.S. Securities and Exchange Commission (SEC) filings by companies that are publicly traded in the United States.	Manufacturer
Medical and pharmacy claims data	Spending estimates from claims data typically do not reflect rebates and other discounts but do reflect dispensing fees. These sources also may not reflect patient spending on drugs when the insurer was not involved (for example, for non-covered drugs or generics purchased at a lower price out of pocket than under the drug benefit).	Payer
National Health Expenditures (NHE) published by the CMS Office of the Actuary (OACT)	NHE spending estimates are reported as overall net drug spending per year, without information on volume or drug mix that make up these estimates. These estimates are also limited to drugs dispensed via retail channels.	Payer
MEPS, AHRQ	MEPS data include amounts paid by patients and payers for separately billed prescription drugs. These data measure spending at gross, pre-rebate prices and may be subject to some recall bias. They are, however, one of the only sources that can reliably describe spending by patients with different types of health insurance and drug coverage (for example, group versus individual private coverage).	Payer

Approach

We address the goals and research questions described above using a literature review and our own analyses of drug spending from several data sources.

Literature Review

We searched PubMed and Google Scholar for peer-reviewed papers related to prescription drug spending and price trends (search terms are included in Appendix B). We limited the searches to studies of the U.S. market and those focused on primary or secondary research. We supplemented these results with gray literature from industry groups, consulting and data

analysis firms, and government entities identified via Google searches. While we did not impose a formal publication date range for our search, we focused on studies from 2010, the year in which the ACA passed, onward.

After retrieving the resulting articles, team members scanned the titles and abstracts for initial relevance to the research questions. After excluding the articles that were not relevant, we extracted information from the remaining articles on each study's methods, results, and limitations and entered the data into a spreadsheet. While reviewing these articles, we identified additional relevant sources, primarily gray literature and white papers that were cited in the text and included them in our review. A researcher then synthesized the findings across studies for each research question addressed in this chapter.

Data Source and Methods Overview

The following paragraphs summarize the data sources and methodological approaches used for analyses in this chapter. See Appendix B for more information.

Medical Expenditure Panel Survey Data

MEPS is a set of surveys of individuals and families that includes information on use of health services, costs of services, and sources of payment (including detailed insurance types), among other things (AHRQ, 2019). One of the components of the MEPS surveys is a Prescribed Medicines file detailing specific prescription fills and associated payments to pharmacies for each sampled individual. For the purposes of this work, we used MEPS Household Component Full-Year Consolidated Files from 2014 to 2020 linked to Prescribed Medicines files from the same years to examine trends in per capita annual drug spending at pharmacy prices by payer, the same amount by therapeutic class, and annual payments to pharmacies among enrollees in individual versus group plans.

National Health Expenditures published by the CMS Office of the Actuary

OACT constructs NHE estimates of spending on drugs from a variety of sources. These estimates are limited to drugs dispensed via retail channels and therefore exclude physician-administered drugs and drugs paid as part of another health care service (for example, during an inpatient hospital stay). OACT's drug spending estimates reflect its assumptions related to rebates and other discounts for brand-name drugs. We used these files to examine trends in national spending on drugs at net prices from 2014 to 2022.

NHE uses a wide range of data sources when calculating spending estimates for prescription drugs and their rebates. For its total prescription drug spending values, the NHE staff combines the Census of Retail Trade data from the U.S. Census Bureau with the IQVIA National Prescription Audit. Private insurance estimates are calculated using data from MEPS, the U.S. Census Bureau, the American Medical Association, the American Hospital Association (CMS,

2021), and IQVIA.[22] For spending by commercial insurers, the NHE adjusts for rebates using MLR data from CCIIO. Spending by other third-party payers and programs is calculated using program or budget data.

For public insurance programs, the NHE uses administrative data to calculate spending net of rebates. NHE uses the CMS-64 data, which are state-level quarterly expense reports, to calculate expenses for the Medicaid program. The Medicare estimates are produced using the Trustees Report data and summary claims data. The Trustees Report includes estimates of DIR, which are the manufacturer and pharmacy rebates among Medicare Part D plans. The most recent Trustees Report estimated that DIR percentages of total drug costs increased from 12.9 percent in 2013 to 29.1 percent in 2021 (Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2023).

MEPS and NHE Analyses

We implemented descriptive analyses using both MEPS and NHE to examine annual trends in retail-dispensed gross and net drug spending, respectively. Using both data sources, we calculated total spending trends by year across all payers in the United States and the proportion of spending by payer source. For MEPS, we also calculated annual rates of (1) total and mean gross and out-of-pocket drug payments among individuals enrolled in group, Marketplace, and off-Marketplace individual market plans and (2) total gross and out-of-pocket drug spending by a selection of therapeutic classes.

IQVIA NSP Data and Analyses

We analyzed an extract of IQVIA NSP data covering all drugs for calendar year 2022 provided by ASPE. The IQVIA NSP data estimate the volume and sales of U.S. pharmaceutical products purchased by retail, mail, long-term care, and other channels across all payers. To construct the NSP data, IQVIA standardizes and combines information from audits of invoices and other transaction-level data sourced from a convenience sample of manufacturers, distributors, pharmacies, and other stakeholders. IQVIA then projects these data to approximate U.S. total volume and sales using a proprietary approach. While the underlying audit data used to construct the IQVIA NSP are from a convenience sample, IQVIA describes covering 90 percent of the retail pharmacy market through its source data collection. The IQVIA NSP data are at the level of each combination of 11-digit National Drug Code (NDC) and several other characteristics, including distribution channel and brand versus generic status. Our analysis focuses on comparisons of volume and spending across four brand versus generic categories: brand-name originators, branded generics, unbranded generics, and "other."

Importantly, IQVIA NSP data list total payments for drugs from distributors, pharmacies, hospitals, and other buyers to manufacturers at invoice prices. While these amounts might

[22] IQVIA was previously called "Quintiles-IMS" and "IMS Health."

include certain on-invoice discounts (such as prompt payment discounts), they do not reflect off-invoice discounts, such as rebates paid by drug companies to PBMs or payers. To approximate payments at manufacturer net prices, we adjusted prices for brand-name originator drugs downward by 37.2 percent, a factor reported in a separate IQVIA report.[23]

Results: Trends in Prescription Drug Spending

Key Findings

- Manufacturer list (gross) prices are increasing faster than net prices after rebates.
- Increases in spending at manufacturer gross and net prices exceed increases in the volume of drugs sold.
- Gross spending on retail prescription drugs among private payers varies between group, Marketplace individual market, and off-Marketplace individual market plans.
- Despite overall increases in gross and net drug spending over the past decade, out-of-pocket drug spending as a share of total gross spending has generally decreased.
- Greater declines in per-enrollee out-of-pocket gross drug spending compared with per-enrollee total drug spending suggest that changes in prescription drug benefit design may have reduced cost sharing.
- Increases in prescription drug spending over the past decade were disproportionately driven by high prices of a small number of brand-name specialty drugs, including but not limited to biologics and provider-administered drugs.

Overall Spending at Manufacturer Gross and Net Prices

Several studies have found that average manufacturer gross prices across brand-name drugs have increased over the past decade, with net prices increasing at a slower rate. Using SSR Health data among 599 brand-name drugs from 2015 to 2018, Sood and colleagues estimated that mean list prices increased annually by 12.3 percent, while mean net prices increased by 6.4 percent per year (Sood et al., 2020). Other studies using SSR Health data have found similar trends to Sood and colleagues, though analyses limited to new products yielded greater increases in manufacturer list and net prices compared with analyses limited to existing products (Rome, Egilman, and Kesselheim, 2022; Hernandez et al., 2020a; Kakani, Chernew, and Chandra, 2020; Hernandez et al., 2019). However, it is difficult to compare across studies, as each study used a different approach in its sampling and weighting of drug products. Other limitations are that SSR Health data only provide net prices from the perspective of the manufacturer, rather than the payer. They also do not include details on actual rebate amounts, as other types of discounts make up the difference between gross and net manufacturer prices. Furthermore, some drugs lack reliable SSR Health net price data and are excluded from most studies.

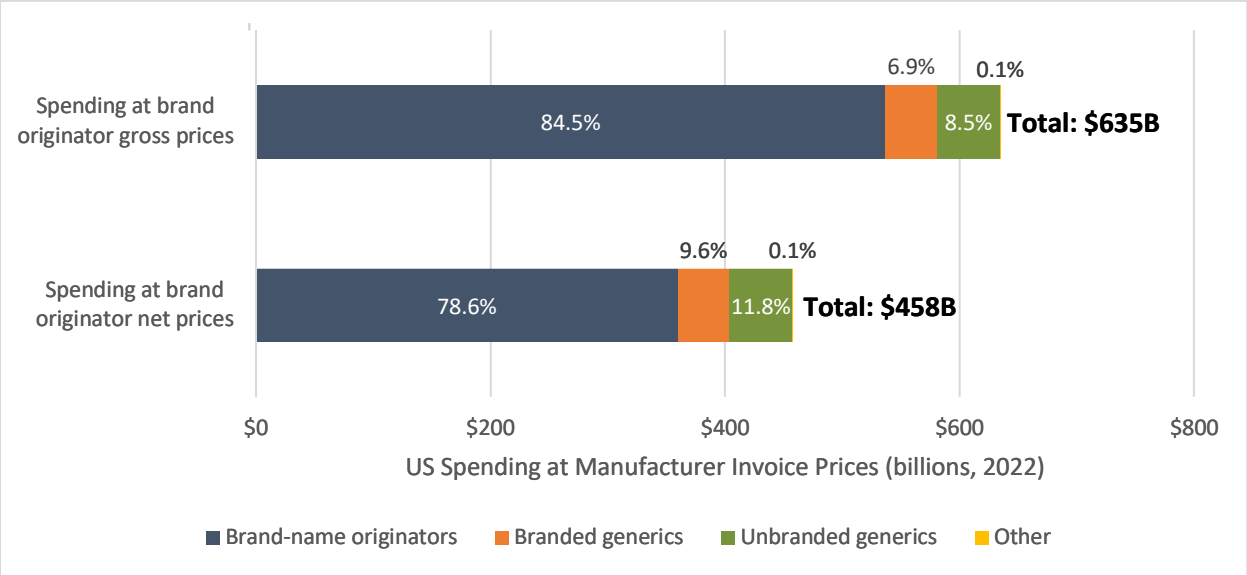
These increases in gross and net prices have coincided with overall increases in volume of drugs dispensed and, by consequence, increases in drug spending. In a 2023 report, IQVIA calculated volume of drugs dispensed (as measured by defined daily doses [DDDs]) to have increased annually by 2.3 percent, from 176.9 billion in 2017 to 242.6 billion in 2022 (IQVIA, 2023). IQVIA also estimated that payer drug spending at gross prices has increased at an annual rate of 6.9 percent from 2011 to 2022, from $412 billion in 2011 to $858 billion in 2022. This

[23] We calculated the 37.2 percent as 1 minus the 2022 ratio of net to invoice prices measured across protected brand drugs from IQVIA, 2023.

increase in gross spending is greater than the IQVIA estimates of 4.7 percent year-on-year compound increases in payer spending net of rebates (from $365 billion to $603 billion). Given the greater increases in gross and payer net spending compared with increases in volume, these findings suggest that increases in prices, particularly among new products, may be driving these overall increases.

Differences between gross and net prices from the manufacturer perspective are also important. Figure 3.1 presents a high-level comparison of manufacturer revenue at gross versus net prices using IQVIA NSP data.[24] Brand-name "originator" drugs (as opposed to branded generics[25]) account for about 85 percent of the gross amounts received by manufacturers and, after subtracting $158B for rebates, 79 percent of net revenue. Unbranded small-molecule generics, which are inexpensive, therapeutically equivalent versions of older brand-name drugs, account for nearly all generic fills in the United States and about 9 and 12 percent of manufacturer revenue in terms of spending at gross and net prices, respectively.

Figure 3.1. Shares of U.S. Manufacturer Revenue at Gross and Net Prices, by Drug Category



SOURCE: Author analysis of IQVIA 2022 NSP data for prescription drugs only.
NOTE: Spending on brand-name originator drugs is one-third less at manufacturer net prices compared with manufacturer gross prices following Mulcahy et al. (2021a). Sales amounts for branded generic, unbranded generic, and "other" drug categories are the same in both cases. "Other" includes primarily hospital administered intravenous solutions and non-drug products.

[24] We assumed a gross-to-net discount of one-third for brand-name originator drugs and no discount for branded generics, unbranded generics, and "other" drugs.

[25] The "branded generics" category includes drugs marketed under a brand name but approved for sale through a generic regulatory pathway or various other pathways that differ from those used by most new brand-name drugs (such as the 505(b)(2) pathway).

IQVIA uses a variety of sources to calculate these estimates, each of which has its limitations. For volume of drugs and gross manufacturer spending, IQVIA uses its NSP data, which represent internal audit data of wholesaler acquisition cost (WAC) prices from a convenience sample of companies and products, to project to the total market of drugs. For payer net spending, IQVIA does not have access to direct spending values and thus uses a combination of other sources to estimate this metric using audit data, the NHE data, and estimates from manufacturer invoices and net revenue. Given that IQVIA audit data represent a convenience sample, it is unknown whether the sampling approach is representative of the entire market. IQVIA then uses proprietary projection methods for estimating spending at the population level, which we are unable to validate. By contrast, the data elements from RxDC will offer information on actual rebate amounts for individual drugs. These reporting requirements will help produce more valid estimates of overall spending net of rebates. Moreover, RxDC offers opportunities to decompose gross-to-net trends at a subnational level and unpack heterogeneity between plan sponsors and issuers, between PBMs, and across drug categories.

Spending Among Retail-Dispensed Drugs

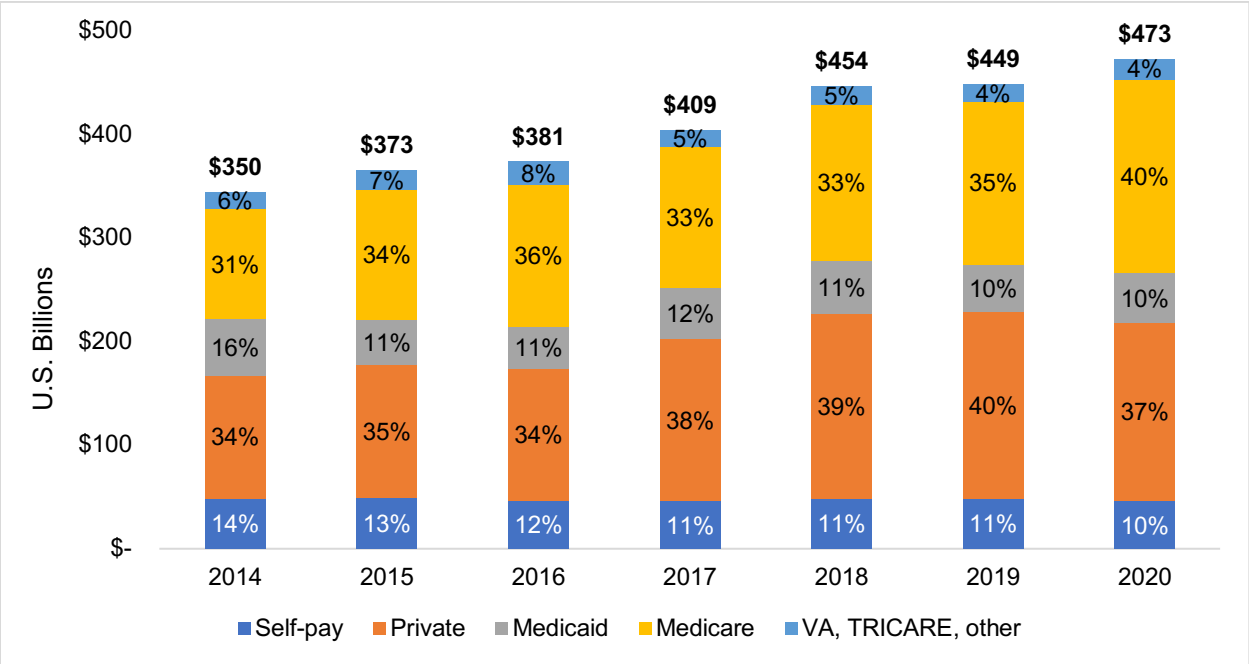
Payer Gross Drug Spending

In our analysis of the MEPS data, we found that payer gross spending among retail-dispensed drugs increased at an annual rate of 5.1 percent, from $350 billion in 2014 to $473 billion in 2020 (Figure 3.2). Spending by private insurers increased at a greater annual rate of 8.7 percent, representing 34 percent of gross drug spending in 2014 and 40 percent in 2019. Medicare spending also had a larger annual increase of 8.0 percent, while Medicaid spending experienced a modest annual decline of 3.0 percent during the study period. The larger increases in spending among private insurers and Medicare may be due to overall increases in the share of the population enrolling in these two payer categories. Increasing enrollment among private insurers is likely due to the increasing share of the population with drug coverage from ESI, as this period coincided with declines in unemployment rates after the 2008 recession and the later implementation of the ACA (U.S. Bureau of Labor Statistics, 2022). Likewise, the increase in Medicare enrollment is due to increases in the percentage of the population above age 65 (U.S. Census Bureau, 2020).

Our analysis of MEPS data suggests more modest growth in payer gross spending compared with IQVIA's reported increases in gross manufacturer spending. One likely reason for the difference is that MEPS covers retail-dispensed prescriptions only, while IQVIA covers a broader set of drugs: Spending on non-retail-dispensed drugs is increasing at a greater rate than spending on retail-dispensed drugs (Parasrampuria and Murphy, 2022). Nonetheless, the exclusion of provider-administered drugs in the MEPS data limits their utility in quantifying changes in drug spending. Other limitations of using the MEPS dataset are that it does not include spending estimates net of rebates, and it is limited to U.S. civilians and those who are not

institutionalized. It also is subject to the general limitations of self-reported survey data (although MEPS confirms the spending levels with pharmacies).

Figure 3.2. MEPS-Estimated Retail-Dispensed Prescription Drug Spending at Gross Prices (in billions), 2014–2020



SOURCE: RAND analysis of MEPS data.
NOTE: VA = Department of Veterans Affairs. Totals may not sum to 100 percent due to rounding.

Payer Net Drug Spending

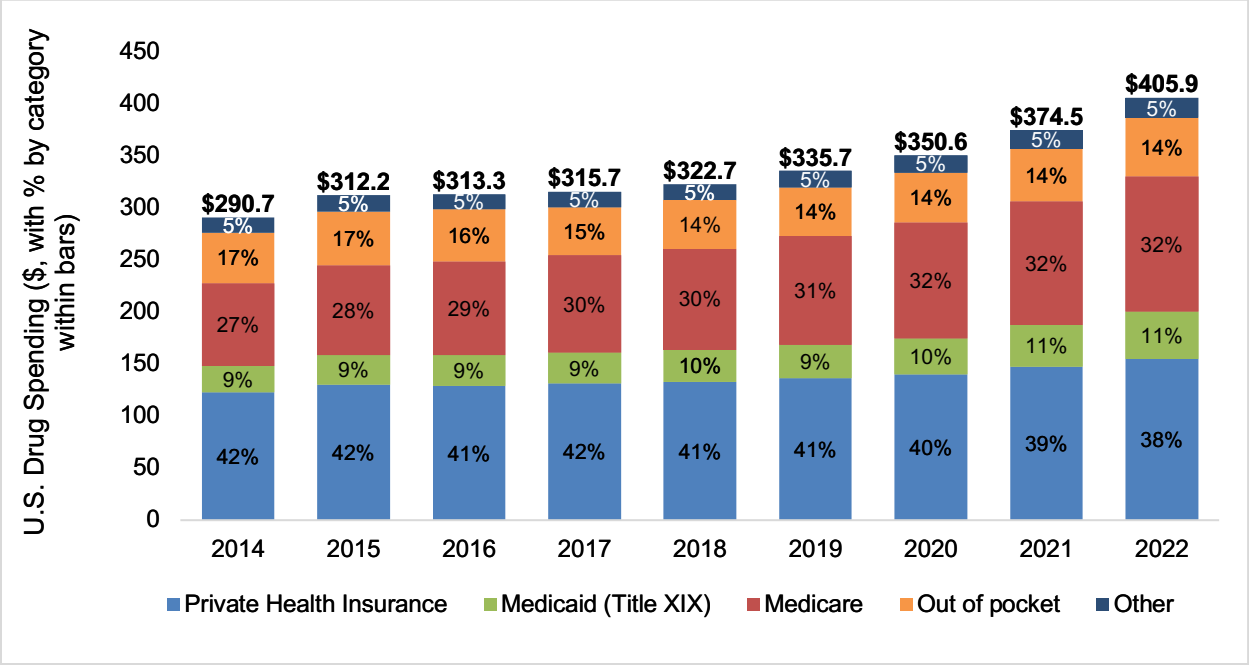
The NHE data include estimated payer net drug spending trends from 2014 to 2022 for drugs dispensed in retail settings. Compared with the 2014–2022 payer gross spending described above, total payer net spending increased at a lower annual rate of 3.4 percent, from $290.7 billion in 2014 to $350.6 billion in 2020 (Figure 3.3). These increases have disproportionately been driven by increasing Medicare and Medicaid spending on drugs (at 6.7 and 6.0 percent annual increases, respectively, over the same period) compared with slower, 2.4 percent annual growth in private insurance spending on retail-dispensed drugs, from $122.8 billion in 2014 to $140.3 billion in 2020.[26] Over the most recent three years of available data (from 2020 through

[26] The relative reduction in total spending from private insurance is likely related to the 2020 onset of the COVID-19 pandemic and Public Health Emergency, which affected both employment patterns and access to health care services.

2022), payer net drug spending increased at a much faster rate at 7.9 percent overall, 8.2 percent for Medicare, 15.8 percent for Medicaid, and a lower 5.2 percent for private insurance.[27]

NHE staff assemble estimates of net payer and patient spending on prescription drugs from a range of sources, including Part D plan-level DIR data reported to CMS and issuer/market segment/state-level estimates from MLR filings for private insurance (CMS, 2021). These input factors apply across a plan sponsor or issuers' entire, aggregated spending on prescription drugs. However, the applicability and magnitude of rebates varies substantially between drugs. NHE's net spending estimates therefore cannot be used to approximate payer net spending for individual drugs or categories of drugs (for example, brand-name versus generic drugs). These estimates also do not account for changes in the volume or mix of drugs purchased by these plans over time.

Figure 3.3. NHE-Estimated Net Drug Spending, 2014–2022



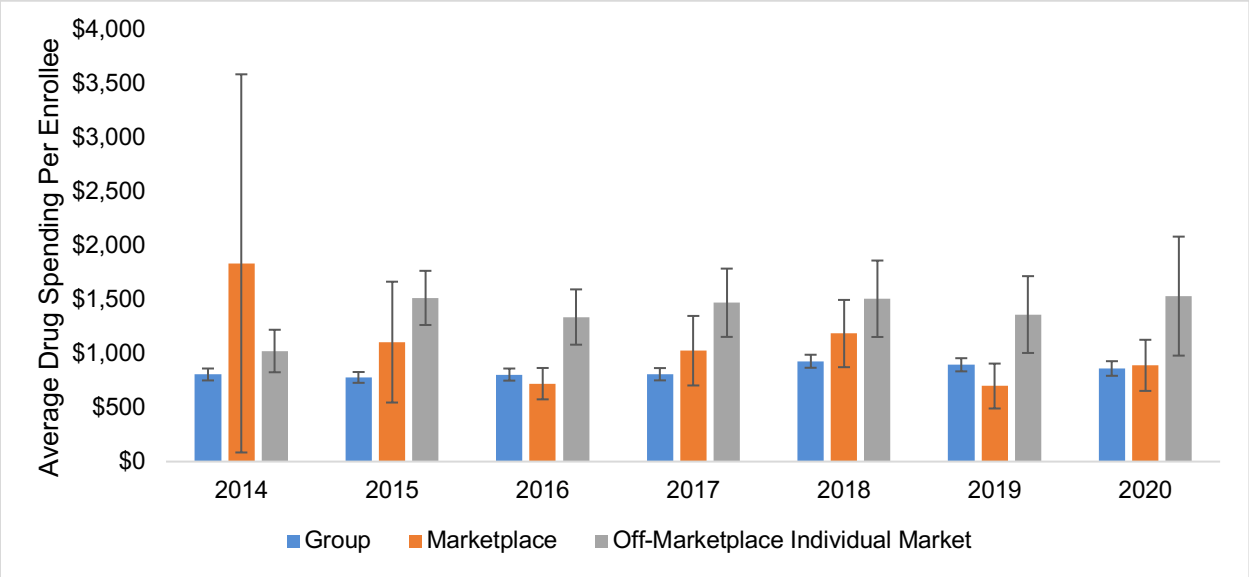
SOURCE: RAND analysis of NHE data.
NOTE: "Other" includes the Children's Health Insurance Program (CHIP) (Title XIX and Title XXI), the Department of Defense, the Department of Veterans Affairs, and other third-party payers and programs. The number at the top of each bar is total spending in billions. Percentages may not add to 100 percent due to rounding.

[27] We address changes 2020 through 2022 separately because we do not have MEPS data for comparison for these years.

Per-Enrollee Total Retail Prescription Drug Spending by Group, Marketplace Individual Market, and Off-Marketplace Individual Market Plans

Gross spending on retail prescription drugs among private payers also varies between group, Marketplace non-group, and off-Marketplace non-group plans. In our analysis using MEPS data from 2014 to 2020, we found that average spending per enrollee in group plans modestly fluctuated and was consistently lower than $1,000 in each year (Figure 3.4). Average spending among Marketplace non-group plans started at over $1,500 in 2014 (driven, along with the very high variance for that single year, by an outlier observation) but then decreased to below $1,000 in subsequent years. From 2015 to 2020, average drug spending among off-Marketplace non-group plans was higher than among group and Marketplace non-group plans, ranging between an average of $1,300 to $1,600 per enrollee. Because MEPS does not include rebate-adjusted amounts or nonretail drugs, this data source is limited in addressing overall trends in spending at net prices to payers. Relatively consistent MEPS spending per capita (from Figure 3.4) compared with modestly increasing private spending on prescription drugs (Figure 3.2) suggests that an increase in enrollment, rather than in prices per se, may be an important contributor to spending growth.

Figure 3.4. MEPS-Estimated Average Annual Drug Spending Per Enrollee Among Group, Marketplace, and Off-Marketplace Non-Group Plans, 2014–2020



SOURCE: RAND analysis of MEPS data.
NOTE: Weighted enrollees in group plans were 158,127,077 individuals in 2014 and 160,231,301 individuals in 2020. Weighted Marketplace individual market plan enrollees were 4,637,801 individuals in 2014 and 8,634,582 in 2020. Weighted enrollees in off-Marketplace individual market plans were 7,162,967 in 2014 and 5,060,335 in 2020.

Recent analysis by Plummer and colleagues (Plummer et al., 2022) that covered all prescription drugs and estimated spending before and after rebate adjustments complements our MEPS analysis. Using MLR filings from 2015 to 2019, they calculated that pre-rebate drug costs

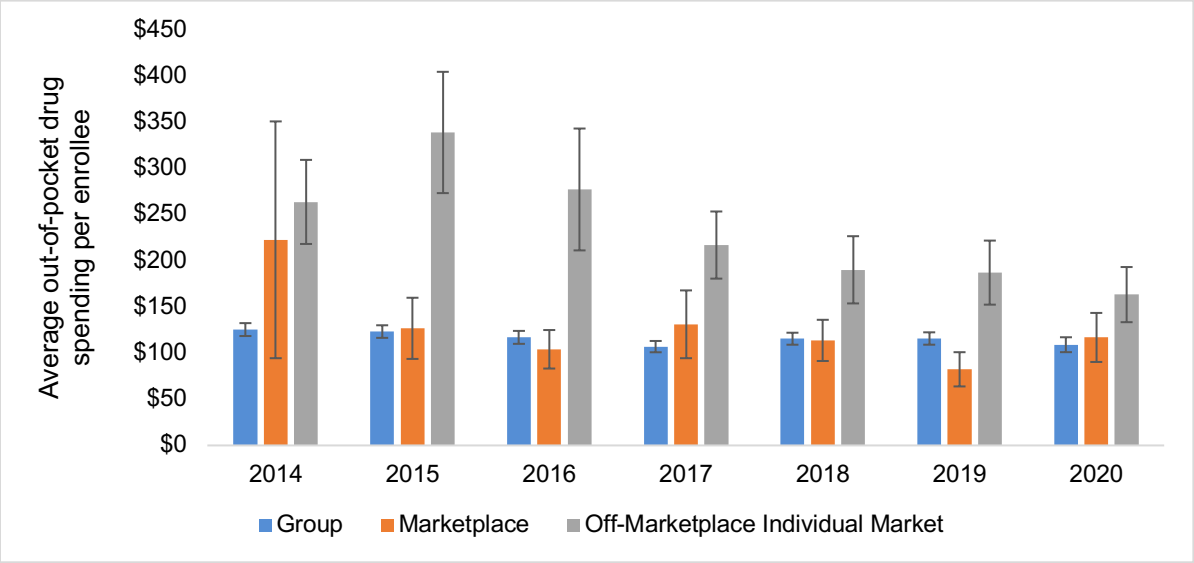
per covered life (PCL) per year among individual market (Marketplace and non-Marketplace) plans increased by 68 percent, far greater than the increases among small (45 percent) and large (24 percent) group plans. Increases in post-rebate drug costs were smaller in magnitude but followed a similar trend of the largest increases occurring in individual market plans (55 percent), followed by small group (24 percent) and large group (8 percent). While individual market plans experienced the greatest increase in median rebate percent during the study period, these plans had lower rebate percentages than group plans. Given their source for rebate information, this study has the same general limitations as the NHE analysis, in that rebates for brand-name drugs are likely to be larger than their reported estimates.

Per-Enrollee Out-of-Pocket Retail Prescription Drug Spending by Group, Marketplace, and Off-Marketplace Individual Market Plans

Despite overall increases in gross and net drug spending over the past decade, total out-of-pocket drug spending for patients has fluctuated modestly. IQVIA estimated that out-of-pocket spending increased slightly, from $76 billion in 2011 to $79 billion in 2021, while MEPS (Figure 3.4) estimated that total out-of-pocket costs declined slightly by the end of the study period.

Similar to the trends in person-level total drug spending, average out-of-pocket spending at the person level also varied by group, Marketplace individual market, and off-Marketplace individual market plans. Out-of-pocket costs among those enrolled in group plans fluctuated modestly, while out-of-pocket costs for those enrolled in Marketplace plans peaked in 2014 at $223 but then declined to $117 by 2020 (Figure 3.5). The average out-of-pocket spending among off-Marketplace individual market enrollees peaked in 2015 at $339, after which it steadily declined to $163 in 2020, a reduction of 52 percent. Out-of-pocket spending among those enrolled in group plans remained fairly constant over time, decreasing slightly during the study period, from $125 in 2014 to $109 in 2019.

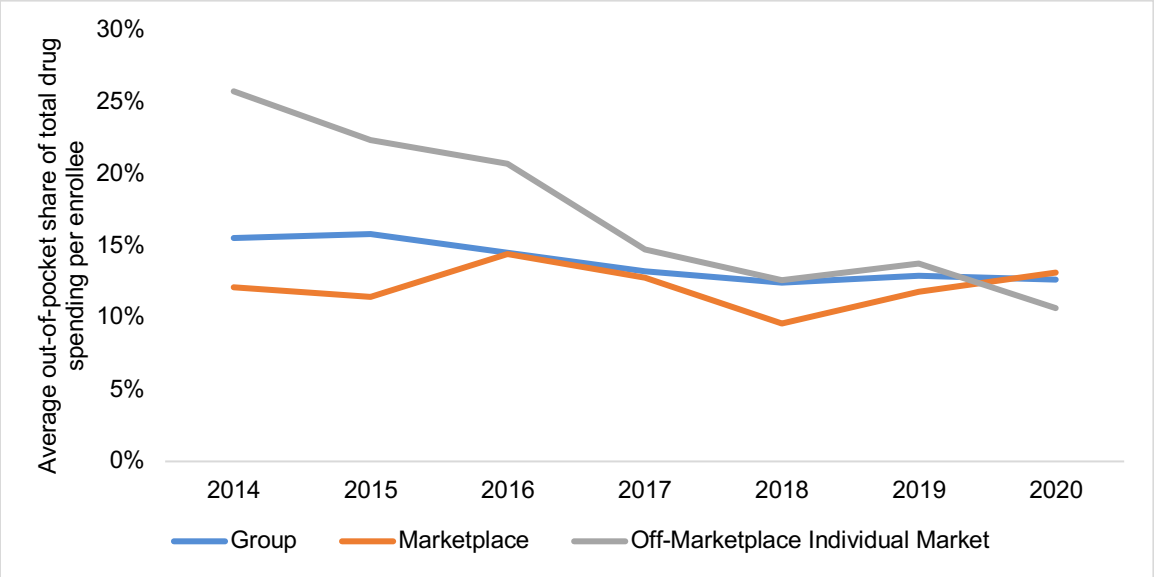
Figure 3.5. MEPS-Estimated Average Annual Out-of-Pocket Drug Spending Per Enrollee Among Group, Marketplace, and Off-Marketplace Individual Market Plans, 2014–2020



SOURCE: RAND analysis of MEPS data.
NOTE: Weighted enrollees in group plans were 158,127,077 individuals in 2014 and 160,231,301 individuals in 2020. Weighted Marketplace individual market plan enrollees were 4,637,801 individuals in 2014 and 8,634,582 in 2020. Weighted enrollees in off-Marketplace individual market plans were 7,162,967 in 2014 and 5,060,335 in 2020.

Greater declines in per-enrollee out-of-pocket amounts (from Figure 3.5) compared with per-enrollee total drug spending (from Figure 3.4) could indicate changes in prescription drug benefit design that reduced cost sharing. In Figure 3.6, we show that those enrolled in off-Marketplace individual market plans experienced a marked decline in the share of drug costs that they paid out of pocket. This trend is consistent with the decline in mean out-of-pocket spending among off-Marketplace individual market plans in Figure 3.5. These trends might be the result of changes in enrollment composition in off-Marketplace individual market plans, because relatively healthy, unsubsidized individuals initially enrolled in Marketplace plans might have switched to off-Marketplace individual market plans as Marketplace premiums increased during this time period (Parys, 2018). By contrast, group and Marketplace plans experienced relatively constant shares of drug costs paid out of pocket over time.

Figure 3.6. MEPS-Estimated Percent of Out-of-Pocket Drug Spending out of Total Drug Spending Among Group, Marketplace, and Off-Marketplace Individual Market Plans, 2014–2020



SOURCE: RAND analysis of MEPS data.
NOTE: The group plan sample size was 158,127,077 individuals in 2014 and 160,231,301 individuals in 2020. The Marketplace individual market plan sample size was 4,637,801 individuals in 2014 and 8, 8,634,582 in 2020. The off-Marketplace individual market plan sample size was 7,162,967 in 2014 and 5,060,335 in 2020.

As with overall spending in the group, Marketplace, and off-Marketplace individual market segments, per-enrollee out-of-pocket spending trends were also subject to substantial heterogeneity in drug use, with a substantial proportion of enrollees with little to no drug spending, compared with Medicare; as such, overall out-of-pocket spending trends might mask a substantive heterogeneity in these market segments.

Spending on Brand-Name Specialty Drugs

Increases in the U.S. Food and Drug Administration (FDA) approval rates, volume dispensed, and prices of brand-name specialty drugs have contributed to the overall growth in drug spending over the past decade (Congressional Budget Office, 2021). The increasing number of unique specialty drugs available has played a major role in this trend, from 3 percent of unique drugs among a collection of privately insured plans in 2003 to 11.8 percent of drug products in 2014 (Dusetzina, 2016). Likewise, from 2010 to 2017, the proportion of specialty drug volume increased from 1 to 2 percent out of all retail-dispensed drugs, corresponding to an increase of 2–5 percent of the population obtaining a specialty drug. Despite these relatively small proportions in volume of patient populations and dispensed drugs, Hill and colleagues used MEPS data to estimate payer gross spending on retail specialty drugs, which increased at an annual rate of 14.5 percent, from $61.1 billion in 2010 to $157.3 billion in 2017 (Hill, Miller, and Ding, 2020). This

estimate is considerably greater than our MEPS estimate for all retail-dispensed drugs (a 5.9 percent annual increase from 2014 through 2020; see Figure 3.2).

Spending on Provider-Administered Drugs

Drugs administered or dispensed in provider settings have represented an increasing share of overall drug spending. In an IQVIA analysis of NSP data, gross manufacturer drug spending attributable to non-retail-dispensed drugs increased from 32 percent in 2017 to 35 percent in 2022. During this time, spending on non-retail-dispensed drugs increased at an annual rate of 9.4 percent, from $192 billion in 2017 to $300 billion in 2022, compared with an annual increase of 6.5 percent in retail-dispensed drug sales (IQVIA, 2023). Rebates are common for retail-dispensed drugs but uncommon among provider-administered drugs, so these reported trends likely underestimate the actual difference in changes in net spending between these two drug groups.

Studies spanning earlier time periods have also estimated larger spending increases in provider-dispensed drugs compared with retail-dispensed drugs. In an analysis of First Databank and pharmacy claims from a single health plan from 2008 to 2016, Hernandez and colleagues found that brand-name injectable drugs, which are dispensed more frequently by providers than by pharmacies, increased by 15 percent in gross spending, compared with an increase of 9 percent in gross spending among brand-name oral drugs (Hernandez et al., 2019). Likewise, a prior ASPE report examining Medicare fee-for-service Part B spending from 2006 to 2017 estimated that per-enrollee provider-dispensed drug spending increased by 8 percent compared with 3 percent per-person increases in retail-dispensed drugs (Nguyen and Sheingold, 2020). A notable limitation of these studies is that they are limited to specific payers and may not generalize to the full extent of provider-dispensed drugs.

These overall increases in provider-dispensed drug spending are disproportionately attributable to a small number of drugs that are either new or have undergone sharp price increases. From 2008 to 2016, there was a 53 percent increase in cost per drug claim in Medicare Part B yet a decrease in the overall volume of drugs dispensed. However, the drugs that disproportionately drove these increases in spending had a combination of increases in costs per claim and volume during this time. These include drugs categorized by the authors using CVS Caremark reference files as “specialty drugs” (48 percent increase in cost per claim and 6 percent increase in utilization), ophthalmic preparations (13 percent increase in cost per claim and 238 percent increase in utilization), and antiarthritic and immunologic agents (117 percent increase in cost per claim and 19 percent increase in utilization) (San-Juan-Rodriguez et al., 2021). By 2017, the 20 drugs with the highest payment amounts in Medicare Part B accounted for 60 percent of Part B drug spending (Nguyen and Sheingold, 2020).

The federal 340B drug discount program sets ceiling prices for outpatient drugs dispensed by certain categories of eligible hospitals, clinics, and other providers. The 340B program has important implications for physician-administered drugs, as well as other outpatient pharmacy-

dispensed drugs. In a study using Medicare Part B claims data, Desai and McWilliams found that hospital eligibility for the 340B program was associated with increases in the number of patients receiving Part B drugs and the number of Part B hematology-oncology and ophthalmology drugs dispensed (Desai and McWilliams, 2018). Other studies have found increases in oncology spending and chemotherapy administration rates associated with 340B participants compared with non-340B hospitals (Medicare Payment Advisory Commission, 2019; U.S. Government Accountability Office, 2015). Despite these increases in spending and volume, the savings from these programs have not been associated with expanded care or lower mortality rates among patients receiving care from 340B-participating providers (Desai and McWilliams, 2018).

Spending on Biologics

Biologics represent a large portion of the increases in spending among drugs dispensed in both provider and retail-based settings. Among drugs launched between 2008 and 2021, biologics had on average 2.2 times higher manufacturer list prices compared with small-molecule drugs (Rome, Egilman, and Kesselheim, 2022). The number of biologics available has also made up an increasingly large share of new drugs that have been approved by FDA, at 27 percent of new products from 2015 to 2019. Thus, the overall share of Part B drug spending on biologics has grown considerably, from $5.6 billion in 2006 to $18.6 billion in 2017, while Part B spending on small-molecule drugs only increased from $4.5 billion to $5.6 billion during the same time period (Nguyen and Sheingold, 2020). Biologics also accounted for $12 billion in gross spending in Medicare Part D in 2019 (HHS, 2022c).

While provider-administered biologics rarely have rebates that affect the overall net spending on these drugs, rebates are more commonly used in retail-dispensed biologics. In a study examining four case studies of biologics, San-Juan-Rodriguez and colleagues estimated list and net prices of filgrastim, pegfilgrastim, infliximab, and insulin glargine using SSR Health data from 2007 to 2018, which includes pre- and post-periods of corresponding biosimilar entries for these biologics. In two of these four cases, list prices increased at faster rates than net prices (pegfilgrastim and insulin glargine), while the others (filgrastim and infliximab) experienced relatively parallel increases over time. For infliximab and insulin glargine, net prices started declining once biosimilars were introduced, while filgrastim and pegfilgrastim experienced decreases in the two to three years before biosimilars became available (San-Juan-Rodriguez et al., 2019). Thus, the trends of changes in list and net prices vary by each individual biologic, which limits our ability to estimate the net price of an individual drug based on a rebate rate spanning across a basket of drugs. Moreover, these findings are limited in representing net prices paid to manufacturers, not by payers.

The disproportionate spending on biologics is primarily due to their high prices, which is a result of a lack of competition and available substitutes. Biologics are protected from direct competition from biosimilars for a period of 12 years by regulatory exclusivity, which is longer than the seven-year period afforded to new small-molecule drugs. Moreover, the process for

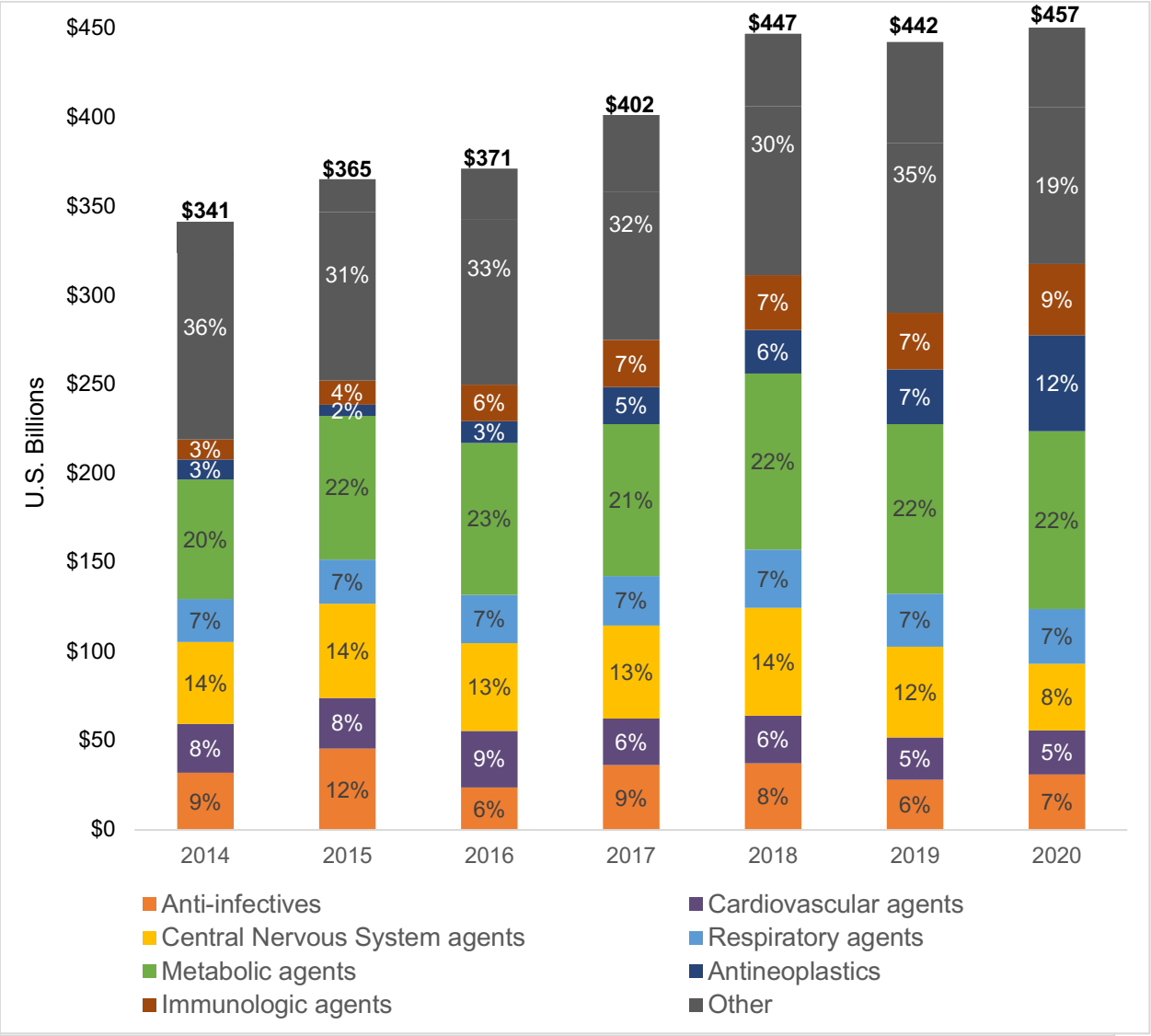
producing a biosimilar is more challenging than for producing generics of small-molecule drugs. Even when biosimilars are available, there are concerns that consumers may not use biosimilars in the ways they use generics, because biosimilars are generally not interchangeable in the same way that generics are with their brand-name reference drug counterparts (Congressional Budget Office, 2021; Kolbe et al., 2021). As of September 2023, 42 biosimilars have been FDA-approved for 12 reference biologics (FDA, 2023), and it is expected that the increased use of biosimilars will reduce overall spending on biologics by $38.4 billion between 2021 and 2025 (Mulcahy et al., 2022).

Spending by Therapeutic Class

Changes in gross and net drug prices vary widely by therapeutic class. In a study by Hernandez and colleagues using SSR Health data, list prices increased at a faster rate than net prices across all therapeutic classes studied from 2007 to 2018 (Hernandez et al., 2020a). The difference between changes in list and net prices was greatest among noninsulin antidiabetic agents, where list prices increased by 12.3 percent per year and net prices increased only by 2.1 percent. Conversely, the difference between changes in list and net prices were smallest among antineoplastics (cancer drugs), where list prices increased by 4.4 percent per year and net prices increased by 2.9 percent. Other classes with relatively small differences between changes in list and net prices included tumor necrosis factor inhibitors (used to treat autoimmune disorders, such as rheumatoid arthritis and psoriasis) and multiple sclerosis agents (Hernandez et al., 2020a).

We examined the proportion of payer gross spending among retail-dispensed drugs in MEPS representing the following therapeutic classes: anti-infectives, cardiovascular agents, central nervous system agents, respiratory agents, metabolic agents, antineoplastics, immunologic agents, miscellaneous agents, and other (Figure 3.7). Of these classes, antineoplastics experienced the largest increase in share of drug spending, from 3 percent in 2014 to 12 percent in 2020. This was followed by immunologic agents and miscellaneous agents (both starting from 3 percent in 2014 to 9 percent in 2020 for immunologic agents and 11 percent in 2020 for miscellaneous agents). Other classes, such as anti-infectives, cardiovascular agents, and central nervous system agents, experienced declines in their share of total spending. These trends suggest that the changing mix of spending by therapeutic classes may be contributing to the overall increases in drug spending during this time period. Many of the drugs that are part of the therapeutic classes that experienced increases in their share of spending are considered specialty drugs and/or biologics (Mullican and Francart, 2016). These therapeutic classes also encompass drugs dispensed in provider settings that are not included in our MEPS analysis, so these estimates likely understate the actual increases in spending during this time period.

Figure 3.7. MEPS-Estimated Gross Drug Spending by Therapeutic Class, 2014–2020

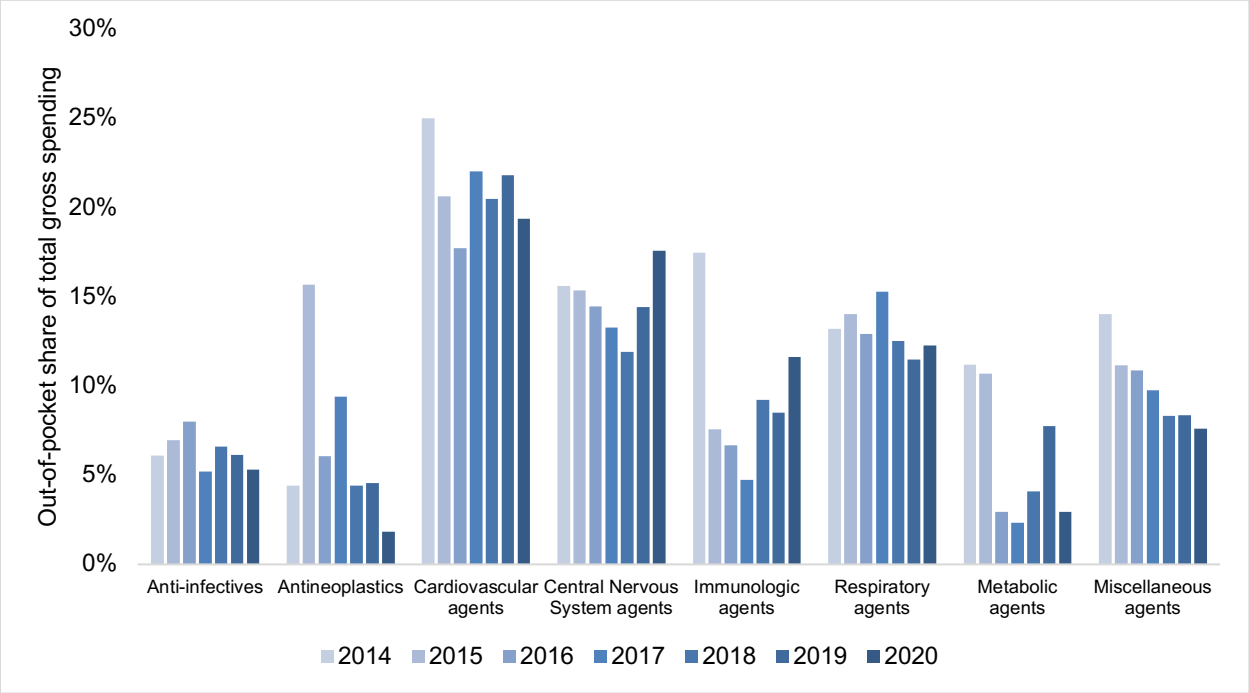


SOURCE: RAND analysis of MEPS prescription event data.
NOTE: "Other" includes all other classes not separately reported combined, including the "Miscellaneous agents" class in MEPS data. Percentages may not add to 100 percent due to rounding. The annual totals in this figure do not exactly match those in Figure 3.2. This figure stems from analysis of the MEPS prescription event data rather than from information from the MEPS household file. There may be slight differences in sample size and weights.

Among nearly all therapeutic classes, out-of-pocket spending as a proportion of gross spending either fluctuated or decreased from 2014 to 2020 (Figure 3.8). The only therapeutic class with a slight increase in this proportion was central nervous system agents (from 16 percent to 18 percent of gross costs paid out of pocket). However, given the overall reduction in gross spending for drugs in this class, total out-of-pocket spending decreased from $7.2 billion to $6.6 billion from 2014 to 2020. While out-of-pocket spending as a proportion of total spending at gross prices decreased for antineoplastics, the larger overall increase in gross spending for this

therapeutic class led to a near-doubling of total out-of-pocket spending, from $498 million in 2014 to $986 million in 2020. While respiratory and miscellaneous agents also experienced declines in the percent of spending paid out of pocket, aggregate out-of-pocket spending likewise increased for these drugs by $581 million and $3.0 billion, respectively. A key feature that may influence spending trends among therapeutic classes and subclasses is the degree of competition in the class; Section 204 data may provide opportunities to disaggregate and assess therapeutic class differences according to those in which drugs are subject to greater or lesser market competition.

Figure 3.8. MEPS-Estimated Percentages of Out-of-Pocket Spending as a Share of Gross Spending by Therapeutic Class, 2014–2020



SOURCE: RAND analysis of MEPS data.

Spending on Generics

Generics have slowed the growth in overall prescription drug spending, constituting approximately 90 percent of drugs dispensed but only 20 percent of gross drug spending (Association for Accessible Medicines, 2021). Despite overall generic drug prices declining (Teasdale et al., 2022), a small share of generic drugs—typically older injected or infused generic drugs that are also in shortage—have been experiencing sharp increases in price during a short time period, often referred to as *price spikes*. Price doubling among Medicare Part D retail-dispensed drugs has increased in frequency, with one study estimating 1 percent of generics doubling in price in 2007 and 4 percent doubling in price in 2013, and another study estimated an

increase from 3 percent of generics doubling in price in 2010 to 7 percent doubling in price in 2015 (Joyce et al., 2018; U.S. Government Accountability Office, 2016). In an analysis using IQVIA NSP data that examined both retail and provider-dispensed drugs, Conti and colleagues estimated that out of 6,182 generic products, the median price increase between 2013 and 2014 was 2 percent, yet 23 percent of drugs experienced increases greater than 20 percent (Conti, Nguyen, and Rosenthal, 2018). However, in a recent study by Patel and colleagues using the Medicaid state drug utilization data, generic price spikes had modestly declined, from 8 percent of drugs in 2014 to 6 percent in 2017 (Patel, Kesselheim, and Rome, 2021).

Lack of competition and shortages may be contributing to these generic price increases. Multiple studies have found that generic products with less-competitive markets (that is, fewer manufacturers or greater market concentration) experience greater price increases (Nguyen et al., 2021) and are more likely to experience price spikes (Conti, Nguyen, and Rosenthal, 2018; Dave et al., 2017). However, more-recent research suggests that recent price spikes may be less sensitive to competition (Hernandez et al., 2020b). Additionally, generics represent the majority of drugs that experience a shortage (FDA, 2020), which has led to price increases following the shortage to incentivize greater production of these drugs (Dave et al., 2018; Alevizakos et al., 2016).

Key Takeaways

Through our review of the literature and our own analyses, we found that increases in U.S. prescription drug spending at gross prices over the past decade were disproportionately driven by high prices of a small number of specialty drugs, biologics, provider-administered drugs, and price spikes among generics. Changes in total and per capita drug spending at gross prices were, however, more modest for those with private coverage than for those with public coverage.

Across all drugs and the broader U.S. market, several studies found that spending at gross prices was increasing at a faster rate than spending at net prices; increases in spending in terms of both gross and net prices were greater than increases in volume alone (Sood et al., 2020; Rome, Egilman, and Kesselheim, 2022; Hernandez et al., 2020a; Kakani, Chernew, and Chandra, 2020; Hernandez et al., 2019). Plans sold on the individual market appear to have the largest relative increases in spending at both gross and net prices (Plummer et al., 2022). However, all of these findings were based on limited and incomplete data on net prices and spending at net prices, which were unavailable from the commercial payer perspective and/or estimated as a sum across a large basket of drugs.

In contrast with these prior studies, RxDC data offer exact rebate amounts for private insurance by therapeutic class, as well as the opportunity to examine variation in payer net drug spending by plan sponsors, issuers, and their PBMs. The RxDC data also include information on out-of-pocket spending. We found some evidence that cost-sharing decreased over time in aggregate and became more similar over time between individual and group insurance markets.

However, these aggregate trends likely mask important changes in out-of-pocket spending for specific drugs and therapeutic classes that could be further investigated using RxDC data.

Chapter 4. Empirical Evidence on Links Between Premiums, Benefit Design, Drug Prices, and Drug Spending

Research Questions

- What is the relationship between spending on prescription drugs at net prices and premiums?
- Are these relationships different when considering spending on drugs at gross prices?
- Are there differences in relationships for different market segments?

Conceptually, premiums for prescription drug coverage, the design of prescription drug benefits, drug prices, and spending on drugs are interconnected, each affecting the others within a given plan year and over time. Some of the relationships between these concepts are clear:

- Drug spending is the product of drug prices (for example, net prices to payers) and utilization.
- Higher drug spending will, holding all else constant, lead to higher premiums.
- Plan sponsors and issuers set premiums in future periods based on prior experience (that is, prior spending) and projections of future spending.
- PBMs and their plan sponsor and issuer clients use negotiation leverage, at least when they have it, to constrain growth in drug prices and therefore spending.
- PBMs and their clients use a range of benefit design tools to constrain utilization and, therefore, spending on drugs.
- PBMs themselves consider their own margins rather than the margins of their clients and may, all else equal, prefer high-gross-cost, high-rebate products over less expensive alternatives.

Given this complexity, predicting and estimating associations between just two of these interconnected concepts—for example, links between drug spending and premiums over time—is difficult. Furthermore, because spending on prescription drugs is dwarfed by spending on physician, hospital, and other non-drug health care, and because spending in these non-drug areas is increasing as quickly as or faster than spending on drugs, it is difficult to isolate the specific effect of changes in drug spending alone on premiums covering both medical and pharmacy benefits, particularly in the volatile post-ACA period.

Broadly, payers and PBMs may prefer to respond to expected or actual changes in drug spending by modifying other aspects of benefit design—for example, formulary structure, prior authorization requirements, or cost sharing going forward—before changing premiums. These targeted responses may be most feasible when a single or small number of drugs have outsized effects on drug spending trends. While there would not be an empirical relationship between drug spending and premiums in this case, there may well be other important implications of changes in drug spending on patients' access to drugs and out-of-pocket spending. However,

when all targeted approaches to constrain drug spending growth are exhausted, increases in drug spending must at some point be reflected in higher premiums for drug coverage.

Approach

We conducted a literature review focusing on studies and papers relevant to the research questions in this chapter. Our literature review approach to answer research questions in this chapter mirrored the approach described in Chapters 2 and 3. Many of the articles we identified fell into two categories: those addressing the implications of rebates to different stakeholders and those investigating the role of PBMs in prescription drug markets and spending.

Drug Spending at Status Quo Net Prices Versus Alternatives

There is limited empirical literature on the specific contributions of rebates and negotiated net prices for brand-name drugs on spending, relative to alternative approaches. A few research papers and reports have highlighted the point that the growth in drug spending after accounting for rebates and net prices is lower than the growth of drug spending calculated using list prices alone (Kakani, Chernew, and Chandra, 2020; Center for Improving Value in Health Care, undated; see Chapter 3 for more details). However, these papers only highlight the importance of including rebates and other discounts when calculating manufacturer net revenue or payer net spending. They do not address what drug spending would be if the current rebate-based system to determine net prices were replaced with an alternative system.

Understanding the impact of rebates, or the absence of rebates, on drug spending requires setting up the relevant policy and market counterfactual. For example, theoretically, compared with a scenario without rebates but with the same availability of drugs, the same offerings of formularies, and the same list prices, the existence of rebates reduces drug spending, but it is unclear in what policy and market environment such a scenario would occur. There is already some concern that the negotiation system that allows rebates may drive up list prices. There is also evidence that in settings without rebates, such as generic markets, PBMs and manufacturers use similar tools, such as spread-based contractual arrangements,[28] that may have similar impacts on spending and consumer welfare. Furthermore, there is concern that PBMs may reclassify rebates as fees when rebates receive more regulatory scrutiny (Clalabrese, 2008). Finally, the magnitude of rebates and the appeal of large relative rebates to PBMs (either as a source of net revenue for the PBM or for marketing purposes) may have important implications on the mix of drugs easily available to patients and prescribers on formularies (Socal, Bai, and Anderson, 2019). This may be of special concern in cases in which drugs with the largest proportional rebates differ from the drugs with the lowest net cost to payers.

[28] Under spread pricing arrangements, PBMs receive a predetermined, flat rate for fills of a certain prescription drug and retain the margin between this amount and their acquisition cost.

Some recent studies have attempted to estimate the welfare implications of PBMs. For example, Mulligan presents a back-of-the-envelope estimate of the value of PBM services at $145 billion annually, based primarily on assumed parameter values and simplifying assumptions for tractability (Mulligan, 2022). Other in-progress research takes a similar approach. However, given the current gaps in knowledge and the lack of an appropriate counterfactual, these studies are more useful as frameworks for assessing the value of PBMs rather than as sources of reliable point estimates. There remain many outstanding questions regarding the impacts of PBMs.

Relationships Between Drug Spending and Premiums

Researchers have examined the question "What contributes to premium growth?" broadly. However, this literature has not disentangled the unique contribution of drug spending. Instead, in this literature, all medical care is grouped into a single category, as opposed to administrative cost or insurer profits. For example, a 2008 article explored how insurer profits and administrative costs affected premiums in California and found that 85 to 90 percent of premium growth can be explained by the cost of care (Sood, Daugherty, and Ghosh, 2008). We have not found any literature that breaks down how the cost of each type of service contributes to premium growth. Absent a specific drug spending effect, the contribution of drug spending on premium growth may be proportional to the contribution of drug spending growth to growth in total medical care spending. This is broadly consistent with actuarial practice, where plans offering both health and drug benefits often separately model expenses under the drug benefit using prior-year information; in other words, the combined premium reflects expectations for changes in spending across the medical and drug benefits combined.

From an actuarial perspective, projections of drug spending may influence premiums in only a blunt fashion. Based on our key informant discussions, actuaries project aggregate drug spending forward to estimate next-year spending. The level of sophistication of these projection models varies, with some accounting for more granular categories of drugs (for example, brand-name versus generic drugs) separately. Only rarely are adjustments made to these projections in response to market changes for an individual or narrow set of drugs. For example, while some projection models included ad hoc adjustments for major new product classes, such as PCSK9 inhibitors, hepatitis C treatments, and COVID-19 therapeutics, ad hoc adjustments to drug spending projections for other drugs appear to be uncommon.

When premiums serve as a key feature for plans to attract enrollees choosing between plans in the commercial market, there might not be a one-to-one relationship between drug spending (or medical spending in general) and premiums. If drug spending at net prices increases, there are other plan features, such as cost sharing and network breadth, that insurers could change before increasing premiums. Furthermore, while premiums are relatively easily compared across competing plan offerings, the complexity of benefit design makes it much more difficult for

patients to identify, let alone compare, different benefit designs or changes in benefit design. Some anecdotal evidence suggests that insurers prefer the arrangement of low premiums, high cost sharing, and high list price over the alternative of high premiums, low cost sharing, and low list price, potentially for these reasons (Grassley and Wyden, 2021). At the same time, there are also regulations, such as the establishment of tiered plans based on actuarial value on the ACA Marketplace, that constrain how much insurers can change benefit design and generosity.

Relationship Between Drug Spending and Other Consumer Outcomes

There is some research showing the association between the magnitude of the difference between drug spending at gross versus net prices (in other words, the magnitude of rebates) and out-of-pocket costs. A recent study found that a $1 increase in rebates was associated with a $0.02 higher out-of-pocket amount in commercial data from 2014 to 2018 (Yeung, Dusetzina, and Basu, 2021). This association, while modest in magnitude, was statistically significant. Part of the mechanism behind this association may be that rebates are associated with higher list prices, to which coinsurance is tied. On average, a $1 increase in rebates was found to be associated with a $1.17 increase in list price in one study (Sood et al., 2020) and a $2.09 increase in another (Yeung, Dusetzina, and Basu, 2021). It is important to note that this finding was the result of a cross-sectional comparison between drugs that have rebates and drugs without rebates. The studies do not say how list price and out-of-pocket costs would change for any given drug if rebates were eliminated.

As described in Chapter 3, the magnitude of rebates reflects a number of contextual factors, including the absolute and relative cost and benefit of a drug, the competitive landscape of the drug market, and the PBM's ability to shift demand through the use of formularies and other tools. There is limited literature linking these contextual factors to rebates and, subsequently, to consumer outcomes. One study on Medicare Part D showed that a patient's share of drug costs is higher for more competitive drug classes, suggesting a positive association between drug class competition, rebates, and out-of-pocket cost (Lakdawalla and Li, 2021).

Empirical Estimates of Stakeholder Margins

Quantitative Estimates

Payer spending on drugs at net prices is the most relevant spending quantity from the perspective of potential links to premiums and benefit design. Payers' initial outlays at gross prices and later final costs at net prices reflect markups along the drug supply chain. While these margins have important implications on drug spending, there is very limited evidence on their magnitude in either absolute or relative terms.

Two reports systematically estimate margins across stakeholders, and they generate similar estimates. In their 2017 white paper Flow of Money Through the Pharmaceutical Distribution

System, Sood and colleagues used data from SEC filings, National Average Drug Acquisition Cost (NADAC),[29] and National Average Retail Price (NARP)[30] to estimate average profit margins within sectors and across the pharmaceutical supply chain (Sood et al., 2017). On average, they estimated that manufacturers had gross margins of 71 percent and an average net profit of 26 percent of sales. Other stakeholders had more modest margins, with pharmacies at 20 percent gross and 4 percent net, insurers at 22 percent gross and 3 percent net, and PBMs at 6 percent gross and 2 percent net.

A 2019 report by Pew Charitable Trusts, which used a combination of secondary sources, including surveys from the Berkeley Research Group and KFF, similarly estimated retained revenues by stakeholder. In particular, they calculated that pharmacies retained 19 percent of revenues (that is, gross margin), PBMs retained 7 percent, and manufacturers retained 60 percent of sales. This report also estimated that the revenue PBMs have received for administrative fees, spread pricing, and DIR increased from $5.9 billion in 2012 to $16.6 billion in 2016 (Yu, Atteberry, and Bach, 2018).

Other sources, particularly industry reports, have estimated margins specific to PBMs and the pass-through of rebates to insurers. For example, in its internal analysis of rebates in commercial plans, CVS Health estimated that its PBM, CVS Caremark, has decreased the percentage of the rebate that it retained over time, from 27 percent in 2011 to 6 percent in 2017, while average rebates increased from $78 to $254 per member during the same time period (CVS Health, 2018). Express Scripts, another PBM, reported that it retains 5 percent of rebates, though nearly half of its clients obtain a 100 percent pass-through of rebates (U.S. Securities and Exchange Commission, 2018). In one of Express Scripts' contracts, it also charged administrative fees of either 4.58 percent of the average wholesale price or 5.5 percent of the wholesale acquisition cost of a drug product to health plans (Minn, 2020). Other reports have estimated net profits for PBMs to be as low as 4.5 percent (Roehrig, 2018) and the percentage of retained rebates to be as high as 10 percent (Fein, 2013).

Despite relatively similar margin estimates for stakeholders across these sources, it is not possible to fully assess their validity. Some articles, such as those by Sood et al. (2017) and Pew (Yu, Atteberry, and Bach, 2018), offer greater transparency in their calculations and use either surveys or government datasets to produce their estimates. By contrast, the industry reports use self-reported numbers from PBMs themselves, and they do not disclose their methods or underlying sources used to produce these estimates. For estimates of retained revenues or profit margins, it is largely unknown what proportion of these calculations represent retained rebates, administrative fees, and revenues from spread pricing.

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[29] NADAC represents an average of drug acquisition costs by drug grouping, drug category, and pharmacy type. These data are submitted by retail community pharmacies to Myers and Stauffer LC, which contracts with CMS to calculate NADAC.

[30] NARP was a CMS-administered survey, which collected drug prices that were paid to pharmacies by Medicaid, cash, and certain third-party payers. This survey was suspended in 2013.

There are policies and regulations that may affect margins. One example is the MLR regulation on insurers. The ACA requires insurers to meet minimum MLRs and pass excess profits back to consumers (or split them between employers and consumers, in the case of ESI). We found limited direct empirical evidence on how MLR laws affect margins per se. Interviews with insurers when the requirement was first announced suggest that insurers were adjusting premiums and reducing broker commissions, but the aggregate effect of these steps on margins is unclear (U.S. Government Accountability Office, 2014). There is one report showing that the implementation of ACA's MLR rules has limited insurer profit, but it does not show who benefited from these limits and in what form (whether through payments to enrollees or changes to benefit design) (Hall and McCue, 2019).

Key Takeaways and Opportunities for Analysis of RxDC Data

There is an extremely limited literature estimating the specific links between premiums, benefit design, and drug spending. The dearth of available evidence likely stems from the complex and dynamic relationships between these interconnected concepts. For example, in the case of increasing spending on drugs at net prices, insurers and their PBMs could just as easily modify benefit design rather than adjust premiums—and may prefer to do so. A handful of studies found positive but modest relationships between the magnitude of rebates—that is, the difference between payer spending at gross versus net prices and out-of-pocket spending for consumers. This suggests a potential partial link between drug spending and benefit design, rather than to premiums directly. Another likely driver of the limited literature in this area is the lack of data structured to link premium, benefit design, and drug spending information. The scope of the Section 204 data collection requirements and the RxDC data offer new opportunities in this regard. The RxDC data collection templates cover both premiums and drug spending at payer net (and gross) prices. To the extent that RxDC data in these two areas can be linked, future analysis could explore at least the correlation between drug spending and premiums. However, as described in the following chapters, there are several practical limitations of using RxDC data in this way.

The RxDC data cover only certain aspects of benefit design—for example, out-of-pocket spending and per capita utilization in certain of the data reporting templates. Later chapters describe limitations in using these data to fully characterize benefit design and identify changes in benefit design over time. In sum, while RxDC data offer important new avenues for analysis on prescription drug spending, significant data scope and methodological limitations will complicate analyses that aim to directly use the RxDC data to estimate associations between drug spending and premiums.

Chapter 5. Illustrative Analyses of 2020 and 2021 RxDC Data

This chapter outlines the structure of RxDC data files and presents illustrative analyses of the inaugural RxDC data for plan years 2020 and 2021. As described in Chapter 1, the RxDC system was developed by HHS, the Department of Labor, and the Department of the Treasury (the "Departments") to collect health care and drug spending, utilization, premium, and other information from issuers and plan sponsors as required in Section 204 (of Title II, Division BB) of the CAA,2021. As of September 2023, ASPE, CCIIO, and their contractors continue to validate and analyze the RxDC data submitted to date. This ongoing activity is key to resolving discrepancies and standardizing the data structure and format; as a result, a full analysis of 2020 and 2021 RxDC data is not yet feasible. The illustrative analyses in this chapter are intended to convey key areas for future analysis of RxDC data with relevance for policy development. The findings presented in this chapter should be considered preliminary; later analysis of the RxDC data may produce substantively different results from similar analyses.

RxDC Data Structure and Overview

Each RxDC submission includes

- between one and eight data files (labeled D1 through D8) covering information described in Table 5.1 aggregated across plans, as described in detail below
- plan-level characteristics files
- narrative responses describing submitters' methodologies and assumptions underlying the data tables and plan-level files.

Our analysis focuses on information captured across the eight RxDC data templates summarized in Table 5.1.

Table 5.1. RxDC Data Template Contents

Data Template	Short Description	Content
D1	Premium and life years	Average premiums, total premiums, and member life years
D2	Medical spending	Spending and cost sharing by medical spending categories
D3	Top 50 most frequent brands	Net spending, number of paid claims, utilizing members, dosage units, and cost sharing for each of the top 50 drugs
D4	Top 50 most costly drugs	Net spending, number of paid claims, utilizing members, dosage units, and cost sharing for each of the top 50 drugs
D5	Top 50 drugs with largest spending increases	Net spending, number of paid claims, utilizing members, dosage units, and cost sharing for each of the top 50 drugs with largest spending increases over the year
D6	Total prescription drug spending	Net spending and rebates totaled across all drugs
D7	Rebates by therapeutic class	Net spending, number of paid claims, utilizing members, dosage units, cost sharing, and rebates for each therapeutic class
D8	Rebates for the top 25 drugs	Net spending, number of paid claims, utilizing members, dosage units, cost sharing, and rebates for each of the 25 drugs with the highest rebates

The Departments provided submitters with a crosswalk mapping NDCs to standardized "RxDC drug names" and "RxDC classes" for the purposes of defining a drug and a therapeutic class in the "top drug" templates (D3, D4, D5, and D8) and for template D7 (rebates by therapeutic class).[31] NDC-to-RxDC drug name mappings primarily used standardized active ingredient names from RxNorm with active ingredients missing from RxNorm assigned to a unique drug name for the purposes of RxDC. Similarly, therapeutic class mappings relied primarily on FDA's Effective Pharmacologic Class (EPC) assignments, with some RxDC-specific class values to address active ingredients omitted from EPC.

The initial RxDC instructions required that annual submissions for templates D1 and D3 through D8 be aggregated by, at most, the level at which the corresponding D2 template was submitted, which was typically the issuer or TPA, market segment, and state level.[32] In other words, each issuer/TPA would make only one submission for all of its plans within state and market segment for each RxDC year. RxDC specifies seven mutually exclusive market segment categories:

[31] The crosswalk file is available at CMS (2023c).

[32] More specifically, RxDC uses geography including each state, the District of Columbia, and U.S. territories (American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands).

1. self-funded large employer plans[33]
2. self-funded small employer plans
3. fully insured large group market
4. fully insured small group market
5. individual market
6. student health plans
7. FEHB Program plans.

For brevity, we refer to the combination of issuer/TPA, market segment, state, and year as the "initial RxDC reporting level" in this chapter. Aggregation at this level involves summing enrollment, utilization, and spending across plans in most cases. In other words, if drug spending was $50,000 in Plan A and $100,000 in Plan B, an issuer/TPA covering just those two plans within a given segment and state would report drug spending of $150,000. Aggregation also affects the scope for rank-ordered lists in some RxDC templates, as described below.

Implications of Nonstandardized Aggregation Approaches

The intent behind the initial instructions was for the RxDC reporting level to be the "hub" by which submissions from different entities (such as TPAs, PBMs, etc.) could be linked. For example, if a PBM served plans offered by two issuers, that each aggregated to the level of issuer, the PBM would have to make two rather than one set of market segment-state submissions—one for the first issuer's plans and another for the second issuer's plans. The initial instructions required issuers/TPAs to submit the names and TINs for other submitters, such as PBMs, at the plan level to facilitate linkages across templates. For example, for a given plan, an issuer might submit templates D1 and D2 containing enrollment and total medical spending information, while a PBM might submit templates D3 through D8 containing information on prescription drug utilization, spending, and rebates.

To encourage data reporting in the first collection year, CMS allowed submitters to aggregate data in different ways—for example, at the level of the plan sponsor, issuer, or PBM instead of the issuer/TPA; CMS has subsequently renamed the issuer/TPA identifying fields to "Company" (CMS, 2023a).[34] As we discuss later in this chapter, a more flexible approach to aggregation introduces practical challenges when attempting to combine information across templates submitted at different levels of aggregation—for example, combining information from a D2 template aggregated at the issuer/TPA level and information from a D6 template aggregated at the PBM level.

[33] The RxDC instructions (CMS, 2023a) note that large employers are "generally considered" to have "more than 50 employees."

[34] The revised CMS instructions state "within a state and market segment, you should aggregate data for plans that are associated with the same plan sponsor, issued by the same issuer, administered by the same TPA, or reported by the same reporting entity" (CMS, 2023a).

This broader flexibility also obfuscates the precise scope of the "issuer/TPA" name and tax identifier fields in RxDC data submissions. These fields are sometimes issuer/TPA entities, sometimes PBMs, sometimes employer plan sponsors, and sometimes other entities entirely. While we consider the issuer/TPA, market segment, and state level as the "RxDC reporting level" for analyses in this report, the "issuer/TPA" dimension must be interpreted broadly and variably given the aggregation flexibility afforded to submitters.

Due to this process of allowing submitters to aggregate data differently, **RxDC reporting level combinations cannot be linked across templates in all cases.** This limitation is particularly salient when the only way to conduct an analysis is by linking data across templates. For example, to directly compare premiums to per capita drug spending, data on premiums, enrollment, and drug spending at net prices must be linked across multiple templates.

Overlap in RxDC Submissions

Table 5.2 notes the number of unique submissions at the RxDC reporting level in the first collection year. The number of unique submissions varied across the RxDC templates. For example, of the 76,418 submissions at the RxDC reporting level:

- 53,606 (70 percent) had a corresponding "total prescription drug spending" template (D6)
- 17,206 (23 percent) had a corresponding "medical spending" template (D2).

In general, submission rates for individual templates were higher for Tables D3 through D8, which include information on prescription drug spending, utilization, and rebate information typically reported by PBMs, and lower for templates D1 and D2, which include premium, enrollment, and medical spending information typically reported by issuers and TPAs.

As noted above, inconsistent levels of aggregation across templates introduce important limitations on the analyses that are feasible using data combined across templates. For example, to address questions about the relationship between rebates and premiums, premium and life years (from D1) must be linked with total prescription drug spending (from D6), rebates by therapeutic class (from D7), or rebates for the top 25 drugs (from D8). However, of the 22,190 RxDC reporting level combinations with a submitted premium and life year template (D1), 47 percent or 10,340 combinations have a corresponding rebate by therapeutic class template (D7). Looking in the other direction, only 22 percent of RxDC reporting level submissions with a D7 template have a corresponding D1 template. Of the 76,418 combinations of the RxDC initial reporting level, only 8,084 (10.6 percent) have a set of eight completed templates at the same level.

Table 5.2. RxDC Template Relationships, Count of Submitted Templates (n), and Share of Responses with a Submitted Template (%)

Data Template	Number (n)	Share (%)
All RxDC initial reporting level combinations (Issuer/market segment/state/year)	**76,418**	**100%**
Of those, the number and share matching to a submission including:		
D1: Premium and life years	22,190	29.0%
D2: Medical spending	17,206	22.5%
D3: Top 50 most frequent brands	37,348	48.9%
D4: Top 50 most costly drugs	41,237	54.0%
D5: Top 50 drugs with largest spending increases	40,961	53.6%
D6: Total prescription drug spending	53,606	70.1%
D7: Rebates by therapeutic class	47,508	62.2%
D8: Rebates for the top 25 drugs	43,215	56.6%
With templates for each of D1 through D8	8,084	10.6%

SOURCE: Authors' analysis of D1 through D8 templates (April 26, 2023, extract).
NOTE: Counts of RxDC reporting level records overall and for each template are reported after cleaning is applied to string market segment and state fields to remove leading and trailing spaces and unexpected characters. Counts are pooled for reference years 2020 and 2021. Percentages are the share of total unique RxDC reporting level combinations with a submission for the indicated template (of 76,418 unique combinations).

The imperfect overlap between submitted templates is likely due to different approaches to aggregation utilized by reporting entities, lower submission rates for some types of entities (for example, issuers) compared to others (for example, PBMs), submitters reporting incorrect tax identification numbers (TINs), and a range of other factors, several of which are being explored by CMS, ASPE, and contractors. Under the flexibility provided by the Departments, some PBMs might have aggregated at a higher (i.e., more aggregated) level than required by the initial RxDC instructions. In these cases, D3–D8 data (e.g., spending on prescription drugs) reported in the more-aggregated PBM submissions cannot practically be apportioned out to correspond with more narrowly scoped D1 and D2 template submissions, which are often from individual issuer/plan sponsor clients of the PBM. Relatedly, in cases in which an issuer or plan sponsor worked with multiple PBMs or other vendors (for example, with one main PBM and another PBM covering a specific carved-out benefit), different levels of aggregation complicate and, in some cases, prevent combination of the separate submissions.

Because submitters aggregated in different ways, it is impossible to gauge whether reporting was "complete" in the sense that each of the initial RxDC reporting level combinations is represented in at least one submission for each of the eight RxDC templates. However, given the many fewer D1 and D2 template submissions compared with D3 through D8 template submissions, and given the fact that more-aggregated PBM submissions should have led to fewer, not more, D3 through D8 submissions compared with plan sponsor/issuer D1 and D2

submissions, it appears that many plan sponsors and issuers may not have submitted data as required.

Analytic Approach Given RxDC Data Limitations

Given the substantial barriers to combining across submissions and templates, the illustrative analyses in this chapter rely in almost all cases on data **from a single submission and from a single template** (i.e., only the total prescription drug spending template [D6]), rather than data from multiple RxDC templates linked at the initial RxDC reporting level. Furthermore, the illustrative analyses typically **focus on ratios** (that is, a comparison of one reported number to another) reported within a given template. This approach addresses concerns that three PBMs submitted data aggregated in different ways. By focusing on proportional rather than absolute differences, results may still be comparable even under different approaches to aggregating and reporting data.

Methods for Illustrative Analyses

The illustrative analyses use data from the subset of RxDC template submissions meeting all of the following criteria applied at the submission-template level (that is, we applied these criteria for templates D1, D2, etc., for analyses relying on these individual templates):

1. There is only one reporting entity at the RxDC reporting level for the relevant template. We excluded cases in which multiple reporting entities (that is, multiple TINs—for example, two PBMs) reported templates at the same initial RxDC reporting level. This step excluded relatively few submissions from the illustrative analyses.[35]
2. The template is not a duplicate from the same reporting entity. We counted exact duplicate submissions only one time for the illustrative analyses. In cases in which the same submitting entity submitted multiples of the same template at the initial RxDC reporting level but with different information on each submission, we used the last submitted version of the template.
3. For analyses in which we directly compared 2020 and 2021 reference years, we restricted our analysis to cases at the initial RxDC reporting level where there were submitted templates for both years.

[35] Combinations for which multiple reporting entities submitted data may represent separate benefits (e.g., general pharmacy benefits versus specialty pharmacy benefits) or duplicative information. Of the five data files used in these descriptive analyses, the total prescription drug spending template (D6) had the lowest percentage of multiple reporting entities (1.8 percent), and the top 50 most frequent brands template had the highest percentage of multiple reporting entities (2.8 percent).

4. For distributional analyses of the ratio of net to gross total spending on prescription drugs, we restricted our analysis to cases at the initial RxDC reporting level where gross spending was at least $1,000 in both years.[36]

Each analysis therefore includes only a subset of the submitted templates of each template type. The samples used in the illustrative analyses and the results in this chapter should not necessarily be considered representative across all entities required to report RxDC data or the specific entities that actually reported data. We report the number of submitted templates reporting to each illustrative analysis in the tables and figure notes in the next section.

Comparisons of Spending at Gross and Net Prices

Several analyses focus on the relationship between reported spending on prescription drugs at gross prices (before rebates are applied) versus at post-rebate net prices, including overall findings and comparisons across geographies, RxDC market segments, and specific therapeutic classes. The data for overall, by market segment, and by geography comparisons of spending at gross and net prices are from the total prescription drug spending template (D6). We calculated the ratio of net to gross spending by dividing net spending, reported as "total spending" in the RxDC data files, by the sum of the same variable (net spending) and the "total rebates, fees, and other remuneration" field, which includes rebates retained by PBMs, rebates retained by insurers, rebates passed to members at point of service, net transfers of other remuneration from manufacturers to PBMs/insurers, and net transfers of other remuneration from pharmacies to PBMs/insurers. Note that this amount does **not** include other payments from insurers and plan sponsors and issuers to PBMs, such as per capita and other service fees.

We used similar data from the rebates by therapeutic class template (D7) for analyses along that dimension. We selected five RxDC drug classes for the comparison across therapeutic classes, four of them with generally large differences between gross and net prices (per findings from Mulcahy et al., 2021a):

- a major oral anticoagulant class, factor Xa inhibitors, including apixaban (Eliquis) and rivaroxaban (Xarelto)
- insulin analogs, including insulin aspart (Novolog) and insulin lispro (Humalog)
- tumor necrosis factor blockers, including the primarily retail-dispensed biologics adalimumab (Humira) and etanercept (Enbrel)
- a class of antihyperglycemics, glucagon-like peptide (GLP)-1 receptor agonists, including dulaglutide (Trulicity) and semaglutide (Ozempic).

The fifth therapeutic class, kinase inhibitors, includes many biologic oncology drugs, such as palbociclib (Ibrance) and ibrutinib (Imbruvica), for which gross-to-net discounts are small in magnitude (see Mulcahy et al., 2021a).

[36] Note that other analyses did not impose the $1,000 gross spending restriction. We added this extra restriction for descriptive analyses of net-to-gross spending to exclude highly variable and potentially misleading ratios calculated off very-small-ratio numerators or denominators.

Analysis of Patient Cost Sharing by Therapeutic Class

We calculated the ratio of member cost sharing to total payer spending at gross and net prices on prescription drugs for the same therapeutic classes described above using data from the rebates by therapeutic class template (D7), because member cost sharing is not reported in the total prescription drug spending template (D6).[37]

Comparing Net and Gross Prices for the Most Rebated Drugs

We calculated the implied net and gross prices per claim for specific drugs by dividing reported drug-level spending amounts by reported drug-level claim line volumes using data from the rebates for the top 25 drugs template (D8). This analysis focused on an illustrative set of drugs in the same therapeutic classes listed above. We chose to report these implied prices at the claim level rather than the unit level because volume in RxDC is reported at "the smallest form in which a pharmaceutical product is administered or dispensed," and some respondents may have reported volume in terms of different units.[38]

Analyzing Patterns of Top 50 Drug Lists

We used data from the top 50 most frequent (that is, in terms of number of claims) brand-name drugs template (D3) and the top 50 most costly drugs (that is, in terms of payer net spending) template (D4) to examine patterns in these ranked lists. Taken together, reporting entities ranked thousands of drugs in these lists. We restricted our analysis to lists that included at least one factor Xa inhibitor, a common class of oral anticoagulant drugs, as an indicator for whether the plans associated with the RxDC reporting level submission offered general pharmacy benefits (in contrast to only medical benefits, only specialty pharmacy benefits, carve-out benefits, or over-the-counter-only [OTC-only] benefits).[39] We used the same set of therapeutic classes as in prior analyses. Ninety-three percent of the most frequent brand lists and 78 percent of the most costly lists included at least one factor Xa inhibitor (pooled over 2020 and

[37] This analysis used data only from D7 rather than combining information across templates.

[38] There are several sources and standards to determine the "unit of measurement" for measuring quantity dispensed in prescription drug claims. Medicare Part D uses primarily the National Council for Prescription Drug Programs (NCPDP) assignments, while other government data collection efforts (such as Average Manufacturer Price reporting to Medicaid) use units of measurement that are slightly different. As an example of a difference, one data source might count 2mL vials in terms of a count of vials (that is, one each), while another might count 2mL vials in terms of a number of milliliters (that is, two each).

[39] This restriction may bias against inclusion of RxDC reporting level combinations in the student market segment, where oral anticoagulant use may be less common.

2021).[40] For these restricted lists, we examined the median rank of drugs by the share of lists reporting the drug.

Results

Ratio of Net to Gross Total Spending on Prescription Drugs

Across all market segments, the ratio of spending at net versus gross prices was 0.80 in 2020 (in other words, net prices reflected a 20 percent discount off gross prices) and slightly smaller at 0.78 in 2021, suggesting higher relative gross prices in 2021 versus 2020. The ratio varied slightly across RxDC market segment categories, with the lowest 2020 and 2021 ratios in the self-funded large employer plans segment and the highest 2020 and 2021 ratios in the individual market segment (Table 5.2). The largest self-funded group health plans may be able to negotiate better contractual terms and therefore lower net prices from PBMs. However, demographic, geographic, and clinical differences in covered populations; compositional differences in the mix of drugs used; and PBMs' approaches to allocate lump sum rebate payments from drug companies across market segments could also contribute to the differences between market segments reported in Table 5.3. While the magnitudes are quite different, the general finding across market segments in Table 5.3, with the smallest gross-to-net discounts in the individual market and the largest gross-to-net discounts for large group and self-funded plans, align with at least one recent study (Plummer et al., 2022).

[40] Of these lists, 99 percent of the 2020 and 2021 most frequent brand lists also included at least one insulin analog, and 91 percent of the 2020 most costly lists and 88 percent of 2021 most costly lists also included at least one insulin analog.

Table 5.3. Ratio of Net to Gross Spending, Overall and by Market Segment

Market Segment	RxDC Reporting Level Combinations (count in millions)	Gross Spending 2020 ($ millions)	Net to Gross Ratio 2020	Gross Spending 2021 ($ millions)	Net to Gross Ratio 2021
All market segments	17,493	190,006	0.795	199,083	0.779
Self-funded large employer plans	7,213	101,140	0.782	106,993	0.767
Small group market	4,796	17,167	0.799	16,851	0.779
Large group market	3,075	39,675	0.797	38,724	0.776
Self-funded small employer plans	1,761	3,884	0.821	4,139	0.808
Individual market	425	21,740	0.839	25,434	0.825
Student market	148	650	0.833	643	0.803
FEHB Program plans	75	5,749	0.798	6,300	0.792

SOURCE: Authors' analysis of data from the total prescription drug spending template (D6) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the total prescription drug spending template (D6). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting >$0 in gross total spending by the same entity in both reference years.

Table 5.4 reports the same 2020 and 2021 ratios of total spending at net and gross prices by RxDC reporting geography. Ratios were generally between 0.75 and 0.90 across states and years. Utah had the highest ratio of net to gross spending in 2020 and 2021, while West Virginia had the lowest ratio of net to gross spending in 2020 and New Jersey had the lowest ratio in 2021. The magnitude of geography-level ratios was highly correlated over time (Figure 5.1). All geographies except for Michigan, West Virginia, and Puerto Rico reported a decrease in the ratio of net to gross total spending from 2020 to 2021. As with the market segment comparison above, these observed differences can be due to a range of factors, including differences in the characteristics of patients and the mix of drugs used across geographies. Furthermore, differences in PBM and insurer market share—for example, Kaiser Permanente's large regional role in Pacific states—may also contribute to the differences in Table 5.4.

Table 5.4. Ratio of Net to Gross Spending, by Geography

Geography	RxDC Reporting Level Combinations (count in millions)	Gross Spending 2020 ($ millions)	Net to Gross Ratio 2020	Gross Spending 2021 ($ millions)	Net to Gross Ratio 2021
All geographies	17,493	190,006	0.795	199,083	0.779
Alabama	110	2,742	0.804	3,098	0.777
Alaska	51	303	0.812	327	0.803
Arizona	182	2,670	0.786	2,261	0.762
Arkansas	105	1,627	0.810	1,840	0.798
California	551	15,362	0.830	14,141	0.809
Colorado	169	2,393	0.838	2,280	0.822
Connecticut	316	3,067	0.787	3,453	0.754
Delaware	217	962	0.793	1,017	0.777
District of Columbia	87	4,383	0.780	4,643	0.765
Florida	1,456	10,294	0.791	11,558	0.772
Georgia	374	6,384	0.788	6,531	0.775
Guam	10	64	0.819	69	0.797
Hawaii	42	1,025	0.813	1,066	0.803
Idaho	82	864	0.929	766	0.906
Illinois	685	8,718	0.769	10,122	0.756
Indiana	640	2,076	0.785	2,024	0.768
Iowa	157	1,285	0.805	1,415	0.794
Kansas	141	1,202	0.756	1,304	0.746
Kentucky	217	2,034	0.808	2,479	0.783
Louisiana	201	2,647	0.821	2,876	0.787
Maine	85	775	0.813	532	0.799
Maryland	252	5,198	0.792	5,681	0.779
Massachusetts	228	4,493	0.794	5,203	0.782
Michigan	453	3,990	0.787	3,921	0.791
Minnesota	129	5,986	0.796	6,089	0.774
Mississippi	107	662	0.790	762	0.750
Missouri	233	4,055	0.790	4,237	0.780
Montana	99	263	0.804	282	0.790
Nebraska	86	962	0.759	995	0.743
Nevada	116	1,196	0.780	1,105	0.750
New Hampshire	60	814	0.793	685	0.780
New Jersey	321	5,692	0.763	6,325	0.742
New Mexico	68	630	0.769	668	0.763
New York	503	13,328	0.783	13,790	0.765
North Carolina	247	7,155	0.765	7,478	0.755
North Dakota	29	528	0.765	574	0.763
Ohio	1,562	7,583	0.785	6,729	0.766
Oklahoma	443	1,688	0.771	1,798	0.758

Geography	RxDC Reporting Level Combinations (count in millions)	Gross Spending 2020 ($ millions)	Net to Gross Ratio 2020	Gross Spending 2021 ($ millions)	Net to Gross Ratio 2021
Oregon	121	2,002	0.842	2,084	0.825
Pennsylvania	455	7,398	0.766	7,857	0.754
Puerto Rico	2,085	816	0.887	1,582	0.922
Rhode Island	85	924	0.751	982	0.747
South Carolina	123	2,196	0.784	2,455	0.753
South Dakota	1,384	608	0.791	697	0.791
Tennessee	212	5,590	0.809	6,125	0.785
Texas	719	15,318	0.766	16,909	0.754
Utah	114	3,817	0.937	4,064	0.933
Vermont	29	243	0.812	239	0.781
Virginia	476	6,397	0.805	5,328	0.788
Washington	350	5,157	0.841	5,877	0.827
West Virginia	92	813	0.732	1,032	0.767
Wisconsin	353	3,258	0.786	3,378	0.772
Wyoming	67	300	0.801	275	0.784

SOURCE: Authors' analysis of data from the total prescription drug spending template (D6) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the total prescription drug spending template (D6). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting >$0 in gross total spending by the same entity in both reference years. The U.S. Virgin Islands and Northern Mariana Islands were omitted due to small sample size (N<10).

Figure 5.1. State-Level Ratios of Net to Gross Spending in 2020 Versus 2021

SOURCE: Authors' analysis of data from the total prescription drug spending template (D6), April 26, 2023, extract.

Average net-to-gross ratio overall, by market segment, or by state masks substantial underlying heterogeneity in ratios across submissions. For example, a lower net-to-gross ratio for a particular market segment or state may mask a relatively higher ratio for a subset of submissions. Figure 5.2 illustrates the share of RxDC submissions (on the vertical axis) accounting for different magnitudes of the net-to-gross ratio (on the horizontal axis). This histogram and others that follow use two colors—blue and red—to compare distributions for 2020 versus 2021 submissions. Purple-shaded areas are in common across both years, while blue-shaded areas are only in 2020 and red-shaded areas are only in 2021.

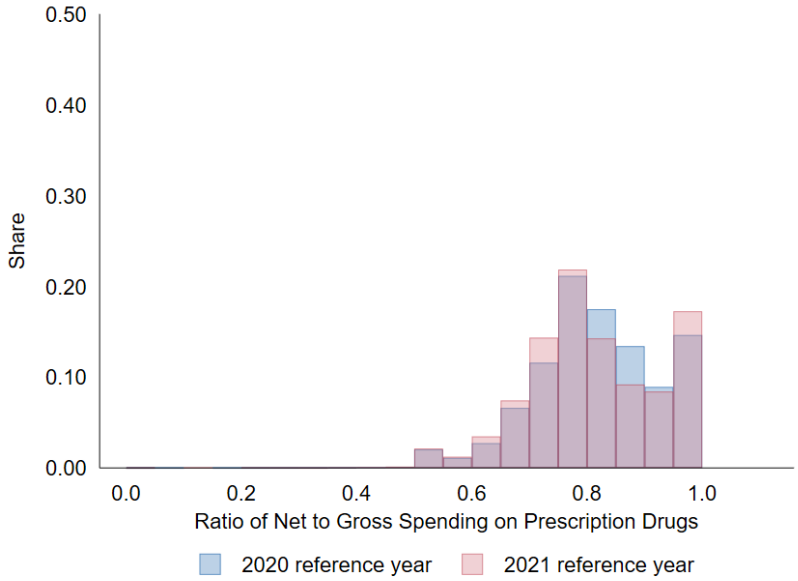
In Figure 5.2, about 21 percent of responses in both 2020 and 2021 had a ratio between 0.75 and 0.80 (the tallest bar in the middle of the chart). In 2020, the mean and median ratios across submissions were 0.816 and 0.811, respectively.[41] The mean and median ratios across submissions were lower in 2021 (0.811 and 0.798, respectively).

About 15 percent of 2020 submissions and 17 percent of 2021 submissions reported net-to-gross ratios greater than or equal to 0.95 (see the rightmost bars in Figure 5.2). Ratios around 1.0 are not consistent with prior research finding substantial gross-to-net discounts for brand-name drugs (see, e.g., IQVIA, 2023; Mulcahy et al., 2021a). There are several potential explanations for submissions with equal or near-equal spending at gross and net prices. First, these submissions could be from medical (rather than pharmacy) plans that reported data for vaccines, OTC medicines, or other products that are not typically rebated. Second, submissions with ratios around 1.0 could represent offerings from PBMs that bypass rebates, offering lower transactional prices immediately at the point of sale. Third, ratios near 1.0 could reflect unanticipated allocation steps by submitters such that ratios for some RxDC reporting levels are relatively lower and others are relatively higher than expected. Finally, submitters in these cases may have intended to submit rebate information (or intended for another entity to report rebate information) separately, but ultimately the information was not submitted.[42] Regardless of the reason for these ratios around 1.0, including them in analyses of net-to-gross ratios will pull the overall average upward, relative to excluding them from analysis.

[41] These mean ratios are similar but not identical to those in Table 5.4. The Table 5.4 ratios reflect the sums of spending at net versus gross prices across all submissions, while the ratios in this paragraph are the mean ratio across submissions.

[42] We limited our initial analyses to cases with just a single reporting entity for the relevant template. Of the five data files used in these descriptive analyses, the total prescription drug spending template (D6) had the lowest percentage of multiple reporting entities (1.8 percent), and the top 50 most frequent brands template had the highest percentage of multiple reporting entities (2.8 percent). In some excluded cases, different submitting entities may have intended for CCIIO to combine multiple of the same submitted template. For example, a plan sponsor may have submitted template D6 with prescription drug gross spending information, while a PBM may have submitted the same template with just rebate amounts.

Figure 5.2. Ratio of Net to Gross Spending, Distribution

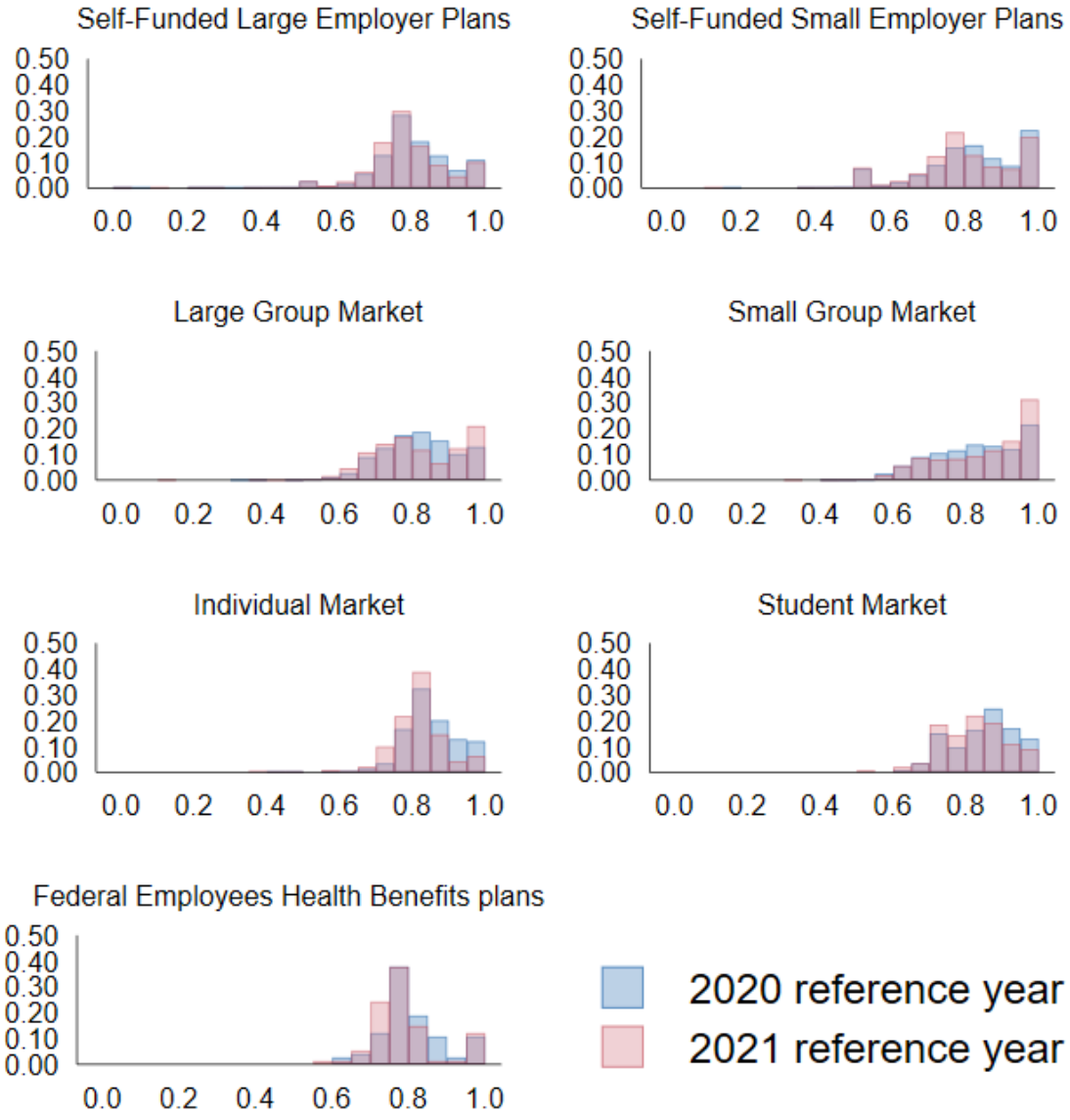


SOURCE: Authors' analysis of total prescription drug spending template (D6) data, April 26, 2023, extract.
NOTE: Net total spending on prescription drugs is reported as total spending in the total prescription drug spending template (D6). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting >$1000 in net total spending by the same entity in both reference years. Combinations with ratios greater than 1.0 are not reported. N = 14,520 combinations of issuer-market segment-state.

Figure 5.3 illustrates the same net-to-gross ratios as in prior histograms but separated into panels, one for each market segment category (panels A through G). The different distributions (that is, the spread of submissions across different net-to-gross ratios) across market segments may reflect the same sources of heterogeneity mentioned above. Interestingly, submissions with ratios between 0.95 and 1 appear to be more common in the self-funded small employer, fully insured large group, fully insured small group, and FEHB Program segments. For example, over 30 percent of the small group market segment in 2021 had ratios of 0.95 or higher. This suggests a possible difference in the products offered or the reporting strategies for issuers and PBMs operating in these segments.

Considering all submissions within a segment (including those with ratios around 1.0), each market segment except the small group market segment experienced a decrease (or shift to the left in the distribution) of the net-to-gross ratio from 2020 to 2021. For example, for self-funded large employer plans, the mean ratio decreased from 0.807 in 2020 to 0.791 in 2021 (median decreased from 0.797 to 0.780). This suggests growth in list prices over time, increases in the magnitude of rebates over time, or a combination of both.

Figure 5.3. Ratio of Net to Gross Spending, Distribution, by Market Segment



SOURCE: Authors' analysis of total prescription drug spending template (D6) data (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the total prescription drug spending template (D6). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting >$1000 in net total spending by the same entity in both reference years. Combinations with ratios greater than 1.0 are not reported. Self-funded large employer N = 6,886 combinations of issuer-market segment-state; self-funded small employer N = 1,373; large group market N = 2,611; small group market N = 3,047; individual market N = 383; student market N = 146; FEHB Program N = 74.

Table 5.5 reports net total spending, gross total spending, and the ratio of net to gross total spending on prescription drugs in the selected therapeutic classes described earlier in this chapter. For each of the therapeutic classes selected, the ratio of net to gross total spending on prescription drugs decreased from 2020 to 2021. Among the selected classes, insulin analogs had

the lowest net to gross ratio, indicating the highest level of rebating among the therapeutic classes considered here, in 2020 (0.520) and in 2021 (0.499). Kinase inhibitors had the highest ratio, indicating the lowest level of rebating among these therapeutic classes in 2020 (0.983) and in 2021 (0.979).

These differences by therapeutic class—higher ratios for kinase inhibitors and lower ratios for insulins—align with findings from prior studies (Mulcahy et al., 2021a). The much lower ratio for insulin analogs reflects the existence of close substitutes, with three manufacturers producing generally substitutable insulin analog products, and the ability of insurers/PBMs to steer patient and prescription decisionmaking and therefore secure large rebates from manufacturers, as described in Chapter 2. In contrast, kinase inhibitors have little competition or leverage to shift prescribing volume, leading to net-to-gross ratios around 1.0.

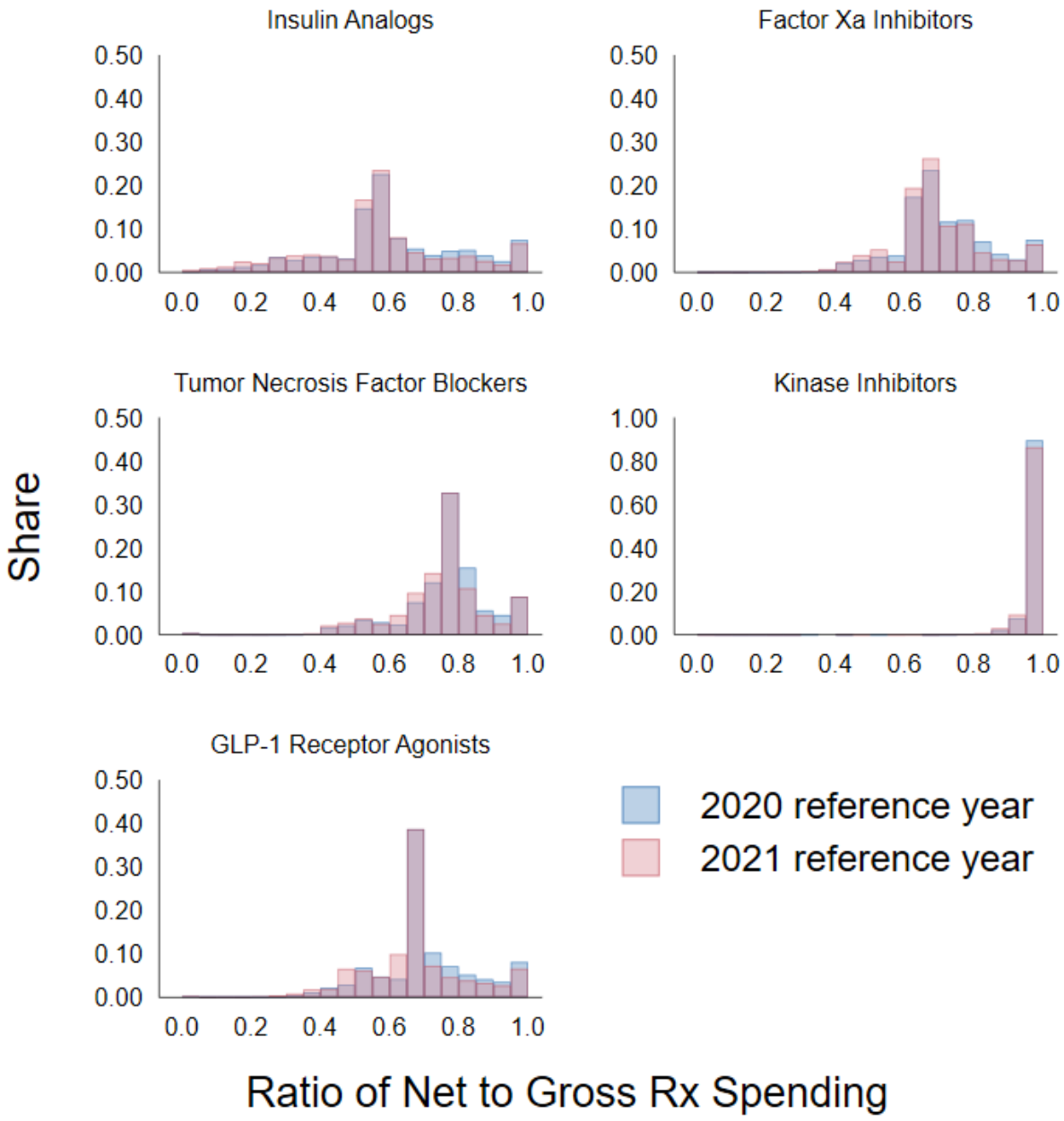
Table 5.5. Ratio of Net to Gross Spending, by Select Therapeutic Class

RxDC Therapeutic Class Name	Number of RxDC Drugs	Net Spending 2020 ($ millions)	Gross Spending 2020 ($ millions)	Net/ Gross Ratio 2020	Net Spending 2021 ($ millions)	Gross Spending 2021 ($ millions)	Net/ Gross Ratio 2021
Insulin analogs	19	5,864	11,277	0.520	5,127	10,266	0.499
Factor Xa inhibitors	6	2,837	4,152	0.683	3,100	4,610	0.673
Tumor necrosis factor blockers	10	16,608	22,183	0.749	17,050	23,241	0.734
Kinase inhibitors	75	7,669	7,799	0.983	8,271	8,445	0.979
GLP-1 receptor agonists	9	6,458	9,810	0.658	7,969	12,583	0.633

SOURCE: Authors' analysis of data from the rebates by therapeutic class template (D7) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates by therapeutic class template (D7). The number of RxDC drugs in each therapeutic class is from the RxDC NDC-level crosswalk. Each RxDC drug represents a unique combination of an active ingredient and, if applicable, brand name. Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity with > $0 gross total spending from the same reporting entity in each year. Insulin analog N = 8,542 combinations of issuer/market segment/state; factor Xa inhibitor N = 9,490; tumor necrosis factor blocker N = 6,477; kinase inhibitor N = 3,939; GLP-1 receptor agonist N = 8,763.

Figure 5.4 compares the distribution of the ratio of net to gross total spending for the same select therapeutic classes across submissions for 2020 versus 2021. The ratios were similar between years with a slight shift leftward (that is, toward lower ratios) from 2020 to 2021, mirroring findings from other analyses in this chapter. In both years and across the select therapeutic classes, the range of the distribution is wide. For insulin analogs, the interquartile range of the distribution was 0.20 in 2020 and 0.17 in 2021. As with these other analyses, it is not clear whether increasing gross prices, decreasing net prices, or a combination of both are driving this decrease in the ratio.

Figure 5.4. Ratio of Net to Gross Spending, Distribution, by Select Therapeutic Class



SOURCE: Authors' analysis of data from the rebates by therapeutic class template (D7) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates by therapeutic class template (D7). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of net spending to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity with > $0 gross total spending from the same reporting entity in each year. Insulin analog N = 19,490 combinations of issuer/market segment/state; factor Xa inhibitor N = 8,542; tumor necrosis factor blocker N = 6,477; kinase inhibitor N = 3,939; GLP-1 receptor agonist N = 8,763.

Ratio of Cost Sharing to Net Total Spending on Prescription Drugs

As described in Chapter 4, patients often pay cost sharing on the list or gross cost of a drug and, as a result, can cover a substantial portion of a drug's net cost to their insurer out of pocket. Table 5.6 reports the ratio of patient cost sharing to net total spending on prescription drugs for select therapeutic classes, across all market segments and geographies, in 2020 and 2021. Table 5.7 reports the ratio of patient cost sharing to gross total spending on prescription drugs for the same select therapeutic classes.

The ratio of patient cost sharing to net total spending varies by therapeutic class, with the lowest cost sharing for kinase inhibitors—at 3.0 percent of net spending and 2.9 percent of gross spending in 2021—and the highest proportional cost sharing for factor Xa inhibitors, at 16.7 percent of net spending and 11.2 percent of gross spending in 2021. Interestingly, while net-to-gross ratios decrease from 2020 to 2021 in nearly all our illustrative analyses, ratios of cost sharing to net cost are increasing for at least some therapeutic classes, providing at least some signal that the proportional decrease in net prices is not being completely passed on to patients via lower cost sharing. The Congressional Budget Office suggests that these savings may be passed onto patients through lower premium increases (Congressional Budget Office, 2022). However, there might be many other changes over time within these therapeutic classes—for example, changes in the mix of drugs used within class that might also partially explain the relatively smaller change in out-of-pocket spending versus total spending at net prices.

Table 5.6. Ratio of Cost Sharing to Net Spending, by Select Therapeutic Class

RxDC Therapeutic Class Name	Number of RxDC Drugs	Cost Sharing 2020 ($ millions)	Net Spending 2020 ($ millions)	Cost Sharing/ Net Ratio 2020	Cost Sharing 2021 ($ millions)	Net Spending 2021 ($ millions)	Cost Sharing/ Net Ratio 2021
Insulin analogs	19	718	5,864	0.122	596	5,127	0.116
Factor Xa inhibitors	6	471	2,837	0.166	517	3,100	0.167
Tumor necrosis factor blockers	10	1,074	16,608	0.065	1,325	17,050	0.078
Kinase inhibitors	75	173	7,669	0.023	246	8,271	0.030
GLP-1 receptor agonists	9	588	6,458	0.091	724	7,969	0.091

SOURCE: Authors' analysis of data from the rebates by therapeutic class template (D7) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates by therapeutic class template (D7). The ratio of cost sharing to net spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity with > $0 gross total spending from the same reporting entity in each year. Insulin analog N = 9,490 combinations of issuer/market segment/state; factor Xa inhibitor N = 8,542; tumor necrosis factor blocker N = 6,477; kinase inhibitor N = 3,939; GLP-1 receptor agonist N = 8,763.

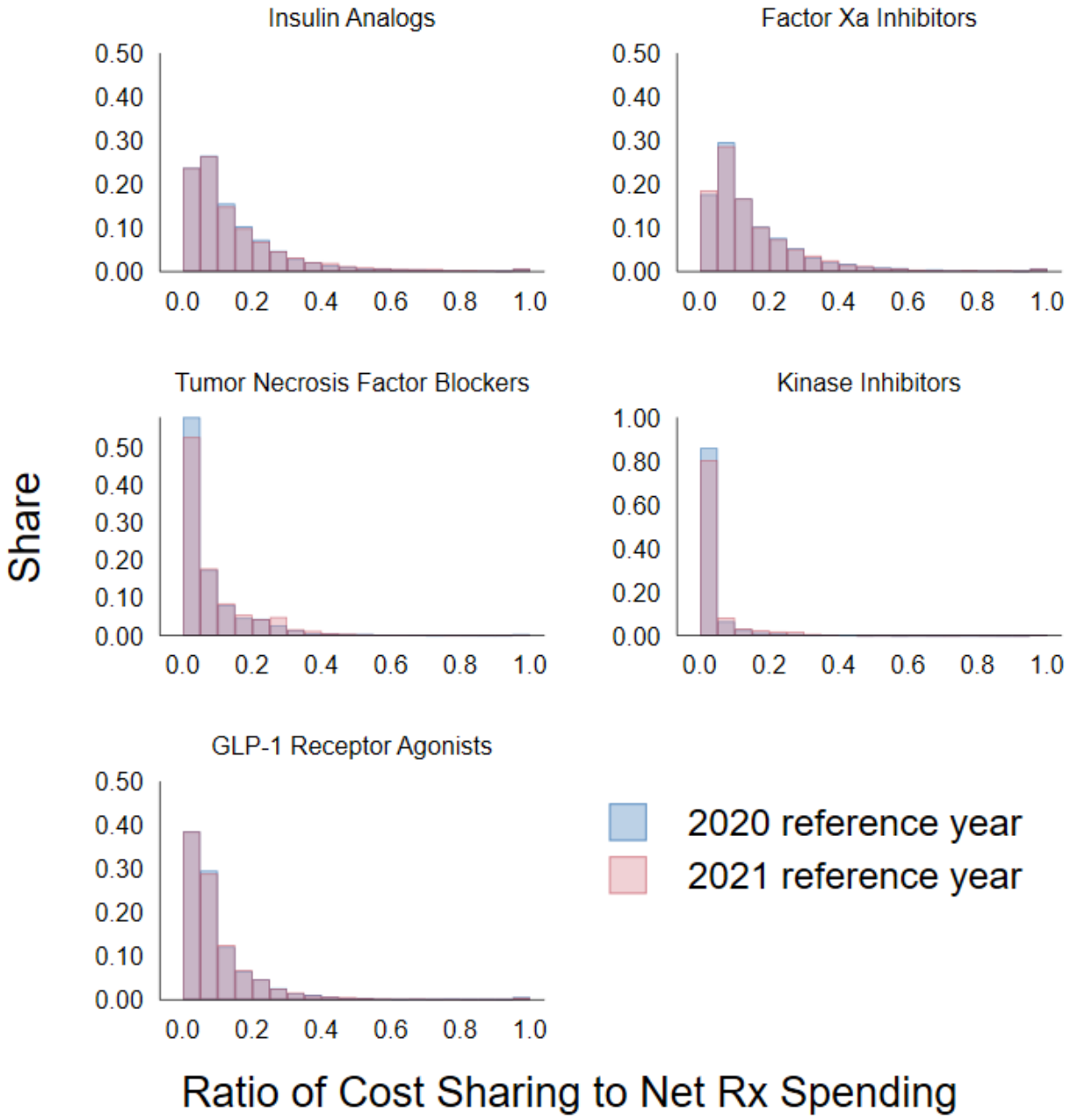
Table 5.7. Ratio of Cost Sharing to Gross Spending, by Select Therapeutic Class

RxDC Therapeutic Class Name	Number of RxDC Drugs	Cost Sharing 2020 ($ millions)	Gross Spending 2020 ($ millions)	Cost Sharing/ Gross Ratio 2020	Cost Sharing 2021 ($ millions)	Gross Spending 2021 ($ millions)	Cost Sharing/ Gross Ratio 2021
Insulin analogs	19	718	11,277	0.064	596	10,266	0.058
Factor Xa inhibitors	6	471	4,152	0.113	517	4,610	0.112
Tumor necrosis factor blockers	10	1,074	22,183	0.048	1,325	23,241	0.057
Kinase inhibitors	75	173	7,799	0.022	246	8,445	0.029
GLP-1 receptor agonists	9	588	9,810	0.060	724	12,583	0.058

SOURCE: Authors' analysis of data from the rebates by therapeutic class template (D7) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates by therapeutic class template (D7). Gross total spending is calculated as net spending plus rebates (current year total rebates/fees/other remuneration). The ratio of cost sharing to gross spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity with > $0 gross total spending from the same reporting entity in each year. Insulin analog N = 9,490 combinations of issuer/market segment/state; factor Xa inhibitor N = 8,542; tumor necrosis factor blocker N = 6,477; kinase inhibitor N = 3,939; GLP-1 receptor agonist N = 8,763.

Figure 5.5 shows the right-skewed distributions of the ratio of cost sharing to net total spending on prescription drugs by select therapeutic classes, across all market segments and all geographies for 2020 and 2021. The median ratio of patient cost sharing to net total spending on insulin analogs was 0.1022 in 2020 and 0.1030 in 2021. The median ratio for factor Xa inhibitors was 0.1086 in 2020 and 0.1084 in 2021. The distribution for tumor necrosis factor blockers was centered around a median value of 0.0390 in 2020 and 0.0464 in 2021. Kinase inhibitors had the lowest median values in 2020 (0.0094) and in 2021 (0.0119). The median ratio for GLP-1 receptor agonists was 0.0645 in 2020 and 0.0643 in 2021.

Figure 5.5. Ratio of Cost Sharing to Net Spending, Distribution



SOURCE: Authors' analysis of data from the rebates by therapeutic class template (D7) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates by therapeutic class template (D7). The ratio of cost sharing to net spending is reported for RxDC reporting level combinations for which data was submitted by a single reporting entity with > $0 gross total spending from the same reporting entity in each year. Insulin analog N = 9,490 combinations of issuer/market segment/state; factor Xa inhibitor N = 8,542; tumor necrosis factor blocker N = 6,477; kinase inhibitor N = 3,939; GLP-1 receptor agonist N = 8,763.

Implied Gross and Net Prices

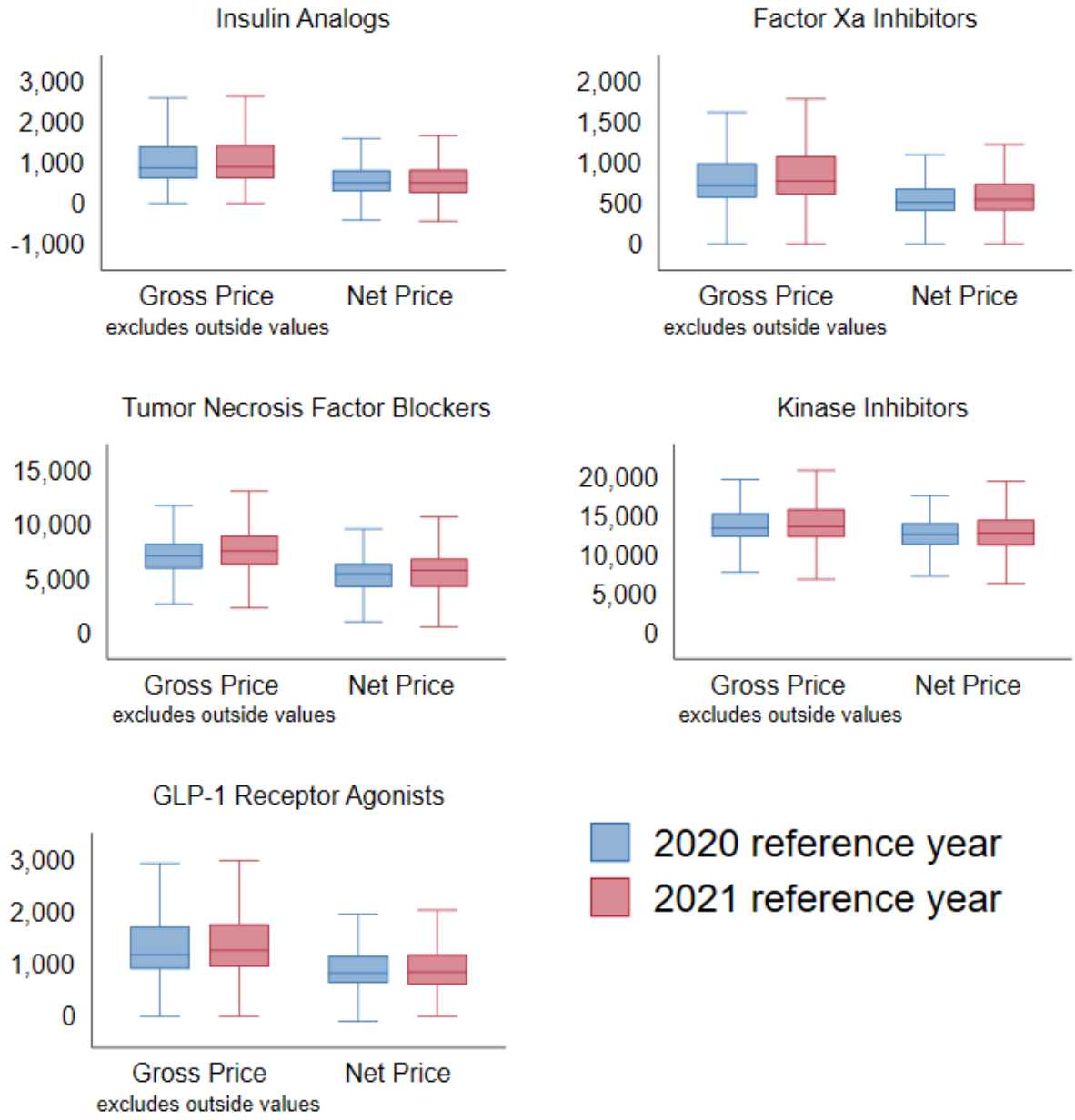
Spending and volume information from RxDC template D8 can be used to calculate implied gross and net prices. These prices and the differences between them vary by therapeutic class, likely corresponding to the existence of close substitutes and the ability of insurers/PBMs to steer patient and prescription decisionmaking, as described in Chapter 2.

Figure 5.6 summarizes the implied gross and net prices per claim for highly rebated insulin analogs, factor Xa inhibitors (anticoagulants), tumor necrosis factor blockers [biological disease-modifying anti-rheumatic drugs (DMARDs], kinase inhibitors (antineoplastic agents), and GLP-1 receptor agonists.

In nominal terms, the median (implied, here and throughout this section) gross price per claim increased for all selected therapeutic classes from 2020 to 2021. The increase was highest in relative terms for factor Xa inhibitors ($56.13 or 7.78 percent) and lowest for kinase inhibitors ($188.98 or 1.41 percent) (Table 5.8). The median net price per claim decreased for insulin analogs from $511.96 in 2020 to $500.47 in 2021 and increased for all other selected therapeutic classes. The increase was highest in relative terms for factor Xa inhibitors ($36.40 or 7.15 percent) and lowest for kinase inhibitors ($165.66 or 1.31 percent). However, in real terms, only gross and net factor Xa prices increased faster than general inflation (U.S. Bureau of Labor Statistics, 2021).[43]

[43] The Consumer Price Index, All Urban Consumers (CPI-U), increased 7.0 percent without seasonal adjustment from December 2020 to December 2021 (U.S. Bureau of Labor Statistics, 2021). The exact time periods covered by individual submissions vary based on plan year start dates that may vary across plans.

Figure 5.6. Implied Net Prices Per Claim, Select Therapeutic Classes



SOURCE: Authors' analysis of data from the rebates for the top 25 drugs template (D8) (April 26, 2023, extract).
NOTE: Prices smaller than the first quartile minus 1.5 × interquartile range or larger than the third quartile plus 1.5 × interquartile range (outside values) are not plotted. Lowest value, first quartile, median, third quartile, and highest value (excluding the outside values) implied net prices per claim and gross prices per claim are plotted. Net total spending on prescription drugs is reported as total spending in the rebates for the top 25 drugs template (D8). Gross total spending is calculated as net spending plus rebates (total rebates/fees/other remuneration). Implied net prices are reported for RxDC reporting level combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting at least one top 25 drug in the therapeutic class in both reference years. Insulin analog N = 9,364 combinations of issuer/market segment/state; factor Xa inhibitor N = 7,808; tumor necrosis factor blocker N = 6,165; kinase inhibitor N = 419; GLP-1 receptor agonist N = 8,453.

Table 5.8. RxDC Median Gross and Net Price per Claim by Therapeutic Class, 2020–2021

RxDC Therapeutic Class Name	RxDC Reporting Level Combinations	Median Gross Price 2020	Median Gross Price 2021	Median Net Price 2020	Median Net Price 2021
Insulin analogs	9,364	$870.60	$894.52	$511.96	$500.47
Factor Xa inhibitors	7,808	$721.38	$721.38	$509.23	$545.63
Tumor necrosis factor blockers	6,165	$7,080.58	$7,080.58	$5,407.38	$5,768.85
Kinase inhibitors	419	$13,393.47	$13,393.47	$12,618.60	$12,784.26
GLP-1 receptor agonists	8,453	$1,179.12	$1,255.96	$819.82	$845.00

SOURCE: Authors' analysis of data from the rebates for the top 25 drugs template (D8) (April 26, 2023, extract).
NOTE: Net total spending on prescription drugs is reported as total spending in the rebates for the top 25 drugs template (D8). Gross total spending is calculated as net spending plus rebates (total rebates/fees/other remuneration). Implied net prices are reported for issuer/market segment/state/reference year combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting at least one top 25 drug in the therapeutic class in both reference years.

Comparison of Ranked Drug Lists

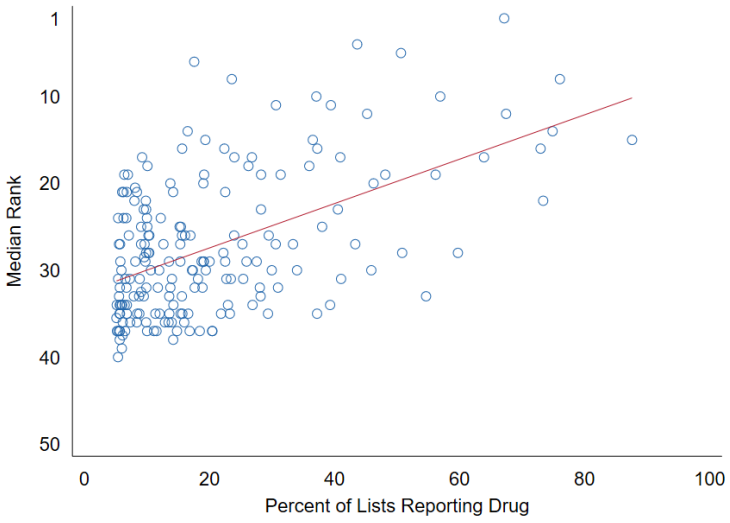
Several RxDC data templates were limited to "top drug" lists in terms of utilization, spending at net prices, and the magnitude of rebates. We anticipated some broad similarities in the drugs included in different submitters' top drug lists—for example, we expected most drugs on top drug by rebates lists would be brand-name drugs with (a) relatively high aggregate sales at gross prices for that submission and (b) relatively high gross-to-net discounts. However, due to differences in benefit design, formulary placement, and enrollee characteristics and case mix, we also expected some variation in the specific drugs included on each list across submissions. We analyzed submitted drug-level rankings to assess the extent of overlap in top drug lists from different submissions.

There were 190 and 194 drugs reported in the top 50 most costly drugs template (D4) in at least 5 percent of submissions in 2020 and 2021, respectively. Figure 5.7 plots the median rank of these drugs in 2020 and 2021 by the percentage of lists reporting the drug. The drug with the lowest median rank in both 2020 and 2021 (#1) was reported on 67 percent of lists in 2020 and 65 percent of lists in 2021. As shown by the cluster of drugs in the bottom left of the scatter plots, there are many drugs that appear on a small percentage of lists, but typically with lower ranks. The upward-sloping linear trend lines illustrate how rank increases as the percentage of lists reporting a given drug increases. In other words, drugs appearing on more lists also had higher spending than other drugs. This makes sense given that there are a small number of high-cost, single-source brand-name drugs that account for a large share of total U.S. spending on prescription drugs.

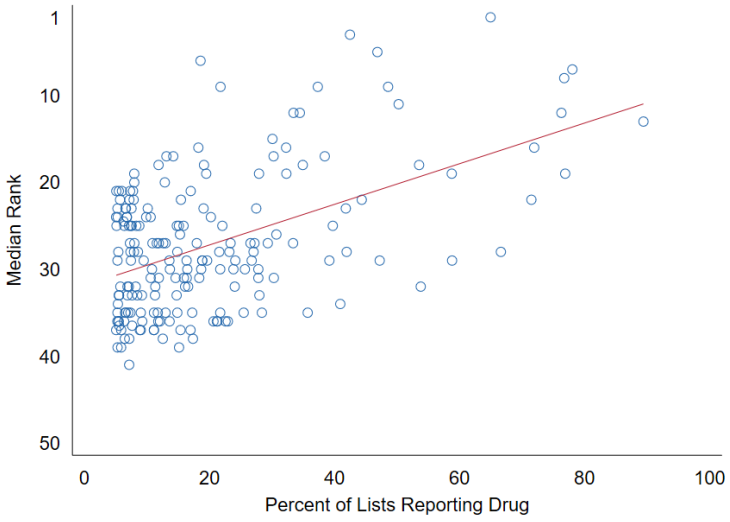
However, some drugs with very high median ranks (10th or higher) were on relatively few lists (in one case for both 2020 and 2021, roughly 20 percent). This could reflect the outcome of bargaining between PBMs and drug companies. For a given therapeutic class with high overall spending, one drug may be the preferred choice by most PBMs and therefore on more lists, while a second, competing drug could be the preferred choice by a minority of PBMs and therefore ranked highly but on a relatively small share of lists.

Figure 5.7. Median Rank of Drugs Reported in the Top 50 Most Costly

A. 2020 Reference Year



B. 2021 Reference Year

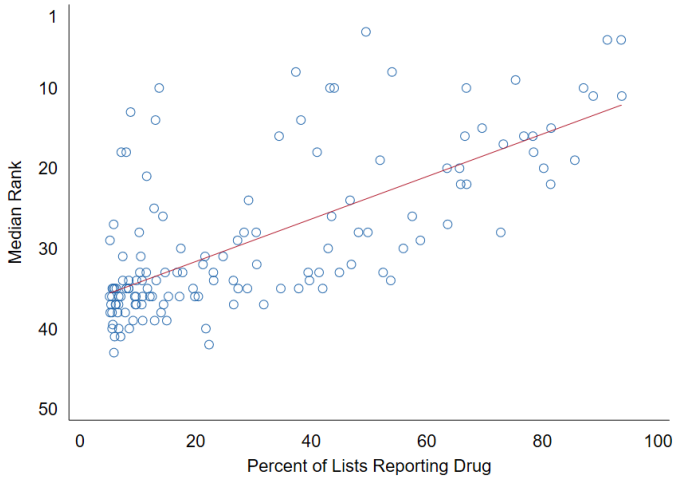


SOURCE: Authors' analysis of data from the top 50 most costly drugs template (D4) (April 26, 2023, extract).
NOTE: Ranked lists are included for issuer/market segment/state/reference year combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting at least one drug in the factor Xa inhibitor therapeutic class. 2020 N = 8,847 combinations and 190 drugs; 2021 N = 10,038 combinations and 194 drugs. Linear best fit line is included.

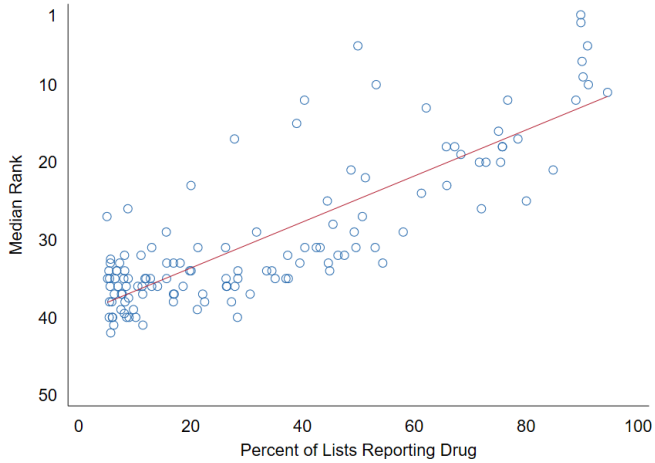
We found similar patterns when analyzing data from a separate template of the top 50 most frequently dispensed drugs. Across these lists, we found 137 and 127 drugs included in at least 5 percent of submissions for 2020 and 2021, respectively. Figure 5.8 plots the median rank of these drugs in 2020 and 2021 by the percentage of lists reporting the drug. The drug with the lowest median rank in 2020 (#3) was reported on 49 percent of lists; the drug with the lowest median rank in 2021 (#1) was reported on 90 percent of lists. Similar to Figure 5.7, Figure 5.8 shows that a higher percentage of lists reporting the drug in the top 50 most frequent brand drugs template (D3) is associated with a higher median rank. However, as in Figure 5.7, there are some highly ranked drugs that are on relatively few lists. There are also more differences in the overall distribution of drugs over time in the charts focusing on top drugs by volume rather than top drugs by spending.

Figure 5.8. Median Rank of Drugs Reported in the Top 50 Most Frequent

A. 2020 Reference Year



B. 2021 Reference Year



SOURCE: Authors' analysis of data from the top 50 most frequent brand drugs template (D3) (April 26, 2023, extract).
NOTE: Ranked lists are included for issuer/market segment/state/reference year combinations for which data was submitted by a single reporting entity and further restricted to combinations reporting at least one drug in the factor Xa inhibitor therapeutic class. 2020 N = 6,715 combinations and 137 drugs; 2021 N = 7,329 combinations and 127 drugs. Linear best fit line is included.

Key Takeaways

We found that submitters used different approaches to aggregate and report data via RxDC. Under the flexibility added to the RxDC instructions, some submitters aggregated at a broader, less granular level than originally required. As a result, we were unable to combine information from different submissions and RxDC templates. More specifically, we could not combine

information on premiums and enrollment, which was typically submitted by plan sponsors or issuers on one set of templates, with information on drug spending and utilization, which was typically submitted by PBMs on different templates. Combining across these submissions and templates is an important step needed for the series of reports to Congress. Given these limitations, we focused on analyses requiring data only from a single RxDC submission and template.

The illustrative analyses presented in this chapter highlight the usefulness of newly collected RxDC information in understanding net spending and prices for drugs and other aspects of commercial drug coverage. We found ratios of spending on drugs at net versus gross prices of roughly 0.8, with modest differences across market segments and geography. This 0.8 ratio appears higher than seemingly similar estimates from other studies (e.g., Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2023; IQVIA, 2023; Mulcahy et al., 2021a).[44] However, these studies focus on net-to-gross ratios from the manufacturer rather than payer perspective (e.g., Mulcahy et al., 2021a), cover markets other than commercial drug coverage (e.g., Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2023), and/or use proprietary modeling to approximate both rebates and payer-paid amounts (IQVIA, 2023).

We found results for specific therapeutic classes that aligned with expectations from prior studies, with relatively lower net prices for insulins, oral anticoagulants, and some other classes, and virtually indistinguishable gross versus net prices for kinase inhibitors, a class including many oncology drugs. Importantly, these illustrative analyses do not address whether these lower ratios are driven by relatively high gross prices, relatively low net prices, or both.

Relatedly, we found generally decreasing ratios for individual therapeutic classes and across all drugs from 2020 to 2021. Again, it is not clear whether changes in gross, net, or both prices are driving these reductions. However, these changes were relatively small in magnitude and reflect only two years of data.

The illustrative analyses do not shed much direct light on the relationship between drug prices, rebates, and premiums or other costs to consumers. In one related finding, the share of spending at net prices paid directly by patients out of pocket seems to have increased for at least some drug classes from 2020 to 2021. If lower net prices are driving the broader decrease in net-to-gross ratios, reductions in net prices might not be passed fully on to consumers via lower out-of-pocket spending. However, consumers might benefit from lower net prices in other ways, such as easier access to drugs or lower premiums.

[44] For comparison, IQVIA (2023) estimated a payer net-to-gross ratio of 0.7 for the entire U.S. market.

Chapter 6. Summary, Recommendations, and Discussion

The Section 204 reporting requirement and RxDC data have the potential to help address an important gap in our understanding of the functioning of U.S. prescription drug markets. Despite substantial and growing enrollment in commercial prescription drug coverage, the net prices ultimately paid by private health insurance plans, issuers, and their PBMs—and the resulting net spending on drugs—have historically not been available to federal policymakers. The RxDC data may also facilitate important new analyses on the links between drug spending, premiums, and other aspects of benefit design.

Findings from Literature Reviews

In our broader review of the literature related to drug coverage and spending, we found that most Americans covered under group coverage or marketplace plans have drug coverage, and about two-thirds of individuals enrolled in non-group plans off exchanges have drug coverage. However, the design of the drug benefits for covered individuals is variable and evolving over time, with "deeper" formularies (that is, those with more tiers), higher deductibles and out-of-pocket caps, and, in some cases, greater use of coinsurance over time. Premiums have also increased over time.

In our analysis of drug prices, we found some evidence that the "wedge" between payments by insurers at gross versus net prices is widening, although, due to data limitations, we did not investigate whether this is driven by increases in gross prices, growing gross-to-net discounts, or both. In any case, a growing wedge between gross and net prices could conceptually yield larger margins for PBMs and might affect PBMs' design of drug benefits, even if rebate amounts are directly passed through to plan sponsors and issuers and PBM revenue comes primarily from fees charged to their clients. Importantly, our findings from the literature related to drug price and spending trends rely on a relatively small number of individual studies. Most of these studies relied on limited and incomplete data on net prices and spending at net prices, considered a perspective other than private coverage for retail-dispensed drugs (as in RxDC), and analyzed either all prescription drugs or narrow sets of drugs rather than retail-dispensed prescription drugs.

One key theme across chapters is that PBMs and payers may respond to prior and anticipated increases in drug spending by adjusting aspects of coverage and benefit design—for example, cost sharing, utilization management, or formulary structure—rather than premiums, to the extent feasible given actuarial value requirements for certain plan types. Insurers generally already set premiums as low as possible because they are particularly salient to buyers of insurance (that is, individuals and their employers) and apply across all enrollees regardless of

whether they use care (DeLeire and Marks, 2015; Abaluck and Gruber, 2011). The impacts of other benefit design features, such as deductibles and cost sharing, are more opaque at the point that consumers choose plans but can have profound implications on total out-of-pocket spending for patients receiving drugs (and, particularly, expensive drugs). Growth in cost sharing (for example, through coinsurance) might further decrease premiums, because a larger share of expenses is paid by patients (that is, the specific individuals using an expensive drug) rather than all enrollees (McDevitt, 2008). Patients taking an expensive drug may not see the realized savings negotiated through PBM rebates. Patients subject to coinsurance-based cost sharing often pay a larger share of total drug costs than is immediately apparent because coinsurance is based on list prices rather than net prices.

RxDC Data Concerns and Limitations

In our initial experience working with 2020 and 2021 RxDC data, we found that plan sponsors, issuers, and other reporting entities used inconsistent and varying approaches to aggregating and attaching identifiers to their submissions. While PBMs often reported the prescription drug spending, utilization, and rebate information, plan sponsors, issuers, and TPAs for medical coverage often reported the premium, enrollment, and medical spending information. In other words, some PBMs submitted data aggregated at the PBM level rather than at the plan sponsor, issuer, or TPA level—in other words, making one submission covering all of their clients' offerings in a given market segment and state. Submitters inconsistently reported plan sponsor, issuer, TPA, PBM, and other employer identification numbers (EINs) in the separate "plan" level templates, leaving unanswered questions regarding the extent of compliance with RxDC reporting requirements among plans and issuers. Overall, we found that only one in ten submitters defined by plan sponsor/issuer, market segment, and state had a full set of eight RxDC data templates.

As a result, we generally could not combine data submitted at different levels of aggregation. For example, we could not reliably link premium and enrollment information (from template D1) to total prescription drug spending information (from template D6). Of the more than 50,000 D6 submissions at the initial RxDC reporting level, only about one in five had a corresponding D1 template. Relatedly, the smaller counts of D1 and D2 template submissions relative to D3 through D8 submissions suggest that at least some plan sponsors and issuers did not report as required, even if their PBMs or other vendors submitted drug-focused templates D3 through D8.

Several other aspects of Section 204 reporting requirements and the structure of the RxDC data raise analytic challenges:

- First, RxDC templates focus on the top 50 drugs by volume and spending and the top 25 drugs by rebates. Limiting these templates to the top 50 or 25 drugs prevents some analysis of PBMs trade-offs between access to drugs and the magnitude of discounts. Submitter rank-ordered lists also create challenges when combining completed templates

at the same reporting level—for example, when a primary PBM and a secondary PBM or vendor both submit a completed rank-ordered template for the same client.
- Second, the RxDC templates sometimes include spending at both gross and net prices, but in other cases only one or the other, and only some templates include counts of unique patients with prescriptions for certain types of drugs. More consistent content across templates could allow for broader analysis of per capita spending at payer net prices, which would inform analyses of changes in drug prices over time, an important component of the Section 204 request.
- Third, the Section 204 reporting requirements exclude information on benefit design, which, along with premiums, is a primary channel through which drug spending can affect patients.
- Finally, much of the drug spending and price information reported in the RxDC D3 through D8 templates appears to be from the PBM perspective rather than the plan sponsor/issuer perspective, with important and potentially large payments from plan sponsors/issuers to PBMs (e.g., service fees or other contractual payments) excluded from the scope of RxDC data collection.

In light of these data limitations, this background report focused on a set of initial, illustrative analyses from 2020 and 2021 RxDC data that

- relied on data from a single RxDC template to avoid the need to match across templates and submissions
- focused on comparisons in relative terms rather than absolute magnitudes to address clearly different approaches to allocation.

Limitations of the 2020 and 2021 RxDC data, due in some cases to a limited statutory scope for collection and in other cases to issues related to data collection implementation, prevented analyses related to

- total per capita drug spending (at net or gross prices), which requires combining enrollment with drug spending information across templates
- total per capita rebate amounts, for the same reason as above
- utilization, prices, or spending (in gross or net terms) by categories of drugs other than therapeutic class—for example, for brand-name drugs versus generic drugs—because no template collects information at this level
- investigating associations between drug and non-drug spending and premiums, which requires linking premium and spending data across templates and a consistent level of aggregation between reported drug and non-drug spending
- amounts paid to and retained by PBMs, which are not included in RxDC reporting
- the completeness of RxDC reporting, which also requires a consistent level of aggregation to define the universe of organizations for which reporting is required.

As we describe in our recommendations below, some of the data limitations that led to our narrow focus for illustrative analyses could be addressed by potential future RxDC technical clarifications and changes.

Findings from Illustrative Analyses

In our illustrative RxDC data analyses, we found that spending on drugs at net prices was on average roughly 80 percent of spending at gross prices, with some but modest variation across market segments and geography. However, we found substantial heterogeneity in submission-specific ratios, which likely reflects differences in how submitters aggregated information more than actual differences in relative gross-to-net prices. Consistent with prior research, we found larger net-to-gross ratios for some classes of drugs with robust competition between brand-name alternatives (e.g., oral anticoagulants and insulins) and smaller ratios for other classes with less competition and PBM leverage to steer prescribing (e.g., oncology). We found some evidence that a slightly larger share of net costs was covered by patient out-of-pocket spending in 2021 versus 2020.

Recommendations for Future Years of Section 204 Data Reporting

We developed a set of seven recommendations to improve future years of Section 204 data reporting and the RxDC, drawing from our synthesis of the literature, discussions with experts, and our analysis of 2020 and 2021 RxDC data. These recommendations do not necessarily represent the views of ASPE. The first five recommendations focus on technical clarification and specific changes to RxDC instructions.

Recommendation 1: Require Reporting at a Standardized, Plan Sponsor or Issuer/Segment/State Level

One of the most serious data limitations of the 2020, 2021, and likely 2022 RxDC data is that the submitted information cannot be standardized at a single unit of analysis. This greatly inhibits combining information from different templates and submissions, which is a necessary step for some analyses of interest, including the specific charge from Section 204 to assess the relationship between drug spending and premiums. The initial RxDC instructions included an "aggregation restriction" that required reporting at a level aggregated no more than the plan sponsor (or issuer or TPA, and more specifically the level of aggregation used in the D2 spending by category template), market segment, and state level. Later changes to RxDC instructions suspended the restriction and permitted aggregation at a broader level. Several submitters, including some PBMs, aggregated data at, effectively, a PBM level, which made linkages between plan-specific premium information (submitted by plan sponsors and issuers) and PBM-level drug spending impossible. A standardized reporting level would also help facilitate reporting in cases in which a single plan sponsor uses more than one vendor—for example, a main PBM and a secondary PBM. This first recommendation is the most crucial to establishing the utility of RxDC data for future analysis. While ending the suspension of the aggregation restriction does not entirely address the issue, data submitted with the aggregation

restriction in place would be considerably more aligned with the underlying D2 spending by category template level of aggregation.

Recommendation 2: Broaden and Standardize How Submitter IDs Are Reported and Linked

This second recommendation is closely related to the first. In order to confirm that submissions are at a single, standardized level, as in Recommendation 1, and in order to match up related submissions at that level, the plan sponsor or issuer should submit a list of which entities are submitting which completed templates on their behalf for a given market segment and state. Then, the respective submissions should all include the plan sponsor/issuer, market segment, and state identifiers to facilitate linkages. As described above, plan sponsors, issuers, and other submitters used the wide range of EIN fields in different ways, and there was no standardized approach to reporting business relationships between submitting entities.

Recommendation 3: Clarify and Require That Amounts Be from the Plan Sponsor/Issuer Perspective

While the instructions indicate that reported spending must be from the plan perspective, in some cases, it appears that data aggregated at the PBM level in templates D3 through D8 were reported from the PBM perspective. This has several important implications for the resulting data. In cases in which PBMs retain a portion of negotiated rebates, the amounts reported via RxDC may include the margin retained by the PBM, which is effectively an expense from the perspective of the plan sponsor or issuer. Furthermore, RxDC does not include fields for reporting payments *from* plan sponsors and issuers *to* PBMs. These payments, which are outside the scope of retained rebates, may in some cases reflect substantial additional coverage costs ultimately borne by payers and patients.

Relatedly, PBMs have some latitude to allocate rebates to specific drugs or clients in cases in which discounts are negotiated over a broader portfolio of drugs and across market segments. While the prevalence of bundling in drug price negotiations is not well understood, the consensus among the experts with whom we spoke for this project is that broader negotiation across drugs is increasingly important in determining plan net prices. Plan sponsors and issuers may have incentives to account for negotiated discounts in certain ways for the purposes of Section 204 reporting. The RxDC instructions could specify how certain PBM revenues and expenses be allocated for the purposes of reporting so that the information is reported fairly and consistently at the plan sponsor/issuer level.

Recommendation 4: Include Enrollment, Spending at Net and Gross Prices, and Out-of-Pocket Spending Consistently Across All Templates

Currently, in cases in which some templates are missing or templates cannot be linked at the RxDC reporting level, the remaining templates are often missing key information that could

otherwise have supported some analysis. For example, enrollment or counts of patients is included in some templates (for example, D1 and D7), but not others; without linking to one of these templates, it is not possible to calculate per capita statistics using data from other templates. While the recommendations above will improve match rates, a second strategy is to require that some information be reported repeatedly across templates. More specifically, reporting total enrollment (in terms of life-years or another standardized metric), spending in terms of both net and gross prices, and out-of-pocket spending on each relevant template would enable some analyses even for incomplete or mismatched submissions.

Recommendation 5: Add High-Level Breakdowns for Single-Source Brand, Other Brand, and Unbranded Generic Drugs

The current RxDC templates do not require information to be reported in such a way that spending at gross versus net prices or utilization can be compared between different broad categories of drugs, with the exception of therapeutic class in template D7. Many of the other statistics available regarding drug spending, the magnitude of gross-to-net discounts, and utilization differentiate at least between brand and generic drugs and in some cases between different types of brand-name drugs (for example, specialty versus nonspecialty). We recommend adding elements to one or more templates—for example, template D6 on total drug spending—to capture total spending at gross and net prices, out-of-pocket spending, and utilization for single-source brand, other brand, and unbranded generic drugs.

The final two recommendations involve system and implementation-based changes to RxDC.

Recommendation 6: Update Documentation and Instructions

Submitters may need some time to react to changes in the level of aggregation, the perspective from which spending is measured, and other potential RxDC refinements. We recommend posting updated technical instructions and documentation as soon as possible to allow submitters time to plan for the 2023 data submission in mid-2024.

Recommendation 7: Engage with PBMs and Plan Sponsors/Issuers on an Ongoing Basis

Several PBMs and other vendors coordinated with their clients throughout prior years of RxDC data collection, providing both information on what the PBM or vendor would submit and information on what was the responsibility of plans and issuers to submit. We recommend working with PBMs and vendors to clarify exactly what information plan sponsors and issuers are required and expected to submit. This recommendation is closely related to Recommendations 1 and 2, which envisage a more central role of responsibility for plans to ensure that reporting is complete and accurate. The Departments could host regular calls with stakeholder groups, both public and one on one, to help in this regard.

Opportunities from Analysis of RxDC Data Going Forward

While the illustrative analyses presented in Chapter 5 begin to get at key policy topics of interest, we believe that fuller analysis of later years of refined RxDC data is needed to address all of the questions posed by the CAA. Our recommendations above lay out several potential changes to RxDC structure and instructions to address the most important RxDC data limitations. Ideally, future years of RxDC data will include these refinements to improve the quality and consistency of the data and the utility of the data in fully addressing the CAA's questions, including questions regarding the association between premiums and drug and other health care spending.

Later analyses of RxDC data could focus more on associations between the magnitude of gross-to-net discounts and implications for consumers, including on premiums and total out-of-pocket spending. As noted above, these analyses would be much more helpful to policymakers if the Section 204 reporting requirements included drug-level out-of-pocket spending and formulary placement. In particular, information about the relative use of tiering, copayments, and coinsurance might be important. Additional data reflecting benefit design and generosity could enable nuanced analyses to help assess how these factors influence demand and how that demand informs the deeper underlying question of how cost sharing aims to reduce moral hazard, which is the overuse of health care by insured patients facing less than the full cost of care. Still, given the available information, it may be possible to identify associations with these higher-level costs to consumers. Such analyses could enable assessment of the degree to which benefit generosity may be declining to allow premiums to remain low and the relative implications across all enrollees, as well as for the subset of patients who use prescription drugs.

As more years of RxDC data are collected, researchers analyzing the data will be able to leverage longer time trends and evolving drug market conditions. Even with this variation over time, identifying the specific effect of a higher or lower net price on premiums and total cost sharing will be challenging given that there are so many other time-varying factors that plausibly affect premiums and cost sharing but cannot be easily controlled for. Despite these limitations, analyses of the future RxDC data have the potential to inform future policies related to drug prices, drug spending, and benefit design.

Appendix A. Prescription Drug Market Overview

This appendix is intended as a primer on stakeholders and incentives in prescription drug markets with a focus on brand-name drugs and how aspects of those markets relate to Section 204 reporting. Those interested in more detail may refer to an earlier RAND report on prescription drug supply chains (Mulcahy and Kareddy, 2021).

Defining *Prescription Drugs*

Prescription drugs include a broad range of products regulated and approved for sale by FDA and dispensed or administered to patients when prescribed by a licensed health care practitioner. Some drugs are also available OTC—that is, available without a prescription, often at a lower dose than their by-prescription counterparts.

Brand-Name Versus Generic Drugs

Many approaches can be used to group and categorize prescription drugs by their characteristics, their clinical use, or on other dimensions. One of the most important distinctions is between brand-name and generic drugs. In the United States, most drugs marketed under a brand name are protected from competition by patents and often by periods of regulatory exclusivity granted by FDA.[45] As a result, these brand-name drugs tend to be very expensive relative to other drugs. In 2021, brand-name drugs accounted for only 9 percent of prescription fills but 82 percent of spending on prescription drugs at gross prices (Association for Accessible Medicines, 2022).

Brand-name small-molecule drugs typically enjoy about 12 to 15 years of "effective patent life" before the first generic competitor enters the market and catalyzes price reductions (Rome, Lee, and Kesselheim, 2021; Grabowski and Vernon, 2000); the length of time is even higher for biologic drugs and biosimilars. In contrast with brand-name drugs, generic drugs are sold under the name of their active ingredient (for example, esomeprazole instead of brand-name Nexium), and there are typically several competing manufacturers of the same generic drug. This competition, paired with pharmacy-level generic substitution and higher pharmacy margins for generics versus brand-name drugs, drives generic prices substantially below the price of the corresponding brand-name drug prior to generic entry (Nguyen et al., 2021; FDA, 2019; Dave, Hartzema, and Kesselheim, 2017).

[45] Some "branded generic" drugs are not protected from competition by patents or regulatory exclusivity but are still marketed under a brand name. Branded generics are relatively rare in the United States but are more common in other countries.

Small-Molecule Versus Biologic Drugs

Another critical distinction is between small-molecule drugs, which are synthesized chemically, and biologics, which are manufactured in living systems. Biologics are more costly to manufacture, harder to describe analytically, and more difficult to copy compared with small-molecule drugs. For these reasons, and because biologics often treat serious conditions, such as cancers, biologics tend to be more expensive than small-molecule drugs. Many new brand-name drugs are biologics rather than small-molecule drugs, and biologics account for an increasingly large share of drug company research and development pipelines (Austin and Hayford, 2021).

Importantly, FDA's regulatory pathway for generic drugs applies only to small-molecule drugs, not biologics, and, as a result, some brand-name biologics have enjoyed far longer than 12 to 15 years of effective patent life. The ACA granted FDA the authority to develop a separate regulatory pathway to approve biosimilars, which are highly similar versions of existing brand-name biologics. The regulatory approval process and requirements for biosimilars differ from those for small-molecule generics: Most importantly, biosimilar developers must conduct some (relatively small) clinical trials, while small-molecule generic manufacturers do not face this requirement. As of August 2023, 12 brand-name biologics were competing with biosimilars, while others are expected in the coming years, resulting in savings for both insurers and patients (Mulcahy et al., 2022; Stern et al., 2021).

Primary Distribution Channel

A third important dimension used to categorize drugs focuses on how drugs reach patients. Most drugs are dispensed via retail pharmacies, including chain drug stores, independent drug stores, and pharmacies in grocery stores or big-box stores. In general, drugs dispensed via mail-order pharmacies have similar flows of product, payments, and information compared with those dispensed via brick-and-mortar retail pharmacies. There are more substantive differences for drugs administered by providers—for example, in physician offices or in hospital outpatient departments. These "physician-administered" drugs often are covered by insurers differently, are paid for differently, and involve different stakeholders than drugs dispensed by retail or mail-order pharmacies. Rebates typically play a much smaller role, or even no role, in determining the net price paid for physician-administered drugs.

Combining Key Characteristics as Related to Section 204 Reporting

RxDC data collection and reporting to date focuses on prescriptions falling under the pharmacy benefit, which primarily flow through retail pharmacies and mail-order distribution channels. The current reporting instructions require a high-level estimation of spending on prescription drugs covered under the medical benefit rather than the pharmacy benefit, including drugs dispensed or administered in physician office, outpatient facility, and inpatient facility settings. However, these amounts are estimates only, and none of the detailed RxDC data

collection templates otherwise reflect spending on drugs covered outside the pharmacy benefit. Later years of reporting under Section 204 may include all prescription drugs (including provider-administered drugs).

Plan sponsors and issuers vary in the extent to which they cover certain drugs—for example, self-injected biologics—under their pharmacy versus medical benefits. In some cases, such as stand-alone Medicare Part D prescription drug plans for those enrolled in fee-for-service Medicare, there are clear delineations between drugs covered under pharmacy and medical benefits. In other cases, this may vary by site of service and drug. As a result, there may be slight differences between plan sponsors and issuers in terms of the set of retail-dispensed drugs considered eligible for the initial years of Section 204 reporting.

Typical Flows of Drugs, Payments, and Information

The following sections describe the stakeholders and the flows of drugs, payments, and information related to prescription drugs in five illustrative scenarios. We use the first scenario, a brand-name drug dispensed via retail pharmacies, to introduce key stakeholders and concepts. We use the other scenarios to describe key differences between the brand-name retail scenario and

- generic drugs dispensed via retail pharmacies
- drugs dispensed via mail-order pharmacies
- drugs administered by providers
- drugs dispensed or administered during an inpatient stay or as part of another health care service.

Several narrow categories of prescription drugs differ from these more general scenarios, including

- vaccines
- radiopharmaceuticals (that is, drugs containing radioactive isotopes)
- contrast media (used for imaging)
- compounded drugs (that is, bulk drugs combined for an individual patient by a pharmacist)
- experimental drugs (that is, drugs undergoing clinical trials)
- drug and device combinations (for example, drug-eluting stents).

While all these categories include prescription drugs subject to the Section 204 reporting requirements, they tend not to be dispensed in retail channels and, as a result, should not factor prominently into the early years of RxDC data. Our description of the typical flow of drugs, payments, and information in this section focuses on more representative examples and does not explore the important differences in stakeholders and relationships for the niche markets listed above.

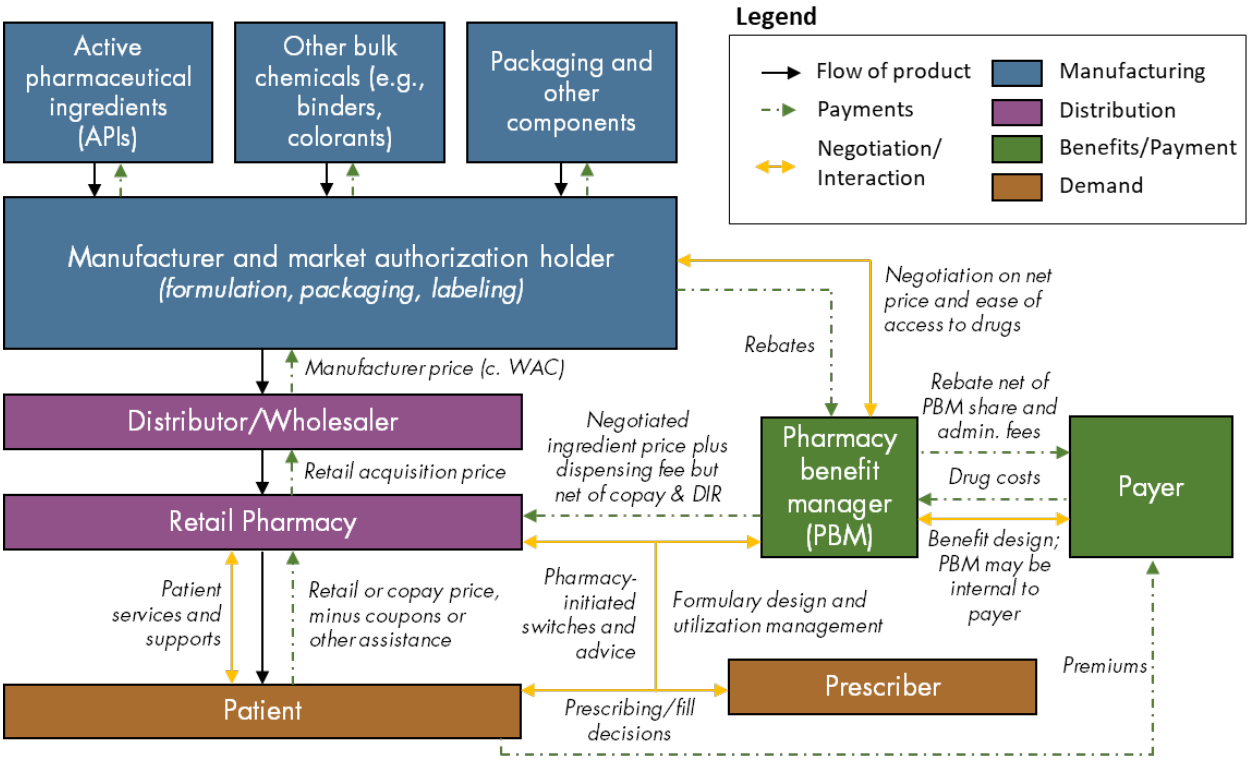
Scenario 1: Brand-Name Drugs Dispensed Via Retail Pharmacies

The supply chain for brand-name drugs dispensed through retail pharmacies involves many stakeholders and complex relationships between stakeholders. Figure A.1 illustrates key stakeholder groups as boxes distinguished by color in four categories (manufacturing, distribution, benefits/payment, and demand) and interactions between stakeholders using arrows in three colors (flows of product, payments, and information). Key stakeholder categories and their primary role in the process include the following, as summarized in Mulcahy and Kareddy (2021):[46]

- **Market authorization holders** have approval from FDA to sell specific prescription drug products. In the simplest case, the market authorization holder is also the **manufacturer, packager, and labeler** of a finished drug product, although these other roles are sometimes contracted out to other companies. Manufacturers themselves purchase **active pharmaceutical ingredients (APIs, which are molecules that have biological effect), bulk chemicals, and other inputs** such as vials and syringes from other companies.
- Finished drug products are shipped to **distributors** that in turn ship drugs to points of dispensing, such as pharmacies and hospitals.
- **Pharmacies** purchase drugs from distributors and, when drugs are dispensed to patients with prescriptions, receive payments from payers or PBMs hired to administer prescription drug benefits.
- For patients with prescription drug coverage, **payers**, which can be health insurers, large employers, or government programs, weigh the generosity of the pharmacy benefit they want to offer (in terms of coverage, cost sharing, etc.) against the cost.
- Based on payer specifications, **PBMs** design and maintain drug formularies to encourage patients and prescribers to use certain drugs in exchange for discounts from market authorization holders paid to PBMs via rebates, a share of which are passed back to payers, and which ultimately could result in lower premiums or other benefits for insured patients. Separately, PBMs maintain networks of pharmacies, including some preferred pharmacies where dispensing fees are lower.
- **Patients** and **prescribers** ideally make joint decisions on which drugs patients should be prescribed. For patients with prescription coverage, these decisions are influenced by the placement of different treatment options on formularies, with typically lower out-of-pocket costs and fewer utilization management requirements applied to alternatives that are more preferred by payers and PBMs. Patients pay some or all of the cost of the drug when filling prescriptions at pharmacies depending on whether they have coverage or other sources of support.

[46] The text in the bullet points that follow is taken verbatim from Mulcahy and Kareddy (2021).

Figure A.1. Typical Supply Chain for Brand-Name Drugs Dispensed Through Retail Pharmacies



SOURCE: Adapted from Mulcahy and Kareddy (2021).

Gross Prices, Negotiating Leverage, and Net Prices

As noted in Chapter 1, there are important differences between list or gross prices attached to the drug by the manufacturer, the net price received by the manufacturer after rebates, and the net cost to plan sponsors and issuers. In cases in which the insurer/PBM does not have leverage to negotiate further discounts—for example, for many oncology drugs—this gross price paid to pharmacies is also the payer's net price (Mulcahy et al., 2021a). However, in other therapeutic classes, including insulins, drugs to treat chronic obstructive pulmonary disease (COPD) and asthma, and DMARDs, the existence of close substitutes and the ability of insurers/PBMs to steer patient and prescription decisionmaking results in substantial leverage over drug companies.

When the PBM is a separate entity from the insurer, the insurer pays the PBM for initial payments to pharmacies and then the PBM returns a share of the negotiated rebates to the insurer. Under "pass-through" contractual arrangements between insurers and PBMs, PBMs retain a percentage of the rebate amount (for example, 3 percent) and return the remainder to the insurer. Under "spread" arrangements, the PBM offers insurers a given price and then retains the margin between an agreed-upon price and the price the PBM ultimately pays to the pharmacy. Typical contracts between PBMs and insurers contain a mix of pass-through and spread

provisions for different categories of drugs and often include additional fees for such PBM services as claims adjudication, dispute resolution, and administration.

Relatively little is known about the specific processes by which drug companies and PBMs negotiate prices. Based on our discussions with key informants and other anecdotes, negotiations often apply across all of a PBM's books of business, although specific policy provisions (for example, Medicare Part D protected classes and Medicaid best-price provisions) occasionally result in separate negotiated prices by market segment. There also seems to be an increasing trend toward joint negotiation for broader portfolios of drugs—for example, requiring a certain discount on smaller drugs by revenue in exchange for a favorable discount on a manufacturer's most important products in terms of revenue.

Patient Cost Sharing

Regardless of the contractual arrangements between insurers and PBMs and the specific negotiated prices, patients often pay cost sharing based on the list or gross price of a drug, not the net price. For patients in the deductible phase of coverage, costs at list or gross prices can be substantial, and patients can quickly meet even a high deductible threshold with the first fill of a brand-name drug. A recent analysis of employer group plans found that average patient-level deductible amounts increased 17 percent over the past five years and the share of enrollees in plans with deductibles of $2,000 or more increased by nearly 50 percent, from 22 percent to 32 percent (KFF, 2023).

Patients' cost sharing for even preferred brand-name drugs—for example, $50 for a prescription filled after the deductible is met and before out-of-pocket limits apply—while less than the total initial amount due to the pharmacy, can exceed the ultimate net price paid by the PBM, and in this case the payer/PBM retains the difference. Basing cost sharing on gross rather than net prices is particularly important for expensive drugs placed by insurers/PBMs on "specialty" formulary tiers in which patients are responsible for a percentage of the payment to pharmacies (at gross prices) as cost sharing (that is, coinsurance). In this scenario, a patient responsible for a certain share of a drug's cost at gross prices may ultimately pay a much larger share of the drug's cost at net prices. For example, a patient responsible for 20 percent coinsurance for a drug costing $10,000 per year at gross prices and $2,000 per year at net prices will pay the entire net cost of the drug out of pocket (that is, effectively without using the insurance benefit at all), while the insurer/PBM ultimately bears no further expense but may still collect a rebate. This phenomenon, as we discuss later, effectively transfers more of the cost of prescription drugs to patients actively using drugs rather than the broader population of individuals insured under the plan.

Other Scenarios

There are important differences in stakeholders and relationships outside the typical scenario for retail-dispensed, brand-name drugs described above. The sections below describe other important scenarios.

Generic Drugs Dispensed Via Retail Pharmacies

Generic drugs are much less expensive on average than brand-name drugs at gross prices (Congressional Budget Office, 2022). Margins for distributors and pharmacies, while larger in relative terms than for brand-name drugs, remain modest given the low unit price. Rebates generally do not factor into the net prices paid by insurers/PBMs for generic drugs. Instead, the terms of contracts between insurers/PBMs and pharmacies are the most important determinant of prices paid for generic drugs. These contracts typically reference maximum allowable cost (MAC) rates updated regularly by the insurer/PBM, as well as clauses linking a portion of payment to pharmacies to performance metrics (for example, generic fill shares) that may not typically be met.

Drugs Dispensed Via Mail-Order Pharmacies

The main difference between prescriptions dispensed by retail and mail-order pharmacies is that mail-order pharmacies are often owned and operated by the insurer/PBM directly. Typically, insurers/PBMs pay a separate dispensing fee to pharmacies, so they are able to eliminate one markup from their ultimate cost by operating the mail-order pharmacy directly. Insurers/PBMs need to weigh this financial benefit against the costs of operating the mail-order pharmacy. In most cases, insurers/PBMs rely on mail-order pharmacy for refills of routine medications used to treat chronic conditions. Patients often face lower cost sharing when filling prescriptions via mail order, and, in some cases, the only option for patients is to fill prescriptions for maintenance medication via mail order.

Drugs Administered by Providers

As noted above, many drugs, and particularly infused and injected drugs, are administered by providers in office or outpatient facility settings. These drugs are bought by providers and then billed to insurers after they are administered. Providers often acquire drugs through group purchasing organizations (GPOs), which are separate price negotiation entities pooling the buying power of multiple hospital systems, physician practices, and other providers. Providers are typically paid rates scaled to the Medicare fee schedule for physician-administered drugs, plus a margin to cover the costs of acquisition and stocking. These rates are based on

manufacturers' average sale price (ASP), including some discounts off gross prices.[47] As a result, rebates are not common for physician-administered drugs.[48]

Drugs Dispensed or Administered During an Inpatient Stay or as Part of Another Health Care Service

The costs for drugs administered during inpatient hospital stays or as part of another health care service (for example, certain outpatient hospital services) are typically paid by insurers as part of the broader health care service rather than individually. There are some important exceptions, most notably for expensive new drugs for which at least Medicare allows separate pass-through payments. While patients are likely responsible for a share of the cost of these broader health care services, they do not face separate cost sharing for individual drugs administered during an inpatient stay.

[47] Drug companies report ASP to CMS quarterly. ASP, which is defined in statute, includes negotiated rebates and off-invoice discounts but does not reflect discounts under the 340B program.

[48] Conceptually, *chargebacks* for physician-administered drugs, where GPOs acquire drugs for one price, sell drugs to their members for a lower price, and then charge the drug company for the difference, are similar to rebates for retail-dispensed drugs. However, the main difference is that insurers/PBMs pay the reduced price initially for physician-administered drugs (rather than arriving at a net price after an ex post rebate). GPOs, in contrast, initially pay a higher price for physician-administered drugs that is later reduced by chargebacks.

Appendix B. Methods Details

This appendix includes detailed methods for Chapters 2 and 3.

Chapter 2 Methods

Literature Review

Inclusion Criteria:

- Study focuses on primary or secondary research—i.e., not a commentary, editorial, etc.
- Study is written in English.
- Study is U.S.-based.

SEARCH TERMS FOR: Background on setting premiums

- Domain 1: Health insurance premiums
    - premium* AND [health OR medical] AND Insur*

AND

- Domain 2: trends
    - Trend* OR Year* OR Time*

AND [

- Domain 2a: Actuarial practices
    - Calculat* OR Determin* OR Actuar* OR Set OR Sets OR Increase*

OR

- Domain 2b: ACA rules
    - MLR OR "Medical loss ratio"]

SEARCH TERMS FOR: Health insurance premiums & spending

- Domain 1: Premiums & spending
    - Premium* AND ["health insurance" OR "medical insurance"] OR Spend* AND ["health care" OR healthcare]

AND [

- Domain 2a: trends
    - Trend*[title]

OR

- Domain 2b: Impact on premiums over time

- [Impact* OR effect* OR drive*] AND [prescription* OR drug* OR pharmac* OR medication] OR [Hospital* OR inpatient* OR "acute care"] OR [physician* OR clinic*] OR ["medical device" OR "outpatient" OR "dental" OR "dentist" OR "home health" OR "long-term care" OR "long term care"]

]

Data Sources

In Chapter 2, we describe the data sources used for the descriptive summaries presented in that chapter. Below, we describe in more detail the specific data summaries pulled from each source.

Kaiser Family Foundation Employer Health Benefit Survey, 2014–2023

Using data from the KFF Employer Health Benefit Survey, we summarized prescription drug coverage, premiums, and other plan benefit design details for employer-sponsored health insurance. We summarized annual health insurance premiums, deductibles, out-of-pocket maximums, coinsurance maximums, use of copays and coinsurance, and use of tiered formularies for 2014–2023. For most summaries, we pulled data directly from the KFF Employer Health Benefit Survey annual reports in order to match the summary data already reported by KFF. For the summary of out-of-pocket maximums, we utilized the raw data from the KFF Employer Health Benefit Survey, weighting firms by the number of covered workers when averaging.

Medical Expenditure Panel Survey Data, 2014–2020

We used the MEPS Household Component Full-Year Consolidated Files from 2014 to 2020 to summarize sources of health insurance coverage and sources of prescription drug coverage. In particular, we used the MEPS data, weighted using the standard person-level weights, to summarize the total number of individuals in the United States who have prescription drug coverage via private group and non-group coverage, Medicare Part D, Medicaid, and other public coverage, as well as the number who were uninsured. Since individuals can report multiple sources of health coverage, we implemented the following hierarchy to create mutually exclusive categories:

1. uninsured for full year
2. Medicare Part D
3. Medicaid
4. private group
5. private non-group
6. other public insurance.

This hierarchy means that our estimates may not match other published estimates of insurance coverage that used non-mutually exclusive categories. We also note that we do not

include coverage by the IHS in any of the above categories, as the National Health Interview Survey and other federal surveys do not classify individuals who have coverage only through the IHS as being insured (Finegold et al., 2021). We also used the MEPS data to summarize the percentage of group and Marketplace/off-Marketplace non-group insurance enrollees reporting having prescription drug coverage under their health plan. However, we note that ACA-compliant Marketplace/off-Marketplace plans are required to include prescription drug coverage as an EHB unless they are grandfathered or grandmothered, but the number of individuals reporting prescription drug coverage under their Marketplace/off-Marketplace plan (between 60 and 70 percent, depending on the year) seemed low, given that the percentage of grandfathered or grandmothered plans is small and gets smaller each year. Therefore, there may be some underreporting of prescription drug coverage in the MEPS data, particularly by individuals covered by Marketplace/off-Marketplace plans.

CCIIO Health Insurance Exchange Public Use Files, 2014–2023

Finally, we used the Plan Attributes PUF and Benefits and Cost Sharing PUF from CCIIO to summarize trends in prescription drug cost sharing in Marketplace plans. We averaged drug deductibles at the plan level and calculated the percentage of plans reporting a separate prescription drug deductible and the percentage of plans using copays versus coinsurance. We also reported the annual Marketplace benchmark premium based on data reported by KFF, per its analyses of CCIIO data.

Chapter 3

Literature Review

Inclusion Criteria:

- Study focuses on primary or secondary research—i.e., not a commentary, editorial, etc.
- Study is written in English.
- Study is U.S.-based.

SEARCH TERMS FOR: Drug rebates in commercial drug coverage compared with the use and impact of rebates in Medicaid and in Medicare Part D

- Domain 1: Rebates
    - Rebate*

AND

- Domain 2: Drugs
    - drug* OR prescription* OR pharmac* OR medication*

AND

- Domain 3: Use and impact
    - Use OR Utilization OR Volume OR Cost* OR Spending OR Price* Afford* OR Saving*

AND

- Domain 4: Payers
    - Commercial OR Private OR Group OR Employ* OR Individual OR Medicaid OR Medicare OR "Part D"

SEARCH TERMS FOR: Margins of rebates that pharmacy benefit managers and other stakeholders keep versus pass through to consumers

- Domain 1: Rebates
    - Rebate*

AND

- Domain 2: Drugs
    - drug* OR prescription* OR pharmaceutical* OR medication*

AND

- Domain 3: Stakeholders
    - Pharmacy benefit manager* OR PBM* OR Manufacturer* OR Wholesaler* OR Distributor* OR Insur* OR Plan* OR Payer* OR Pharmac* OR Patient* OR Consumer*

AND

- Domain 4: Pass-through
    - Pass-through OR "Pass through" OR Margin* OR Profit* OR Retain* OR Spread

Specifications for MEPS Analyses

MEPS is a set of surveys of individuals and families that includes information on use of health services, costs of services, and sources of payment (including detailed insurance types), among other things (AHRQ, 2019). For the purposes of this work, we used MEPS Household Component Full-Year Consolidated Files from 2014 to 2020 to examine trends in payer gross drug spending, spending by a selection of therapeutic classes, and spending among enrollees in individual and group plans.

We used the MEPS Household Component Full-Year Consolidated and Prescribed Medicines Files from 2014 to 2020 to examine trends in payer gross drug spending, spending by a selection of therapeutic classes, and spending among enrollees in group, exchange, and non-group plans.

For our total spending estimates by payer, we multiplied variables on retail prescription drug spending per person in the Consolidated Files by their standard person-level weights and then

summed these amounts for each year. We examined drug spending across the following payer variables: total spending; self or family; private insurance; Medicaid; Medicare; Veterans/CHAMP VA; TRICARE; other federal, state, and local government; workers' compensation; and other. These variables constitute the amount paid by these payers, without considering enrollment duration among individuals.

For our spending estimates by therapeutic classes, we used the Prescribed Medicines File to limit the data to entries from the following classes: anti-infectives, antineoplastics, cardiovascular agents, central nervous system agents, coagulation modifiers, gastrointestinal agents, hormones/hormone modifiers, miscellaneous agents, genitourinary tract agents, nutritional products, respiratory agents, topical agents, alternative medicines, psychotherapeutic agents, immunologic agents, and metabolic agents. We then multiplied variables related to total and out-of-pocket spending by the expenditure-file person weights, which we then summed for each year. In our reported statistics, we combined the remaining following therapeutic classes as "other": coagulation modifiers, gastrointestinal agents, genitourinary tract agents, nutritional products, topical agents, alternative medicines, psychotherapeutic agents, and "miscellaneous agents," a separate therapeutic class in MEPS.

For our estimates of spending among enrollees in group, exchange, and non-group plans, we used the Full-Year Consolidated Files to limit our sample to the following categories with enrollment during the last day of the calendar year:

- Group plans: individuals who indicated that they were enrolled in either employer/union group insurance, private insurance, or ESI
- Exchange plans: individuals who indicated that they were enrolled in private exchange insurance
- Non-group plans: individuals who indicated that they were enrolled in non-group insurance.

We further limited these three samples to those who indicated having prescription drug coverage. We then multiplied observations by person-level weights and reported their means, 95-percent confidence intervals, and sums. For our calculations of mean spending, we winsorized outliers at two times the standard deviation.

Appendix C. Detailed RxDC Template Table

Table C.1 is a detailed table describing the overlap between RxDC submissions at the initial RxDC reporting level of one template type (D1 through D8) with submissions at the same reporting level of another template type (also D1 through D8). The shaded diagonal reports a 100-percent match rate between submissions for the same template. The triangles of cells up and to the right and below and to the left of the diagonal are mirror images of each other. As an example, of 22,190 D1 template submissions, 10,267 (46 percent) had a corresponding D6 template.

Table C.1. Overlap Between Submitted Templates at the RxDC Reporting Level

		D1	D2	D3	D4	D5	D6	D7	D8
D1	*N*	22,190	14,491	10,203	10,453	10,245	10,267	10,340	10,300
	row %	100%	65%	46%	47%	46%	46%	47%	46%
	col %	100%	84%	27%	25%	25%	19%	22%	24%
D2	*N*	14,491	17,206	9,037	9,286	9,082	9,093	9,190	9,173
	row %	84%	100%	53%	54%	53%	53%	53%	53%
	col %	65%	100%	24%	23%	22%	17%	19%	21%
D3	*N*	10,203	9,037	37,348	36,560	35,774	35,207	35,685	35,363
	row %	27%	24%	100%	98%	96%	94%	96%	95%
	col %	46%	53%	100%	89%	87%	66%	75%	82%
D4	*N*	10,453	9,286	36,560	41,237	39,628	38,764	38,701	38,357
	row %	25%	23%	89%	100%	96%	94%	94%	93%
	col %	47%	54%	98%	100%	97%	72%	81%	89%
D5	*N*	10,245	9,082	35,774	39,628	40,961	38,388	38,258	37,955
	row %	25%	22%	87%	97%	100%	94%	93%	93%
	col %	46%	53%	96%	96%	100%	72%	81%	88%
D6	*N*	10,267	9,093	35,207	38,764	38,388	53,606	41,336	41,294
	row %	19%	17%	66%	72%	72%	100%	77%	77%
	col %	46%	53%	94%	94%	94%	100%	87%	96%
D7	*N*	10,340	9,190	35,685	38,701	38,258	41,336	47,508	42,457
	row %	22%	19%	75%	81%	81%	87%	100%	89%
	col %	47%	53%	96%	94%	93%	77%	100%	98%
D8	*N*	10,300	9,173	35,363	38,357	37,955	41,294	42,457	43,215
	row %	24%	21%	82%	89%	88%	96%	98%	100%
	col %	46%	53%	95%	93%	93%	77%	89%	100%

Abbreviations

ACA	Affordable Care Act
AHRQ	Agency for Healthcare Research and Quality
ASP	average sale price
ASPE	Office of the Assistant Secretary for Planning and Evaluation
BARDA	Biomedical Advanced Research and Development Authority
CAA	Consolidated Appropriations Act
CCIIO	Center for Consumer Information and Insurance Oversight
CMS	Centers for Medicare & Medicaid Services
COPD	chronic obstructive pulmonary disease
COVID-19	coronavirus disease 2019
CPI-U	Consumer Price Index, All Urban Consumers
CSR	cost-sharing reduction
DDD	defined daily dose
DIR	direct and indirect renumeration
DMARD	disease-modifying anti-rheumatic drugs
EHB	essential health benefits
EIN	employer identification number
EPC	Effective Pharmacologic Class
ERISA	Employee Retirement Income Security Act
ESI	employer-sponsored insurance
EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
FEHB	Federal Employees Health Benefits
FFE	federally facilitated exchange
GLP	glucagon-like peptide
GPO	group purchasing organization
HHS	U.S. Department of Health and Human Services
IHS	Indian Health Service
KFF	Kaiser Family Foundation
MAC	maximum allowable cost
MEPS	Medical Expenditure Panel Survey
MLR	medical loss ratio
NADAC	National Average Drug Acquisition
NARP	National Average Retail Price
NCPDP	National Council for Prescription Drug Programs

NDC	National Drug Code
NHE	National Health Expenditures
NHEA	National Health Expenditure Accounts
NSP	National Sales Perspectives
OACT	Office of the Actuary
OTC	over-the-counter
PBM	pharmacy benefit manager
PCL	per covered life
PUF	public use files
RxDC	Prescription Drug Data Collection
SBE	state-based exchange
SEC	U.S. Securities and Exchange Commission
TEP	technical expert panel
TIN	tax identification number
TPA	third-party administrator
WAC	wholesaler acquisition cost

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