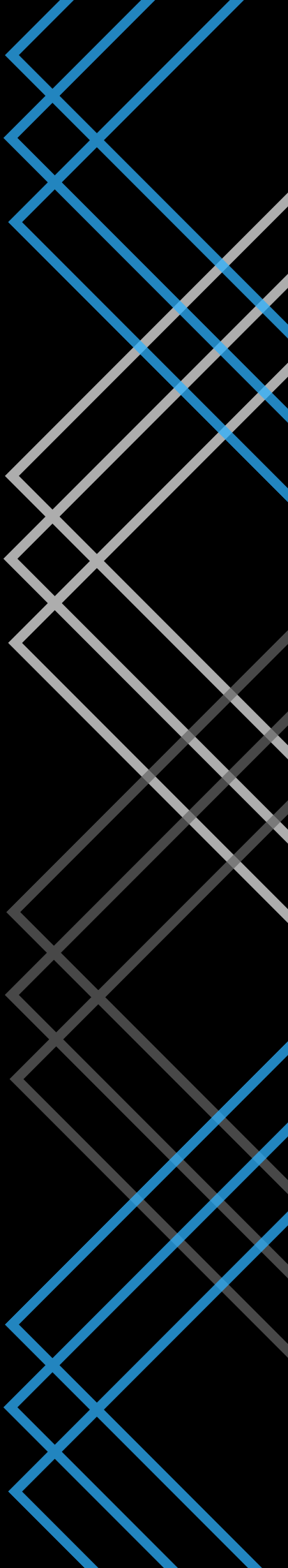




A TANGLED WEB

AN EXAMINATION OF THE DRUG
SUPPLY AND PAYMENT CHAINS

Prepared by the Minority Staff of the U.S. Senate
Committee on Finance
June 2018



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DRUG SUPPLY AND PAYMENT CHAINS

U.S. SENATE COMMITTEE ON FINANCE, MINORITY STAFF

JUNE 2018

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FOREWORD

The rising cost of drugs is one of the most urgent issues facing Americans today. Every week brings news of a promising new drug that will combat or cure a once untreatable illness. But too often American families are left feeling that these therapies are financially out of reach, and that an opaque system of drug manufacturers, insurance companies, and middlemen is driving prices up rather than bringing them down. That's on top of unexplained spikes in prices for once-affordable drugs that have been on the market for years or even decades, putting them out of reach for people that count on them. As a result, families across the country are clamoring for action from their elected officials, regardless of party affiliation.

Escalating costs are also placing pressure on federal health care programs, including Medicare, which provides coverage for more than 58 million Americans. As the Medicare Trustees' report stated this month, prescription drug spending in Part D alone has doubled over the last decade. This growth is unsustainable—and it threatens this nation's ironclad guarantee that all Americans will have high quality health care as they get older.

The Minority staff of the Senate Committee on Finance spent more than a year examining every corner of the pharmaceutical industry, seeking to untangle the complex web of pricing incentives, confidential contracts, and government policies that have combined to push drug prices higher over time as a drug travels from the lab bench to the medicine cabinet or doctor's office.

As this report shows, the various financial arrangements between different businesses in the pharmaceutical delivery system means that every part of the supply chain – except patients and the

Medicare program – stand to benefit from higher prices in some way. Today's report focusing on Medicare, albeit not exhaustive of every aspect of the supply chain, comes after the 2015 bipartisan investigation of Gilead Sciences' \$84,000 hepatitis C drug Sovaldi. The investigation into Sovaldi found that Gilead priced its hepatitis drug to maximize profit with little regard to consequences for patients, Medicaid, and other parts of the U.S. health system.

These findings beg for action from Congress, the Administration, and every stakeholder in the supply and payment chain to once and for all lower the cost of pharmaceutical drugs for patients and taxpayers.

The Trump Administration released a blueprint earlier this year outlining its plan on this issue. This document falls far short of the promises made by the president on the campaign trail.

Bold action and greater transparency are sorely needed to protect American families from financial hardship while ensuring their access to essential care. I've offered legislation to begin untangling the web of financial relationships up and down the supply chain, and this report should inform other proposals moving forward. I am committed to finding solutions that help patients and exposing how the current system comes at the expense of American consumers and taxpayers. Americans have waited long enough.

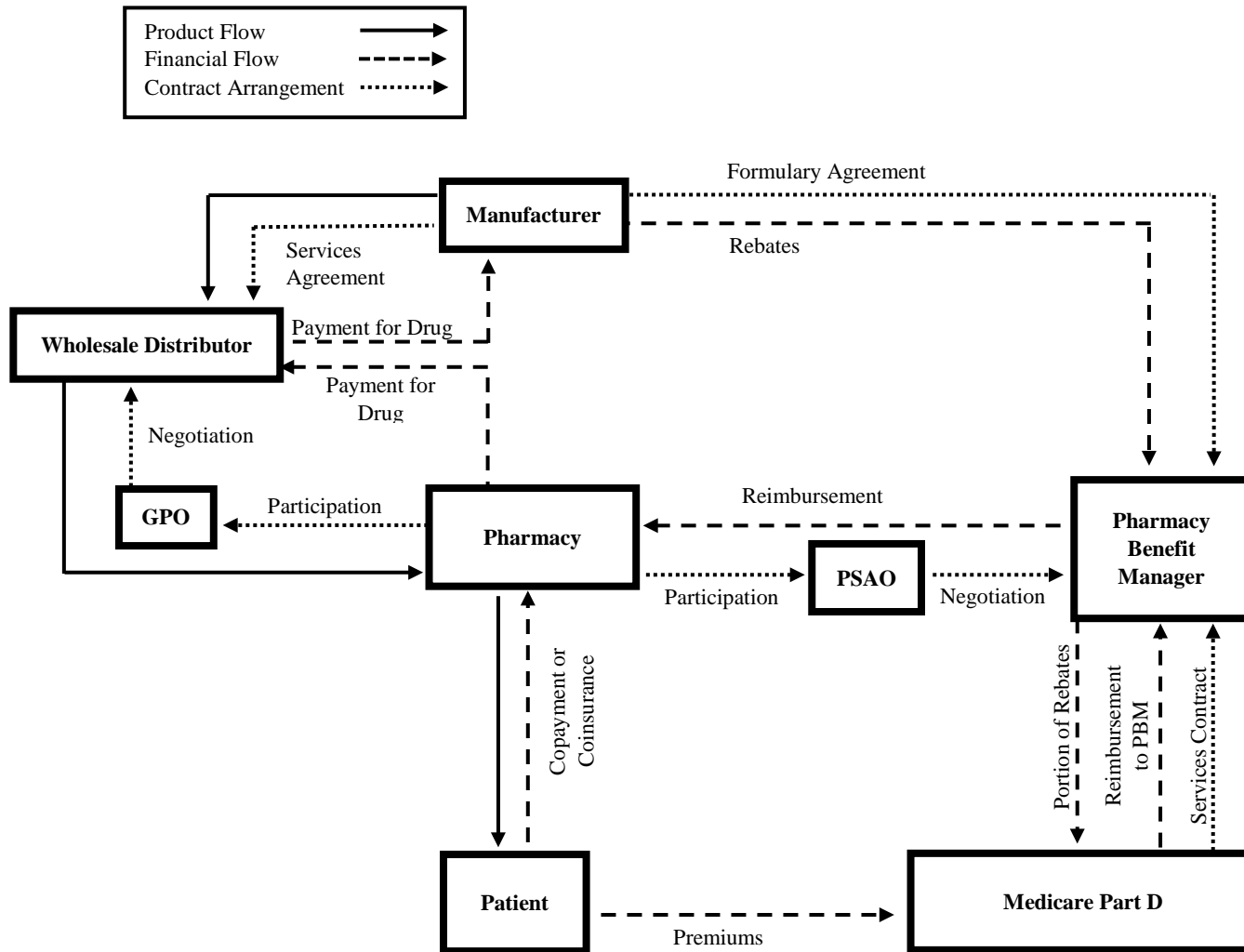


Senator Ron Wyden

ACRONYMS

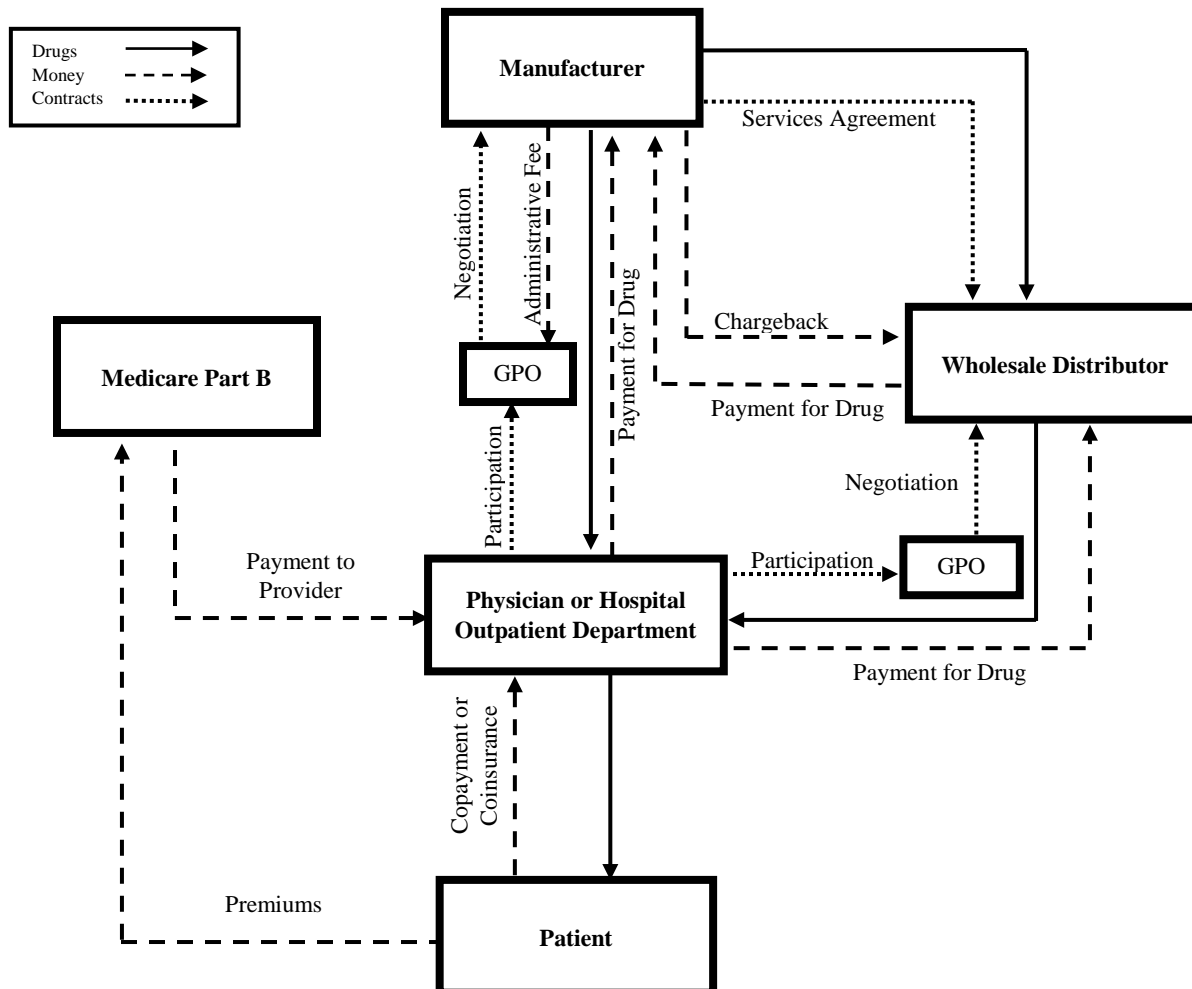
AARP – American Association of Retired Persons
AHIP – America’s Health Insurance Plans
ASP – Average Sales Price
AWP – Average Wholesale Price
BBA – Bipartisan Budget Act of 2018
CBO – Congressional Budget Office
CMS – Centers for Medicare & Medicaid Services
CY – Calendar Year
DIR – Direct and Indirect Remuneration
DOJ – Department of Justice
FDA – Food and Drug Administration
FTC – Federal Trade Commission
GAO – Government Accountability Office
GDP – Gross Domestic Product
GPO – Group Purchasing Organization
HDA – The Healthcare Distribution Alliance
HHS – Department of Health and Human Services
MA – Medicare Advantage
MAC – Maximum Allowable Cost
MedPAC – Medicare Payment Advisory Commission
NASP – National Association of Specialty Pharmacy
NACDS – National Association of Chain Drug Stores
NCPA – National Community Pharmacists Association
OIG – Office of Inspector General
PAP – Patient Assistance Program
PBM – Pharmacy Benefit Manager
PCMA – The Pharmaceutical Care Management Association
PhRMA – The Pharmaceutical Research and Manufacturers of America
PSAO – Pharmacy Services Administrative Organization
REMS – Risk Evaluation and Management Strategies
WAC – Wholesale Acquisition Cost

FIGURE 1: SUPPLY AND PAYMENT CHAIN FOR PART D-COVERED DRUGS (NON-SPECIALTY)



Adapted from: Adam J. Fein, Follow the Dollar Math: How Much Do Pharmacies, Wholesalers, and PBMs Make From a Prescription? (Aug 8, 2017), <https://www.drugchannels.net/2017/08/follow-dollar-math-how-much-do.html>.

FIGURE 2: SUPPLY AND PAYMENT CHAIN FOR PART B-COVERED DRUGS



Adapted from Fein, Adam J. The 2016-17 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, Drug Channels Institute, September 2016, Exhibit 28, http://drugchannelsinstitute.com/products/industry_report/wholesale/

INTRODUCTION

The price of pharmaceuticals continues to soar, putting essential medications out of reach for millions of Americans. In 2016, total prescription drug spending in the United States reached \$328.6 billion, equal to 1.76% of U.S. Gross Domestic Product (GDP), and more than double what was spent in 2002.¹ Furthermore, annual prescription drug spending growth is expected to average 6.3% over the next decade, the fastest of any major health care sector.²

While the Trump Administration has stated its commitment to lowering drug prices, the blueprint it introduced in May will do little to lower costs for American consumers. Simply put, the Administration has fallen far short of addressing the long list of entities and financial relationships that push drug prices – and consumer costs – higher.

This report is not exhaustive; however, it seeks to outline those very drivers in the supply and payment chains for drugs, with a particular focus on the Medicare program. To do so, it describes how various business entities within the supply and payment chains interact, and examines the accompanying financial relationships. In so doing, the report identifies how these market participants directly and indirectly influence the price of drugs, as well as the costs borne by consumers and the Medicare program. This report is silent on the impacts of the Medicaid program, the 340B Drug Discount Program, and the Federal Supply Schedule, on the Medicare program.

Using publicly available documents, the Minority staff of the Senate Finance Committee examined the role of drug manufacturers, wholesale distributors, Pharmacy Benefit Managers (PBMs), Part D plan sponsors, and pharmacies in the pharmaceutical supply and payment chains.

The report describes a complex web of negotiations, contractual arrangements, and financial transactions that determine the price a consumer pays for drugs. It seeks to untangle the web to illustrate the sometimes surprising ways these relationships contribute to higher drug prices and consumer costs. It also points out numerous areas of minimal transparency that would benefit from additional examination.

Rising drug prices affect all consumers who take or are administered medications. While this report concentrates on the cost of drugs in the Medicare program, many of the pathways, supply chains and payment mechanisms described in this report that are not specifically tied to Medicare reimbursements are very similar to those of private insurers

This report adds further insight into the complex world of drug pricing, while adding some clarity to an otherwise opaque system. Ultimately, this report should be used as a catalyst to facilitate discussion on how best to tackle legislative and regulatory changes that can finally take on and address this national problem.

EXECUTIVE SUMMARY

Following the Pill (and the Money)

Medicare is the federal health care program for people ages 65 and older, people with disabilities and people with end stage renal disease. Medicare's drug benefits, covered by Parts B and D, pay for physician-administered outpatient medications and outpatient prescription drugs, respectively.

This report focuses on drug delivery and payment in the context of Parts B and D. However, many of the pathways, supply chains and payment mechanisms described in this report are very similar in the individual and commercial insurance markets.

In general, a drug takes the following path from a manufacturer to a patient:

- For prescription drugs patients obtain at a pharmacy, a drug is made by a manufacturer, delivered by a wholesale distributor to a pharmacy, and dispensed at the pharmacy to a patient, who may use a Medicare Part D plan to help pay for it.
- For drugs administered to patients by physicians in outpatient settings, a drug is made by a manufacturer and, generally, delivered by a wholesale distributor to a health care provider,³ such as a physician's office, hospital outpatient department, or outpatient clinic. The provider then administers the drug to the patient. Part B covers both the drug itself and the drug's administration.

Following the money is more complicated. For Part D drugs, a manufacturer generally sells a drug to a wholesale distributor at a list price set by the drugmaker called the Wholesale Acquisition Cost (WAC), minus discounts negotiated between the parties. The distributor then sells the product to a pharmacy at a price roughly based on the WAC. A beneficiary then buys the drug at the pharmacy after paying some form of cost-sharing set by the individual's Part D plan. Most of the time, a Part D plan retains an intermediary called a Pharmacy

Benefit Manager (PBM) to administer the drug benefit on the plan's behalf. This PBM negotiates with the pharmacy to set the copayment and reimbursement the pharmacy receives for dispensing the medication.

For physician-administered drugs, health care providers use a buy-and-bill model in which a provider purchases the drug directly from a manufacturer or distributor, administers it to a patient, and then submits a claim to Medicare Part B for payment for the drug itself plus a separate payment for administering the drug. Medicare beneficiaries generally pay 20 percent coinsurance for these items and services under Part B, unless they have supplemental coverage.

Financial Incentives

Throughout the supply and payment chains, different businesses exchange rebates, discounts, and other payments to encourage entities to contract with one another or to encourage the purchase of a particular drug. For example, a manufacturer may offer a distributor volume discounts, prompt pay discounts, or chargebacks if the manufacturer contracts directly with a pharmacy or health care provider. A manufacturer may also grant financial incentives or concessions to a PBM, Part D plan, or pharmacy. For example, some manufacturers pay rebates to PBMs or Part D plans in exchange for specific placement of their drug on the plan's formulary. Further, specialty pharmacies and physician practices may negotiate discounts to leverage their purchasing power through Group Purchasing Organizations (GPOs).

Impacts to Consumers

Some stakeholders—particularly PBMs—suggest that rebates and discounts lower the cost of drugs for Medicare beneficiaries because these concessions drive down the price paid for a medication. However, rebate arrangements may allow PBMs and plan sponsors to benefit from high list prices if rebates are based on a drug's WAC. To

this point, manufacturers contend that rebates encourage them to set higher list prices to account for price concessions down the road.

Some stakeholders, including PBMs, argue that rebate arrangements decrease costs for consumers by lowering the actual cost paid for a drug (in effect that the list price is simply a sticker price). However, rebates and price concessions are usually applied to a drug's cost after a consumer buys a drug at a pharmacy. For example, Part D plan sponsors report discounts, rebates, and price concessions they and their contracted PBMs receive to Medicare as Direct or Indirect Remuneration (DIR), which Medicare uses to reduce premiums for Part D plans. While Part D plans may apply these rebates at the point of sale, they generally do not. Rather, plans and PBMs apply rebates toward the plan's premium.

The impact of rebate arrangements among entities handling Part B-covered drugs for beneficiaries is less clear. Payments to providers and cost-sharing obligations under Part B generally hinge on a drug's Average Sales Price (ASP).⁴ Because discounts and rebates lower the net sales manufacturers receive for their products, price concessions may lower a drug's ASP and the patient's out-of-pocket costs. On the other hand, because providers are paid ASP plus 6% for Part B drugs,⁵ manufacturers could be motivated to set higher list prices to encourage providers to administer their product. This may be particularly true for new drugs on the market, whose Part B payments are more likely to be based simply on a drug's list price (WAC) plus 6%.

The Role of Competition

Competition is a critical factor in the drug payment and supply chain that heavily influences a drug's price and the financial arrangements negotiated for a drug's purchase.

Single-source drugs are more likely to have patent and market exclusivity protections that allow a manufacturer to dominate or even monopolize certain therapeutic markets. Accordingly, manufacturers are able to set high list prices for

these products and exert greater leverage in negotiations with downstream purchasers, which increases per-unit revenue. By contrast, multiple-source drugs must compete with equivalent products in the marketplace. For generics, this competition exerts downward pressure on drugs' list prices and allows downstream purchasers to negotiate larger discounts. Downstream purchasers can also negotiate larger discounts for multiple-source brand name drugs, driving down the net price at which manufacturers sell. As a result of these dynamics, while manufacturers realize their largest profits from selling brand name drugs, distributors, pharmacies, and PBMs generally generate their largest profits from the sale and exchange of generics.

In light of this dynamic, some manufacturers engage in strategies to suppress competition in the marketplace and extend their monopolies in the market. In doing so, these manufacturers often leave consumers and payers with more expensive brand name medications, forcing patients to pay larger out-of-pocket costs while driving up Medicare spending. For example, some drugmakers take advantage of extended exclusivity and patent protections through tactics called evergreening or product hopping. Others have used limited distribution networks to stop generic and biosimilar manufacturers from gaining access to drugs for use in clinical trials. Brand name drugmakers also engage in pay-for-delay arrangements with generic manufacturers to slow the entry of generic and biosimilar compounds. Further, manufacturers have used citizen petitions to call for oversight of generic drugs nearing approval, or may bankroll Patient Assistance Programs (PAPs) to encourage consumers to buy expensive medications.

Changes in the Market

Two shifts in the pharmaceutical market have dramatically changed how drugs pass through this payment and supply chain. First, manufacturers increasingly make specialty drugs, which are typically complex and expensive products (such as biologics) used to treat conditions such as

rheumatoid arthritis, multiple sclerosis, and cancer. In response to the increasing numbers of these drugs in the pipeline, other entities in the payment and supply chain have begun offering services tailored for specialty products, and forming arrangements with specialty distributors, pharmacies, and physician practices. These high-cost medications have driven higher drug spending, and have the potential to leave patients with substantially higher out-of-pocket costs.

Beyond the growth of this specialty market, entities across the supply and payment chains are increasingly contracting and consolidating horizontally and vertically. For example, each of the three largest PBMs maintains some form of common ownership with large retail chains and/or specialty pharmacies. Similarly, the three largest wholesale distributors own and operate specialty pharmacies and physician practices. While industry players argue that consolidation may provide efficiencies that lower costs for consumers and Medicare, it is difficult to quantify these effects. Further, this extensive consolidation has obstructed badly needed transparency into the financial relationships among the payment and supply chain's participants.

Factors Driving the Cost of Drugs

This report shows that certain policies and financial arrangements warrant greater scrutiny for their roles in driving higher drug prices in the market at the expense of patients. Some of these include:

- Manufacturers' exclusive control of list price. Manufacturers raise the list price of a drug as needed to boost their revenue. Strategies to limit price increases and encourage greater transparency in price setting are critical to reducing the cost of medications.
- Financial arrangements tied to manufacturer list prices. Financial agreements between drugmakers and distributors, PBMs, and plan sponsors may hinge on the list price of the drug, or increases in the list price over time. Greater transparency into these arrangements is needed

to determine how to prevent such incentives from driving up drug costs.

- Features of the Part B payment framework. The Part B payment structure may encourage manufacturers to set high list prices to boost Medicare payments to providers, particularly for new drugs on the market. Additionally, a recent change by the Centers for Medicare & Medicaid Services (CMS) to Part B payments for biosimilars may reduce price competition and lead to higher costs for beneficiaries and the Medicare program, necessitating close monitoring.
- Features of the Part D drug benefit. The Part D program may reward manufacturers that set high list prices because these higher prices push beneficiaries faster through stages of Part D coverage when drugmakers are required to substantially discount their products. As a result, higher prices leave patients with enormous out-of-pocket costs and the government with increased financial liability.
- Tactics that suppress competition. Greater scrutiny is needed to examine and address the impact of anticompetitive practices that extend manufacturer monopolies and delay the entry of generic and biosimilar products.
- Gag rules at the pharmacy. Some PBMs prohibit pharmacies from informing consumers when a product is less expensive than the copay set by the PBM or Part D plan. In other words, some PBMs are imposing gag rules on pharmacies that restrict pharmacists from letting patients know when buying a drug *without* insurance would be cheaper for the consumer. Under these arrangements, PBMs may pocket or "clawback" the price difference between the copay and list price.
- Accurate reporting of DIR. Some PBMs may be categorizing price concessions as service fees instead of DIR to Part D sponsors. This prevents these concessions from being reported

to the Medicare program and accounted for in calculating Medicare Part D premiums.

- Rebates applied after the point of sale. Part D plan sponsors typically use rebates from manufacturers to offset aggregate benefit costs after the point of sale. While this theoretically lowers premiums for enrollees, applying rebates in this manner leaves beneficiaries with high out-of-pocket costs at the pharmacy counter.
- Consolidation. Vertical and horizontal integration among distributors, PBMs, pharmacies, and physician practices undermine transparency into financial arrangements that may support high drug costs. Greater scrutiny is needed to understand the effects of these mergers and arrangements on drug prices and consumers.

Looking to the Future

On May 11, 2018, the Trump Administration released a blueprint of its plan to address high and rising drug prices in the United States.⁶ This blueprint, called *American Patients First*, suggested that the Administration is interested in taking steps to address some of the concerns and challenges laid out in this report, including

manufacturers' use of limited distribution networks to suppress competition; gag rules at the pharmacy that leave consumers with higher out-of-pocket expenses; and the lack of transparency surrounding rising list prices.

The Administration's stated desire to tackle high and rising drug prices is heartening. However, on their own, the ideas outlined in *American Patients First* are simply not sufficient to reduce costs significantly for Americans. Few of the Administration's proposals seek to meaningfully limit drugmakers' ability to set or raise list prices with impunity. Further, the majority of the President's plan posed questions rather than solutions for the public in the form of Requests for Information.

For the federal government to lower out-of-pocket costs for consumers and reduce Medicare spending on pharmaceuticals, bolder action is needed to hold those in the supply and payment chains accountable for high prices that leave patients with extraordinary bills, push needed medications out of reach, and impose growing burdens on taxpayers. In light of the thinness of the President's blueprint, it does not appear that this Administration is willing to make the fundamental changes necessary to fix this otherwise broken system.

PART I: MEDICARE PARTS B AND D

In 2015, drugs accounted for roughly \$110 billion, or 17% of all Medicare spending that year.⁷ This section provides a brief overview of spending and coverage under Medicare Parts B and D, which cover drugs administered by health care providers in the outpatient setting and prescription drugs patients receive at pharmacies, respectively.

PART B

In addition to coverage of physician visits and other outpatient services, Medicare Part B provides coverage for certain drugs administered in physician offices or hospital outpatient departments through infusion or injection, as well as other limited categories of drugs (for example, certain oral cancer drugs or drugs used with an item of durable medical equipment).⁸ For Part B-covered drugs, beneficiaries generally pay 20% in coinsurance unless they have supplemental coverage.⁹ As reported by the 2018 Medicare Trustees' Report, approximately 53.4 million individuals were enrolled in Part B in 2017.¹⁰

Trends in Spending

For the majority of the last two decades, Part B drug expenditures grew at a rate that exceeded the rest of Medicare spending.¹¹ Part B spending for drugs has increased by 9% each year since 2009,¹² and reached \$25.8 billion in 2015 for program and beneficiary spending.¹³ A small group of drugs

account for a large portion of the program's spending. Just 64 drugs accounted for 81% of spending in 2015.¹⁴

CMS recently published data on Part B spending for 2016.¹⁵ The top 10 drugs by spending for that benefit year are described in Table 1.

Payment Structure

| Table 3. Part B Drug Payment Formulas | |
|---------------------------------------|--|
| <i>Single-Source</i> | ASP + 6% (ASP) |
| <i>Multi-Source</i> | ASP _{Weighted} + 6% (ASP _{Weighted}) |
| <i>ASP Unavailable</i> | WAC + 6% (WAC) |
| <i>Biologics</i> | ASP _{Biologic} + 6% (ASP _{Biologic}) |
| <i>Biosimilars (2017)</i> | ASP _{Weighted} + 6% (ASP _{Ref. Biologic}) |
| <i>Biosimilars (2018)</i> | ASP _{Biosimilar} + 6% (ASP _{Ref. Biologic}) |

Part B payments to health care providers are calculated according to each drug's Average Sales Price (ASP) plus a 6% add-on payment.¹⁶ ASP is defined as the average price realized by a manufacturer for sales of a drug over a calendar quarter net rebates and price concessions. To calculate ASP, manufacturers take all sales to all purchasers and divide that figure by the total number of units of the drug sold. The price must include all discounts, free goods contingent on any purchase requirement, chargebacks, rebates, and

| Table 1. Top Part B Drugs by Spending in 2016 | | |
|---|-----------------|--------------------------------|
| Brand Name | Total Spending | Avg. Spending Per Beneficiary* |
| <i>Eylea</i> | \$2,208,730,191 | \$10,497 |
| <i>Rituxan</i> | \$1,665,667,928 | \$23,815 |
| <i>Neulasta</i> | \$1,375,670,105 | \$14,336 |
| <i>Remicade</i> | \$1,338,726,191 | \$22,925 |
| <i>Avastin</i> | \$1,111,678,356 | \$5,360 |
| <i>Prolia</i> | \$1,086,664,413 | \$2,592 |
| <i>Lucentis</i> | \$1,044,324,411 | \$9,814 |
| <i>Herceptin</i> | \$703,556,745 | \$34,000 |
| <i>Prevnar 13</i> | \$668,534,189 | \$170 |
| <i>Orencia</i> | \$586,532,893 | \$25,636 |

*Total Part B costs divided by the number of unique beneficiaries utilizing the drug.

| Table 2. Top Part D Drugs by Spending in 2016 | | |
|---|-----------------|--------------------------------|
| Brand Name | Total Spending | Avg. Spending Per Beneficiary* |
| <i>Harvoni</i> | \$4,399,701,570 | \$83,321 |
| <i>Revlimid</i> | \$2,661,602,600 | \$75,238 |
| <i>Lantus Solostar</i> | \$2,526,426,478 | \$2,349 |
| <i>Januvia</i> | \$2,440,135,879 | \$2,822 |
| <i>Crestor</i> | \$2,323,133,631 | \$1,489 |
| <i>Advair Diskus</i> | \$2,320,125,120 | \$1,940 |
| <i>Lyrica</i> | \$2,099,262,044 | \$2,462 |
| <i>Xarelto</i> | \$1,955,000,085 | \$2,420 |
| <i>Eliquis</i> | \$1,926,316,212 | \$2,329 |
| <i>Spiriva</i> | \$1,819,084,754 | \$2,013 |

*Total Part D costs divided by the number of unique beneficiaries utilizing the drug.

other price concessions.¹⁷ Manufacturers report ASPs to CMS within 30 days of the close of each calendar quarter. Where sales data are unavailable to calculate ASP, for example in the case of a new drug on the market, Medicare generally calculates payments according to a drug's Wholesale Acquisition Cost (WAC) plus 6%.¹⁸

Medicare assigns a payment code for each single-source drug using the ASP calculated for that product. By contrast, for multiple-source drugs, all generic and brand name versions are given the same payment code using a weighted-average ASP.

Payment differs slightly for biologics and biosimilars. Each biologic has a unique payment code under Part B, regardless of the presence of a biosimilar. Until 2018, biosimilars for a reference biologic were assigned a single payment code using a weighted average ASP (plus 6% of the reference biologic's ASP).

CMS reversed this policy in the Physician Fee Schedule for Calendar Year (CY) 2018 to require the establishment of unique payment codes for each biosimilar product.¹⁹ Accordingly, payments for biosimilars are now based on the ASP of each biosimilar plus 6% of the reference biologic's ASP (see Table 3).

PART D

Part D is a voluntary prescription drug benefit of the Medicare program that provides coverage for outpatient drugs patients purchase at the pharmacy. These plans are offered by Part D plan sponsors, which are private insurers that contract with CMS to offer stand-alone prescription drug plans or Medicare Advantage (MA) prescription drug plans. These sponsors are discussed in greater detail in Part V. As reported by the 2018 Medicare Trustees' Report, approximately 44.5 million individuals were enrolled in Part D in 2017.²⁰

Trends in Spending

Part D spending reached \$100 billion in 2017—double the \$49.5 billion spent by the program a

decade earlier in 2007.²¹ Over the last five years, Part D costs have grown by an average of 8.5% annually compared to 3.7% for GDP during the same period.²² The 10 drugs that accounted for the largest share of Part D spending in 2016 are summarized in Table 2 above.²³

Payment Structure

In general, Part D plans provide beneficiaries with four phases of coverage (an illustration of the CY 2019 Plan Benefit can be found in Table 4):

1. First, beneficiaries pay all drug costs until they reach a deductible.
2. Second, beneficiaries enter the initial coverage phase until they reach a certain level of total drug spending (which includes the spending up to the deductible).
3. Third, beneficiaries enter the coverage gap (also called the “donut hole”) during which time they are responsible for a larger share of drug costs up to an out-of-pocket limit. During this phase, manufacturers are required to discount their prices to ease out-of-pocket spending for consumers. These discounts are only for brand name drugs and biosimilars.
4. Finally, enrollees reach catastrophic coverage. In this phase, patients are responsible for a 5% coinsurance. However, these out-of-pocket costs are uncapped for the remainder of that coverage year.

Table 4: Phases of Coverage in the Part D Benefit for CY 2019

| Phases of Coverage | Cost-Sharing Obligations | | Total Spending | |
|-------------------------|--|---|--|-----------------|
| | | | Out-of-Pocket | Total Spending |
| <i>Deductible</i> | Patient: 100% Up to deductible | | \$0-\$415 | \$0-\$415 |
| <i>Initial Coverage</i> | Patient: 25% Up to \$3,820 | | \$415-\$1,370 Deductible plus 25% of \$3,820 | \$415-\$3,820 |
| <i>Coverage Gap</i> | <i>Brand Name</i> Patient: 25% Manufacturer: 70% Plan: 5% | <i>Generic</i> Patient: 37% Manufacturer: 63% | \$1,370-\$5,100 Patient pays up to Out-of-Pocket Cap | \$3,820-\$8,140 |
| <i>Catastrophic</i> | <i>Brand Name</i> Patient: Greater of 5% or \$8.50 copay | <i>Generic</i> Patient: Greater of 5% or \$3.40 copay | \$5,100 and Up | \$8,140 and Up |

Each year, CMS creates a standard benefit package and updates it based on changes in beneficiaries' average drug expenses.²⁴ Table 4 summarizes the standardized benefit finalized for CY 2019.²⁵

Notably, cost-sharing requirements for Part D beneficiaries changed substantially following the Bipartisan Budget Act (BBA) of 2018, which enacted reforms to the donut hole to require larger manufacturer discounts and lower beneficiary out-of-pocket spending for 2019. Specifically, the BBA decreased beneficiary cost-sharing from 30% to 25% and increased manufacturers' required discount from 50% to 70% for brand name drugs. The BBA also ended exemptions from the manufacturer discount program for certain biosimilars.²⁶

Coverage Requirements

Part D plan sponsors must offer enrollees at least one standard benefit package (or an actuarially equivalent alternative). Plans may be more generous than CMS's requirements. Sponsors offer prescription drug plans with varying premiums, cost-sharing requirements, pharmacy networks, and formularies, which list the drugs covered under the plan.²⁷

Part D plans are not required to cover all prescription drugs. However, plans generally must cover at least two chemically distinct drugs in each drug class for all disease states, with exceptions when only one drug is available to treat a particular disease, or when one drug is clinically superior.²⁸ Part D plans also must cover all or substantially all available drugs in six therapeutic classes, including: anti-retrovirals; immunosuppressants to prevent organ rejection; anti-depressants; anti-psychotics; anti-convulsant agents; and anti-neoplastics.²⁹

PART II: DRUG MANUFACTURERS

Drugmakers play the most important role in determining a drug's cost to patients and taxpayers because manufacturers set a drug's list price. This list price is the basis for rebates, service agreements, and price concessions agreed to with downstream purchasers in the payment and supply chain.

Manufacturers whose products lack generic and biosimilar competitors are best positioned to keep list prices high and generate large profits. Accordingly, manufacturers have taken advantage of a wide array of tactics to suppress competition. Further, manufacturers have increasingly focused on the specialty drug market, where products tend to have fewer therapeutic competitors and are more expensive. These trends have shifted drug supply and payment channels, with key implications for spending under Medicare Parts B and D.

THE ROLE OF MANUFACTURERS

Manufacturers develop, produce, distribute, and market drugs, including single-source drugs, multiple-source drugs, biological products, and biosimilars.³⁰ A single-source drug is the only product available in the market for the particular combination of active ingredient, dosage form, route of administration, and strength. Multiple-source drugs are products with both brand name and generic forms, any of which may be made by more than one manufacturer.³¹ Biological products are large-molecule, complex products that are generally derived from living material, are injectable or infusible, and require careful handling.³² Biosimilars are biological products that have “no clinically meaningful difference” from a reference biological product previously approved by the Food and Drug Administration (FDA).³³

SETTING A DRUG'S LIST PRICE

The price consumers pay at the pharmacy counter is heavily influenced by the list price manufacturers set for the market for the drugs they produce. This manufacturer set price—the Wholesale Acquisition Cost (WAC)—often serves as the basis for beneficiaries' out-of-pocket costs as well as the financial arrangements manufacturers share with distributors, pharmacies, health care providers, PBMs, and plan sponsors along the chain.³⁴ Accordingly, the way in which manufacturers set these prices has critical implications for Medicare drug spending as well as the financial burdens consumers shoulder when seeking medications.

Manufacturers have the exclusive ability to set a drug's WAC, which Medicare defines as “the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price.”³⁵ Drugmakers set prices when a new drug is released to market and can alter them at any time. These decisions often hinge on the competitive position of the drug in the market—that is, whether a drug is single- or multiple-source product as well as revenue considerations.

Single-Source Brand Name Drugs and Biologics

Single-source brand name drugs make up the largest and fastest growing source of drug spending nationally. According to the Association for Accessible Medicines, which represents generic drug manufacturers, brand name drugs are used in only 11% of prescriptions in the United States but account for 74% of drug costs nationwide.³⁶

Manufacturers of single-source drugs and biologics tend to set higher WACs than makers of generics and biosimilars, a difference that helps brand-name manufacturers generate the potential for substantially higher profit margins for their products. These pricing decisions are driven by the factors described below.

Gilead’s Pricing Process. In 2015, Senator Wyden released a bipartisan investigation with Senator Chuck Grassley examining how Gilead Sciences priced its hepatitis C drugs Sovaldi and Harvoni. The probe found that the company convened a committee of senior officials from across the company who worked with consultants to determine a price for the drugs. Internal documents showed the company’s focus was to maximize revenue while identifying a price “just below the level where payers would place significant restrictions on patient access.”³⁷

While the current report examines various factors that may influence drug pricing across the pharmaceutical industry, it is important to note that none of the 20,000 pages of documents Gilead provided during the 2015 investigation showed any evidence that the company considered franchise costs such as research and development or marketing. Gilead’s primary focus was on revenue, payers allowing patient access, and competitive market position.³⁸

Research and Development. Before bringing a pharmaceutical product to market, manufacturers of novel drugs incur substantial costs when conducting research and development. The drug development process is risky and expensive: drugmakers must make sufficient investments to compensate for products that fail to make it to market and to pay for the significant capital costs of conducting preclinical and clinical research.³⁹ Some estimates place the cost of new drug development between \$648 million and \$2.6 billion.⁴⁰

THE COST OF RESEARCH & DEVELOPMENT

Studies indicate that research and development costs have climbed.

GAO recently reported that worldwide spending on research and development increased in real dollars from \$82 billion in 2008 to \$89 billion in 2014. Some manufacturers have also relied on findings from the Tufts Center for the Study of Drug Development, which estimated that total capitalized costs per new FDA-approved drug were approximately \$2.6 billion in 2013 dollars. Notably, because the vast majority of approvals each year are not for novel drugs but modifications to existing drugs, most drugmakers may incur lower research and development costs than indicated by Tufts.

Critics of the Tufts study have raised a number of concerns with its findings. A September 2017 study concluded that the median research and development spending for a cancer drug is only \$648 million, approximately one-fourth of the estimate in the Tufts report. Others have raised concerns that the study’s estimates for the cost-of-capital were overstated, in part because Tufts did not account for tax credits for certain research and development activities. Further analysis of R &D is warranted.

Sources: GAO, Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals (2017); Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 26 (2016); Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA INTERNAL MEDICINE E1-E6 (Sept. 11, 2017); Jerry Avorn, *The \$2.6 Billion Pill – Methodologic and Policy Considerations*, 372 NEW ENG. J. MED. 1877 (May 2015).

Because these costs can be so significant, manufacturers often argue that high list prices for novel products are necessary to reward and sustain drug innovation.⁴¹ However, the prices set by manufacturers sometimes far exceed the levels necessary to offset these investments, as indicated by the large profits reported by drugmakers.⁴² Some manufacturers may not even take research and development into account when setting a drug’s launch price for the market. For example, Senator Wyden and Senator Chuck Grassley found no documents showing that Gilead Science research or other costs into account when it set the prices for Sovaldi and Harvoni, two of the company’s hepatitis C treatments.⁴³

Gilead’s experience with Sovaldi illustrates another trend among manufacturers: the role of mergers and acquisitions in the research and development pipeline. Gilead acquired the molecule underpinning Sovaldi and its subsequent hepatitis C drugs through the \$11 billion acquisition of Pharmasset, Inc.⁴⁴

In 2017, the Government Accountability Office (GAO) cited experts who observed that “traditionally large companies are increasingly relying on mergers and acquisitions to obtain access to new research and are conducting less of their own research in-house.”⁴⁵ A 2005 paper in the *Journal of Financial Economics* was more pointed in its assessment that mergers and acquisitions were a “method for outsourcing research and development” that began in the late 1990s and that “[p]harmaceutical companies, in particular, begin to supplement internal R&D efforts through acquisition,” to address gaps in their development pipelines.⁴⁶

Merger and acquisition activity can be an important driver of revenue for manufacturers. For example, a recent Bain & Co., analysis found that eight large pharmaceutical manufacturers it tracked had generated 70% of their revenue inorganically, of which 80% was attributable to mergers and acquisition.⁴⁷ However, critics argue that this practice may hurt consumers, particularly

in cases like Sovaldi when large companies engage in bidding wars for smaller firms with promising compounds.⁴⁸ Publically held companies then face pressure to generate competitive returns on investment and reward investors for risk. As a result, “subsequent profits are then directed back to shareholders rather than invested in early stage research.”⁴⁹

Table 5. Drug Manufacturers in the 2017 Fortune 500 List

| Company | Rank | Revenue (Billions) | Profit Margin |
|------------------------------|-------------|---------------------------|----------------------|
| <i>Johnson & Johnson</i> | 35 | \$71.9 | 23.0% |
| <i>Pfizer</i> | 54 | \$52.8 | 13.7% |
| <i>Merck & Co.</i> | 69 | \$39.8 | 9.8% |
| <i>Gilead Sciences</i> | 92 | \$30.4 | 44.4% |
| <i>AbbVie</i> | 111 | \$25.6 | 23.2% |
| <i>Amgen</i> | 123 | \$23.0 | 33.6% |
| <i>Eli Lilly and Co.</i> | 132 | \$21.2 | 12.9% |
| <i>Bristol-Myers Squibb</i> | 147 | \$19.4 | 22.9% |
| <i>Biogen</i> | 248 | \$11.4 | 32.3% |
| <i>Celgene</i> | 254 | \$11.2 | 17.8% |

This practice suggests that high launch prices may not be principally motivated to offset the cost of innovation.

Finally, the federal government offsets some innovation-related risk by contributing billions to basic research.⁵⁰ The government also provides tax credits and grants to stimulate research and development of novel drugs and biological products.⁵¹ As a result, one estimate suggests that the federal government financially supports approximately 75% of new drugs.⁵²

Marketing. Companies also set list prices that incorporate the costs of marketing.⁵³ Marketing campaigns can generate substantial expenses: for example, manufacturers spent approximately \$71 billion on promotional activities in 2014, which represented 7.6% of total drug sales that year.⁵⁴ Expenses for promotional activities can far exceed research and development costs: in 2013, for example, Johnson & Johnson reportedly spent \$17.5 billion in sales and marketing compared to \$8.2 billion for research and development.⁵⁵ Similarly, that year, Novartis spent \$14.6 billion

on sales and marketing compared to \$9.9 billion on research and development, while Pfizer spent \$11.4 billion and \$6.6 billion for those activities, respectively.

Competitiveness. A brand name drug's competitive position in the market plays an enormous role in the list price set by its manufacturer. Patents and market exclusivity protections for new drugs grant manufacturers an exclusive segment of a therapeutic market for a limited period of time, insulating manufacturers from pressures that might otherwise keep list prices low.⁵⁶ Accordingly, without competitors, manufacturers have maximum flexibility when setting a drug's initial list price and changing the price over time for an existing product. Notably, drugmakers may base a drug's list price on similar products in the market that are not direct competitors, even if these drugs share little comparative clinical value.⁵⁷

Profits. Brand name manufacturers set list prices to ensure that, after rebates, price concessions, development, and marketing costs are paid, profits will be distributed to investors and owners.

These profits are substantial and rising. In 2017, six of the top 10 drug manufacturers in the Fortune 500 list reported profit margins greater than 20% (see Table 5).⁵⁸ In 2017, GAO reported that two-thirds of drug manufacturers increased their annual profit margins between 2006 and 2015.⁵⁹ These profit margins generally fluctuated between 15% and 20% for the largest 25 manufacturers.

Notably, manufacturers' profits are generally far higher for the sale of brand name drugs compared to generics. One estimate found that brand name drugs generate profits three times larger than those for generic drugs.⁶⁰

Pricing Trends. As reported by MedPAC, the Medicare Payment Advisory Commission, the prices of single-source brand name drugs grew by 142% between 2006 and 2014. By comparison, prices for *all* Part D drugs grew by 8% over the same period when accounting for generic

substitution.⁶¹ Most recently, in a report released in June 2018, the Office of the Inspector General at Health and Human Services (HHS-OIG) found that total reimbursement for brand name drugs in part D increased by 77% from 2011 to 2015, even though the total number of brand name prescriptions decreased 17% during that period.⁶² HHS-OIG also reported that Part D unit costs for brand name drugs rose nearly 6 times faster than the rate of inflation.

Similarly, MedPAC has reported that price increases among Part B-covered drugs were a significant driver in overall spending growth for the program. As MedPAC described:

Price growth [among Part B drugs] accounts for more than half of spending growth, even after accounting for changes in the payment formulas between 2009 and 2014. . . . Total standardized payments grew at an average annual rate of 10.0 percent between 2009 and 2014, with the average standardized payment per drug growing at an average annual rate of 6.0 percent.⁶³

These dramatic price increases can lead to severe financial consequences for patients who depend on brand name drugs for care. For example, in its June 2018 report, HHS-OIG found that the percentage of Part D beneficiaries responsible for at least \$2,000 in annual out-of-pocket costs doubled between 2011 and 2015.⁶⁴ Further, HHS-OIG reported that beneficiaries' average out-of-pocket costs increased 40% over the same period.

Higher prices do not necessarily indicate clinical efficacy. A recent study evaluating the launch prices of 58 anti-cancer drugs from 1995 through 2013 found that benefit- and inflation-adjusted launch prices increased by an average of \$8,500 per year during that period, even though the newer drugs were "not associated with greater survival benefits compared to older drugs."⁶⁵ As explained by the authors, "[I]n 1995 patients and their insurers paid \$54,100 for a year of life. A decade

later, 2005, they paid \$139,100 for the same benefit. By 2013, they were paying \$207,000.”

Transparency. The Wyden-Grassley investigation showed that maximizing revenue was a major consideration when Gilead set prices for Sovaldi and Harvoni.⁶⁶ However, without more data from manufacturers, it is impossible to evaluate the relative weight these factors play in guiding a drug’s list price across the industry. Greater transparency is sorely needed to understand how to target incentives that currently encourage manufacturers to continue raising prices. In the meantime, extraordinary list prices for novel brand name drugs will continue to have significant and lasting consequences for patients seeking care.

Multiple-Source Generics and Biosimilars

While brand name drugs typically generate larger profits, generic drugs account for a far larger portion of drugs sold in the United States. According to the Association for Accessible Medicines, which represents generic drug manufacturers, 89% of prescriptions dispensed in 2016 were generic drugs.⁶⁷ Despite this immense volume, generics accounted for just 26% of U.S. drug spending that year.⁶⁸ In 2015, generic spending rose 7.4% to \$114.1 billion.⁶⁹

Average list prices for generics are 75% to 90% lower than the prices of brand name drugs.⁷⁰ However, pricing for generic drugs has experienced recent volatility, with some generics price increasing up to 1,000%. The factors driving these trends and pricing decisions are described below.

Start-Up Costs. In general, manufacturers of small-molecule products do not conduct research and development for novel drugs and, therefore, do not incur the same level of research and development costs as brand name manufacturers. Estimates suggest that generic products require three-to-five years and between \$1 million and \$5 million to develop.⁷¹ Because biosimilars are

more clinically complex, these large-molecule products require more substantial investments.⁷² The Federal Trade Commission (FTC) has reported, for example, that biosimilars require seven to eight years to develop at a cost of \$100 million to \$250 million.⁷³

Generic Competition. Competition is a critical factor in the pricing of generic multiple-source drugs. By definition, multiple-source drugs must compete with therapeutic equivalents in the marketplace, which drives down the list prices of these medications. To this end, the price of a generic product drops incrementally as generic competitors enter the market.⁷⁴ One FDA study using 2005 data reported that the first generic version of a drug is typically priced only slightly lower than its brand name alternative (at 94% of the brand name retail price).⁷⁵ By contrast, the entry of second and third generic competitors led to more substantial price decreases (to 52% and 44%, respectively, of the brand retail price).⁷⁶ One manufacturer estimated the price of a generic product may fall 20% for each new generic entrant into a market, according to a 2016 GAO report.⁷⁷

While easing the entry of generic competitors into the market may help drive down list and net prices for medications, only about 10% of approved brand name drugs, have no generic competitors.⁷⁸ Further, more than 500 drugs have only one generic competitor, which may sustain or generate higher prices.⁷⁹

Biosimilar Competition. Biosimilars similarly provide consumers with lower-cost alternatives to highly expensive brand name biologics. The Congressional Budget Office (CBO) has estimated that follow-on biosimilars cost 20 to 40% less than their reference biologics.⁸⁰ However, as of June 2018, FDA has approved only 10 biosimilars, making it difficult to examine the extent to which these drugs produce cost savings for consumers and taxpayers alike.⁸¹

Recent developments at CMS may undercut the competitive effects of biosimilars’ entry in the market. In its Physician Fee Schedule for CY

2018, CMS reversed its payment policy for biosimilars by ending its previous practice of grouping biosimilars with the same reference biologic under one Part B payment code.⁸² Beginning this year, each biosimilar is now assigned a unique payment code and paid according to the Average Sales Price (ASP) for that biosimilar (plus a 6% add-on based on the reference biologic's ASP). MedPAC noted that CMS's change could undercut competition, generate higher launch prices for new biosimilars, and lead to higher spending for beneficiaries and the Medicare program.⁸³ As MedPAC wrote:

Assigning each biosimilar to its own billing code could result in higher launch prices than under the current policy because each product would initially be priced using its [WAC]. . . . Putting a product in its own billing code and basing its initial payment rate on WAC gives manufacturers an incentive to set a high WAC at launch and then discount the price to create a large spread between the Medicare payment amount and the provider's acquisition cost.

Monitoring pricing of these products in the coming months will be essential to understanding the full impact of this policy change for consumers and Medicare spending.

Pricing Trends. While generic drugs have generally had a moderating influence on pharmaceutical prices and consumer costs, decisions in recent years by some manufacturers to dramatically increase prices have drawn public, legal and legislative scrutiny.⁸⁴

Overall, generic drug prices have fallen by 59% since 2010, according to a 2016 GAO report.⁸⁵ The American Association of Retired Persons (AARP) found that retail prices for 399 generics widely used by older Americans decreased by an average of 19.4% between 2014 and 2015.⁸⁶

However, despite these larger trends, a number of generics experienced significant price increases that adversely impacted drug-related spending. GAO noted in its report that 315 generic drugs had "extraordinary" price increases of 100% or more from the first quarter of 2010 to the first quarter of 2015.⁸⁷ The number of generic drugs with extraordinary price increases doubled between the first quarter of 2014 and the first quarter of 2015. While most of these price increases were between 100% and 200%, a handful were higher than 1,000%. These price increases were generally sustained for at least one year with little downward movement in following years. Most drugs experiencing these increases, GAO noted, were not among the most highly utilized drugs in the Part D program.

Generic manufacturers offered a number of explanations for these price increases. According to GAO, manufacturers reported that competition was the "primary driver of generic drug prices, as less competition could drive prices higher."⁸⁸ This competitiveness was tied to a number of factors, including "including raw material shortages, production difficulties, consolidation among manufacturers, and a backlog of new generic drug applications awaiting federal review."⁸⁹

These rapid price increases drove up health care costs for consumers and payers nationwide. Higher generic prices led consumers to shoulder larger and sometimes prohibitively high copays.⁹⁰ Further, as the IQVIA Institute summarized, "Generic growth had been a positive driver of [spending] growth from 2013–2015 as the combination of fewer expiries and price increases lifted spending."⁹¹ This impact on spending slowed in 2016, IQVIA wrote, "and declined by \$5.5 billion in 2017 as greater competition in a number of markets drove down prices."

MEDICARE'S INFLUENCE ON LIST PRICES

Features in Parts B and D of the Medicare program may encourage manufacturers to set high list prices.

Part B

As described in Part I, Medicare Part B generally pays providers and suppliers for covered drugs using the ASP plus 6% formula. There has been significant debate over what this add-on payment to providers is meant to cover, with explanations ranging from payment for drug storage to a stipend that allows smaller practices to access drugs.⁹² Critics of this payment structure suggest that it incentivizes health care providers to administer higher-priced drugs, which translate into larger ASPs and add-on payments. In other words, the higher the cost of a drug or biologic, the greater the margin for physicians' offices and hospital outpatient departments.⁹³

Manufacturers may take advantage of these provider incentives by setting high list prices for Part B-covered drugs to generate higher payments for providers and thus, encourage providers to administer their products. While ASP takes into account price concessions, a drug's list price is the starting point for negotiations of these concessions. As a result, a higher list price generally raises the prices paid by purchasers of a product and, thus, the ASP calculated and reported by the manufacturer. As MedPAC explained, "Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions."⁹⁴

These incentives may be even more powerful for new single-source drugs and biologics for which ASP data are unavailable, since payments for these drugs are based on a drug's WAC—the list price without rebates and concessions—plus 6%.

Part B's process for assigning payment codes may also undercut price competition among certain covered products.

First, Medicare assigns a separate billing code to each single-source medication, even when drugs are approved to treat similar conditions. This may insulate manufacturers from competitive pressures to lower their list prices, particularly for drugs with high Medicare market share.⁹⁵ To this point, GAO recently found that Medicare's market share was

at least 50% for 22 out of 84 high-expenditure Part B drugs.⁹⁶

Second, Medicare assigns separate Part B payment codes for each biologic even where biosimilar products exist, reducing price competition between a reference biologic and its biosimilar(s).⁹⁷ As noted above, a recent change in the Physician Fee Schedule for CY 2018 may also undercut competition among biosimilars by requiring each biosimilar to have its own payment code and ASP.⁹⁸

Critically, higher WACs and ASPs ultimately have consequences for beneficiaries because these prices impose higher out-of-pocket costs. Part B beneficiaries generally must pay 20% coinsurance unless they have supplemental coverage.⁹⁹ When these out-of-pocket costs get too high, beneficiaries may be forced to take drugs less frequently than directed, stop taking medications altogether, or take on medical debt.

Part D

Requirements under Part D may also encourage manufacturers to set high list prices that burden beneficiaries with higher out-of-pocket costs. In general, an enrollee's progression through the stages of the Part D benefit is determined by "total drug spending and patient out-of-pocket spending, all of which are based on the list prices of drugs."¹⁰⁰ As a result, some manufacturers may set high list prices to push beneficiaries faster through the Part D benefit's coverage phases, particularly the coverage gap when manufacturers are required to provide substantial discounts.¹⁰¹

CMS states that total gross drug costs—which include Medicare, plan, and beneficiaries payments—"are calculated based on the negotiated prices reported at the point of sale,"¹⁰² where negotiated prices and list price are often "reasonable approximations of each other."¹⁰³ Accordingly, as CMS notes, higher negotiated prices "move Part D beneficiaries more quickly through the Part D benefit. This, in turn, shifts more of the total drug spend into the catastrophic

phase, where Medicare liability is highest (80 percent, paid as reinsurance) and plan liability, after the closing of the coverage gap, is lowest (15 percent).”¹⁰⁴ As a result, this structure also creates an incentive for Part D plans to prefer higher cost drugs that move an enrollee through the benefit package to the catastrophic phase, when the government—not the plan—pays the great majority of prescription drug costs.

Importantly, price concessions and rebates negotiated between Part D sponsors (or their contracted PBMs) and manufacturers or pharmacies are typically applied after the point of sale.¹⁰⁵ This means that higher list prices directly lead to higher cost-sharing for beneficiaries, even if Part D plan sponsors or PBMs negotiate discounts with manufacturers. These out-of-pocket costs can be particularly extreme during the uncapped catastrophic phase of Part D coverage, when beneficiaries pay 5% in coinsurance.

FACTORS IN GENERIC AND BIOSIMILAR COMPETITION

Manufacturers of single-source drugs and biologics engage in activities and arrangements that hinder the entry of competitors in the market. These tactics prevent access to lower-cost generics and biosimilars that otherwise might reduce drug prices and spending. It is important to note that many of the following sections touch on policies and activities that fall outside of the Senate Finance Committee’s jurisdiction; however, this report warrants their inclusion and review given their impact on pricing and total spending by programs and enrolled beneficiaries within the Committee’s jurisdiction.

Exclusivity

Patents. Patents are a signature way in which the Federal Government encourages and rewards innovation. The U.S. Patent and Trademark Office grants patents for a period of 20 years from the date on which an application is filed. Once granted, a person holding a patent can prevent other parties from “making, using, offering for

sale, selling or importing the invention.”¹⁰⁶ Accordingly, patents are critical tools that allow drugmakers to exclusively produce and sell a drug for a segment of the market. Manufacturers also note that patents allow manufacturers to recapture their investment in a product and fund further research and development.¹⁰⁷

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) created patent extensions of up to five years to compensate for prolonged FDA reviews. These extensions may be granted for certain patent-protected drug products that are still in the process of testing and approval and have not yet been marketed.¹⁰⁸

Pay-for-Delay. Manufacturers may delay the entry of generics in the market by using arrangements called “pay-for-delay” or “reverse payment” deals. These arrangements often follow patent infringement claims filed by brand name manufacturers against generic manufacturers who try to sell a product in the market. When such claims are made, the FDA automatically postpones the approval of the generic product for 30 months unless “the patent expires or is judged to be invalid or not infringed.”¹⁰⁹ Some parties then resolve these patent disputes through pay-for-delay settlements where a generic manufacturer agrees to delay the entry of its product for a period of time in return for compensation from the brand name manufacturer.

These arrangements have faced legal scrutiny for perpetuating possible anticompetitive behavior, since these tactics “stifle competition from lower-cost generic medicines” and cost consumers approximately \$3.5 billion every year.¹¹⁰ In 2013, the Supreme Court held that certain reverse payment settlements may violate antitrust laws, particularly when a brand name manufacturer’s patent rights are tenuous.¹¹¹ Following that decision, the number of these settlements decreased from 40 in 2012 to 21 in 2014, suggesting manufacturers are acting more

cautiously before entering into such agreements.¹¹²

Data and Market Exclusivity. Following approval from the FDA, a manufacturer may receive data or market exclusivity rights from the agency grant it a temporary monopoly in the market. As described by MedPAC, data exclusivity prevents generic or biosimilar manufacturers from using the brand name manufacturer's clinical test data as part of a new drug application to the FDA. Market exclusivity prevents the FDA from approving new drug applications for equivalent drugs during the period of protection.¹¹³ For example, the FDA may grant 3, 5, and 12 years of data exclusivity to new drugs with new indications, chemical entities, or biologics, respectively.¹¹⁴

The FDA may also grant 180 days of market exclusivity to the first manufacturer to file an abbreviated new drug application for a generic product, a result of changes in the Hatch-Waxman Act intended to encourage the development of generic drugs.¹¹⁵ Manufacturers of orphan drugs may receive 7 years of market exclusivity, while manufacturers who conduct pediatric studies for their drugs may receive 6 months of exclusivity.¹¹⁶

Evergreening and Product Hopping. Brand name manufacturers may extend their patent or market exclusivity protections by engaging in “evergreening” or “product hopping,” whereby drugmakers make minor modifications to existing drugs to extend their monopoly in a therapeutic market with limited therapeutic value.¹¹⁷ For example, manufacturers may introduce variations—also called line extensions, reformulations, or follow-on products—that involve a new dosage, a new formulation (defined by a drug's route of administration and administration form), a fixed combination of the original product and another active ingredient, or a drug's enantiomer (the mirror image of the product's chemical compound).¹¹⁸

Manufacturers can use these variations to obtain secondary patents or additional years of

exclusivity from the FDA. Manufacturers also can push patients to “hop” or “switch” to the reformulated product by stopping production of the original drug or encouraging health care providers to prescribe the reformulated drug.¹¹⁹ As a result, beyond extending their legal exclusivity rights, drugmakers use evergreening as a tool to preserve access to consumers that might have been lost to generic competitors.¹²⁰

The majority of patents recently granted to drugmakers have been tied to old products, suggesting this practice is prevalent. A recent study of all drugs on the market between 2005 and 2015 found that 74% of new patents were linked to existing rather than new drugs. Furthermore, 80% of the top 100 best-selling drugs acquired a new patent or obtained another type of exclusivity at least once in order to extend protection.¹²¹

The FTC has filed at least one amicus curiae brief arguing that product hopping can qualify as exclusionary conduct in violation of antitrust laws. “[T]he very fact of product-hopping can itself be evidence of monopoly power,” the FTC wrote, adding that product hopping is designed “to preserve high profits that generic versions of the same drug would undercut.”¹²²

Limited Distribution Networks and REMS

Manufacturers may implement limited distribution or dispensing networks to control who distributes, dispenses, and administers their product.¹²³ These limited distribution networks first arose in connection with Risk Evaluation and Management Strategies (REMS), which the FDA can require when it approves a drug or biologic with a known or potential serious risk.¹²⁴ REMS may lead to limited distribution networks by requiring, for example, that distributors, pharmacies, or providers be specially certified to handle a given product.¹²⁵ However, manufacturers may adopt these limited distribution arrangements with or without a REMS requirement.¹²⁶

Manufacturers of generic drugs and others—including FDA Commissioner Scott Gottlieb—

have raised concerns that manufacturers are using limited distribution networks to undermine generic competition in the marketplace.¹²⁷ Limited distribution networks can hinder the ability of outside manufacturers to obtain a brand name product for testing, a necessary component of the drug approval process for generic drugs.¹²⁸ Similarly, the Director of the FDA's Center for Drug Evaluation and Research explained that some manufacturers insert clauses into agreements with downstream entities to prohibit them from selling brand name drugs to generic manufacturers.¹²⁹ In response, brand name manufacturers argue that safety concerns for limited distribution drugs warrant these sale restrictions because manufacturers might be liable for injuries caused by the generic product.¹³⁰

Brand name manufacturers may also prevent generic entry by prolonging their negotiations with generic manufacturers for shared system REMS.¹³¹ In general, a generic drug manufacturer must enter into a single shared system REMS with the brand manufacturer before entering the market.¹³² By slowing down this already challenging process, makers of brand name drugs may be "delay[ing] the entry of safe and effective generic drugs onto the market."¹³³ In 2017, these challenges led the FDA to publish draft guidance to improve the efficiency in the shared system REMS submission and review process.¹³⁴

Citizen Petitions

Section 505(q) of the Federal Food, Drug, and Cosmetic Act allows citizens to file petitions requesting that the FDA take certain actions on generic and biosimilar applications for approval.¹³⁵ For example, petitioners may ask the FDA to reject a drug product application, add warnings to a label, or apply over-the-counter status to prescription drugs.¹³⁶

Reports suggest that brand name manufacturers have used these procedures to delay or prevent the entry of generics. One study of citizen petitions filed between 2011 and 2015 found that brand name manufacturers filed 92% of all petitions

against pending applications for generic drugs.¹³⁷ Another study found that approximately 40% of petitions filed against generic drugs between 2000 and 2012 were filed within a year of a generic's approval, suggesting these petitions were principally aimed at delaying generics' entry into the market.¹³⁸

Drug manufacturers argue that these petitions are an important way to voice scientific or clinical concerns about the safety of generic products. For instance, Mylan contended that a generic version of its EpiPen Auto-Injector did not "meet the standards" to be approved as a generic version.¹³⁹ While this process may be important for manufacturers that want to raise valid and important concerns, delaying generic competition through meritless citizen petitions arguably sustains the monopoly of brand name products by preventing generic competition, which raises prices for consumers and payers.

The FDA took steps in 2016 to address some of these concerns, but these reforms may not have gone far enough to limit brand name manufacturers' abuse of these petitions.¹⁴⁰ In 2017, the FTC filed its first-ever complaint against a brand name manufacturer for its abuse of the citizen petition process.¹⁴¹ The FTC alleged that Shire Viropharma Inc. engaged in an anticompetitive scheme to delay approval of a generic version of an antibiotic, "costing patients and other purchasers hundreds of millions of dollars."¹⁴²

Patient Assistance Programs

Manufacturers also use Patient Assistance Programs (PAPs) to encourage consumers' to buy expensive medications, which allows them to keep drug prices high. In general, PAPs help patients with out-of-pocket expenses when obtaining medications.¹⁴³ However, manufacturers often donate to these programs to increase demand for their products.¹⁴⁴

While these donations are legal, arrangements between manufacturers and PAPs have attracted

increasing scrutiny for their potential anticompetitive effects and violations of anti-kickback requirements. Multiple manufacturers have received subpoenas from the Department of Justice (DOJ) regarding their relationships with allegedly independent PAPs,¹⁴⁵ and one manufacturer recently entered into a \$210 million settlement “to resolve claims that it used a [PAP] as a conduit to pay the copays of Medicare patients” using its drugs.¹⁴⁶ Moreover, in 2017, for the first time in its history, HHS-OIG rescinded an advisory opinion issued to a PAP. The HHS-OIG found that the PAP had provided patient data to one or more manufacturers, allowing the manufacturers to “influence the identification or delineation of [patients’] disease categories.”¹⁴⁷

MARKET CONSIDERATIONS: SPECIALTY AND ORPHAN DRUGS

In recent years, two classes of drugs—specialty drugs and orphan drugs—have received particular attention because of their growing effect on overall drug spending and their increasing prominence in manufacturers’ development and approval pipelines. As will be discussed in more detail later on in this report, this shift has had consequences for the channels that comprise the drug supply chain.

Specialty Drugs

Specialty drugs are highly expensive and complex products that treat conditions such as rheumatoid arthritis and inflammatory diseases, multiple sclerosis, HIV, and cancer.¹⁴⁸ These drugs may have to be administered through injection or infusion, particularly if they are biologics. Further, these drugs generally require special handling, and are administered through specialty pharmacies or by specialist physicians.¹⁴⁹

In the last decade, specialty drug development, utilization, and spending has exploded. Since 2009, over half of all new FDA-approved drugs have been specialty products.¹⁵⁰ Further, the IQVIA Institute reported that of over 630 pharmaceutical research programs in 2016, more

than one-third were focused on products for the specialty market.¹⁵¹

The increased push for specialty drug development may partly be in response to the changing needs of an aging American public.¹⁵² Among Part D enrollees, for example, utilization of specialty drugs grew an average of 20% annually between 2010 and 2014.¹⁵³

Growth in specialty drug spending is primarily attributed to high and growing list prices. In 2017, specialty drugs accounted for 37.4% of prescription drug spending in retail and mail-order distribution channels, even though they accounted for only 1.9% of prescriptions that year.¹⁵⁴ Further, in every year from 2006 through 2015, list prices for specialty drugs increased at a rate higher than general inflation. Between 2014 and 2015 alone, the average list price for the 101 specialty drugs most widely used by older Americans increased by 9.6%.¹⁵⁵ By 2015 the average annual cost of a specialty drug had reached \$52,486.¹⁵⁶

These factors have caused national spending on specialty drugs to grow by more than 15% annually.¹⁵⁷ In the Part D program alone, MedPAC reported that, on average, spending on specialty-tier drugs grew by 37%.¹⁵⁸

While specialty drugs offer essential treatments, they come with high costs to consumers. Because Part B beneficiaries without supplemental coverage are required to pay 20% coinsurance, specialty drug costs are prohibitive for many beneficiaries who need these medications and services.¹⁵⁹ Most Part D plans have created a specialty tier that requires enrollees to shoulder higher cost-sharing obligations ranging from 25%-33%.¹⁶⁰ According to one report, Part D beneficiaries who used one or more specialty drugs were 10 times more likely to reach the out-of-pocket threshold as those who did not.¹⁶¹ This cap will increase to \$5,100 in 2019, indicating the significant financial consequences of these drugs for consumers’ out-of-pocket spending.

Orphan Drugs

Orphan drugs are a class of products intended to treat rare diseases and disorders, which are conditions that affect fewer than 200,000 people.¹⁶² Because of their more limited markets, the Federal Government created incentives to encourage manufacturers to develop these products, including tax credits for certain clinical testing, exemptions from certain user fees in specific circumstances, and an extended period of market exclusivity totaling seven years.¹⁶³ These incentives, however, may have allowed some manufacturers to inappropriately use the orphan drug program to maximize their financial returns. One study found that 45 drugs with orphan status were used over 40% of the time for non-orphan indications.¹⁶⁴

For example, some manufacturers obtain orphan drug status for existing products or seek multiple approvals for the same drug for different orphan-status indications.¹⁶⁵ Orphan drug status grants manufacturers a new period of market exclusivity, meaning manufacturers are then able to increase their product's list price for the new indication as well as all older indications.¹⁶⁶ Manufacturers may also "slice" different indications from the drug to obtain multiple orphan drug indications (and thus multiple exclusivity periods) for a single product.¹⁶⁷ This approach allows manufacturers to prolong their exclusivity period.

In addition to these program incentives, manufacturers may produce orphan drugs to take advantage of limited competition in the market. Orphan drugs, by definition, tend to have few therapeutic competitors because they treat a small population. When combined with the extended period of market exclusivity, manufacturers have virtually no limitations with respect to setting and raising prices.¹⁶⁸ The resulting median price for orphan drugs (\$98,534 per patient per year) is significantly higher than that of non-orphan drugs (\$5,153 per patient per year).¹⁶⁹ Moreover, one study found that the median launch price of orphan drugs has doubled approximately every five years from 1983 through 2014.¹⁷⁰

KEY FINANCIAL RELATIONSHIPS

Manufacturers enter into financial relationships with virtually every other entity in the drug supply chain, each of whom negotiates rebates and price concessions from manufacturers. Manufacturers often point to these arrangements to explain high list prices for their drugs, since concessions reduce the actual sales manufacturers collect.¹⁷¹ However, manufacturer profits remain the largest in the payment and supply chain and continue to rise, indicating that rebates and discounts alone cannot explain these prices.¹⁷²

This section highlights some of the key financial relationships between manufactures and other entities that affect the price of a drug. It emphasizes the opaque nature of the current system, which allows for little insight into how the price of a drug changes, or is otherwise affected by, the terms of these financial relationships.

Wholesale Distributors

Manufacturers sell the majority of their products to wholesale distributors, which distribute drugs to pharmacies (for Part D-covered drugs) or health care providers (for Part B-covered products). The majority of these products pass through one of three companies, McKesson, AmerisourceBergen, or Cardinal Health. Sometimes referred to as the Big Three, they collectively control roughly 85% to 90% of the market.¹⁷³ Notably, in the specialty market, some manufacturers directly distribute products to specialty pharmacies, physician offices or clinics, and hospitals.¹⁷⁴

Brand name manufacturers generally sell drugs to wholesale distributors at the WAC price minus an agreed-upon discount, roughly in the range of 2% to 5%.¹⁷⁵ Some of these deductions—roughly 1% to 2% off the WAC—arise from prompt-pay discounts, which are offered when a distributor pays for the purchased products within a time specified by contract.¹⁷⁶ Other incentives might

include volume discounts, which encourage distributors to purchase drugs in bulk.

Distributors have greater leverage in negotiations with manufacturers of multiple-source drugs because these manufacturers compete to gain a distributor's business. Thus, distributors often secure lower prices from manufacturers when purchasing generics, increasing the spread between the price at which distributors pay and sell a product. For this reason, distributors' profits are higher when handling generics (\$8 for every \$100 spent on a drug at a retail pharmacy) as compared to brand name drugs (\$1 for every \$100).¹⁷⁷

Generic Sourcing Programs. Distributors may offer generic sourcing programs to generic manufacturers to negotiate larger discounts. Under these programs, distributors agree to serve as a manufacturer's preferred or exclusive distributor for certain generic products in exchange for larger discounts or rebates than would otherwise be made available. Distributors may then pass these concessions downstream to pharmacies in exchange for exclusivity contracts or volume commitments.¹⁷⁸

By way of example, McKesson developed SynerGx, a generic drug purchasing program "that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing and one-stop shopping."¹⁷⁹ The Healthcare Distribution Alliance (HDA)—the trade organization for drug distributors—has touted the success of these programs in promoting products, noting that sales for generics included in generic source programs vastly outpaced sales for those in other generic programs.¹⁸⁰

Chargebacks. Another key financial arrangement between manufacturers and distributors is the chargeback. Manufacturers provide a chargeback to distributors to make the distributor whole after a drugmaker directly negotiates with a third party in the supply chain (such as a pharmacy or health care provider), rather than the terms laid out in the manufacturer-distributor contract. Under these

arrangements, distributors may distribute drugs from a manufacturer to a pharmacy or provider and then "chargeback" the difference between a manufacturer's contracted price with a third party and the distributor's invoice price.¹⁸¹

Chargeback arrangements make up a substantial portion of distributors' net sales. HDA reports that the total number of annual chargebacks as a percentage of net sales increased from 26.4% in 2015 to 28.9% in 2016.¹⁸²

Other Services. As discussed further in the following chapter, manufacturers may compensate distributors for a wide range of services beyond distribution.

For example, Merck pays fees to distributors "upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing product returns."¹⁸³ Similarly, Endo Pharmaceuticals maintains distribution service agreements in which "wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current inventory levels and other information" in exchange for fees.¹⁸⁴

Distributors may also provide new product launch support as well as services tailored for the distribution of special drug products.¹⁸⁵ For example, Cardinal Health "provides consulting, patient support, logistics, group purchasing and other services," including "specialty pharmacy services" to support "the development, marketing and distribution of specialty pharmaceutical products."¹⁸⁶

The precise terms of these agreements are typically confidential, including the extent to which these transactions are based on a product's list price. However, some distributors report that service agreements between these entities are tied to WAC.¹⁸⁷ These arrangements—and their dependence on a drug's list price—warrant further

study and require greater transparency to be fully understood.

Part D Plan Sponsors and PBMs

One of the most consequential and least transparent financial relationships in the drug supply chain are those between manufacturers and contracted by Part D plan sponsors and the PBMs. Rebate agreements are the most widely known and discussed arrangement, though manufacturers also provide PBMs and plans with other fees for services.

Rebate Agreements. Manufacturers often provide rebates to plan sponsors or PBMs. In exchange, sponsors and PBMs encourage consumers to use that manufacturer's product. In 2014, CBO estimated that the average rebate for a Part D drug in 2010 was 15% of the list price.¹⁸⁸ According to the 2018 Medicare Trustees' Report, manufacturer rebates totaled 19.9% of total drug costs in 2016, and are projected to climb to over 28% by 2027.¹⁸⁹

Manufacturers generally provide three types of rebates to PBMs or Part D plan sponsors after a pharmacy dispenses a product to patient: (1) formulary rebates, (2) market-share rebates, and (3) price protection rebates.

Formulary rebates are given in exchange for placing a manufacturer's product on the plan's formulary. These rebates can be a substantial source of savings for plans and PBMs: The HHS-OIG found in 2011 that these rebates range anywhere from 0.5% to 75% of a drug's WAC.¹⁹⁰ Manufacturers may offer even larger rebates if their products are placed on a preferred tier, or if their product avoids utilization management techniques such as step therapy or prior authorization. Further, the terms of a rebate agreement may require the plan to implement policies that discourage the use of competitor drugs, including by demanding that the plan implement a higher copayment for the competitor's drug.

Market-share rebates reward plans or PBMs for higher usage of the rebated product as compared to competing therapies. To calculate these incentives, manufacturers look at "the total number of the rebated drugs that beneficiaries used compared to the total number of other drugs used."¹⁹¹ The 2011 HHS-OIG report found that these rebates range from 0.5% to 10% of WAC.¹⁹²

Price protection rebates are a newer arrangement that PBMs favor, according to the Pharmaceutical Research and Manufacturers of America (PhRMA), the major trade group for drug manufacturers.¹⁹³ These rebates compensate plan sponsors and PBMs if the list price rises beyond an agreed-upon percentage or dollar threshold.¹⁹⁴ As a result, these rebates mitigate the financial burdens plan sponsors bear as drug prices go up. Thus, as MedPAC notes, this arrangement undercuts the incentive that PBMs and plan sponsors have to object to higher list prices for a rebated product, even though higher list prices continue to impact consumers' cost-sharing obligations.¹⁹⁵

Rebate arrangements are poorly understood, as parties maintain that these arrangements are proprietary and confidential and that increased transparency could result in higher costs for consumers.¹⁹⁶ However, certain patterns and trends are important to note: First, brand name manufacturers provide the vast majority of rebates to plan sponsors and PBMs, with generic manufacturers rarely offering these financial incentives. Second, these rebates increase where products have therapeutic competitors, meaning there are few, if any, rebates offered for products with no therapeutic equivalent.¹⁹⁷ This also means specialty medicines often do not come with any significant discounts or rebates.¹⁹⁸ Third, because plan sponsors must cover "all or substantially all" drugs in six therapeutic classes, plan sponsors and PBMs cannot use the same bargaining tools available for other drugs, which leads to fewer rebates for products in these therapeutic classes.¹⁹⁹ Finally, the negotiating power of the relevant parties plays a role in the size of the rebate or

discount. Plan sponsors often contract with PBMs to administer their pharmacy benefits because these entities have greater bargaining leverage with manufacturers.²⁰⁰ As an example, internal documents showed that Gilead Sciences considered Express Scripts and CVS Caremark among its “must win” accounts owing to their “size and influence,” while developing its contracting and rebate strategy for its second generation hepatitis C drug Harvoni.²⁰¹ Similarly, plan sponsors with more covered lives generally obtain higher rebates as compared to smaller plans.²⁰²

Administrative Fees. In addition to discounts and rebates, manufacturers may enter into fee-based arrangements with PBMs or plan sponsors that are based on WAC prices and “[are] for services that the PBM provide[s] to the manufacturers, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors.”²⁰³ In its annual report, for example, Express Scripts noted that it receives fees from manufacturers for managing rebate programs.²⁰⁴ In addition, manufacturers may pay fees to PBMs as compensation for administration of formularies or for other bona fide services, as discussed in Part IV.²⁰⁵

Implications for Drug Pricing. Discounts and rebates have lowered the cost of drugs for Part D plan sponsors. For example, one study reported that Part D plans negotiated discounts valued at more than 35% of WAC for brand name drugs (accounting for rebates and concessions).²⁰⁶ To this point, some manufacturers argue that rebates and discounts have led them to increase list prices to preserve their profits.

However, the widening gap between total drug spending on a list-price basis (which does not include rebates, discounts, and other price concessions) and spending on a net-price basis (which includes these deductions) undercuts this justification.²⁰⁷ According to one report, net spending increased by 4.8% in 2016 while spending on a list-price basis grew by 5.8%,

indicating that manufacturers are raising list prices beyond the extent necessary to account for changes in rebate amounts. Since 2006, total drug spending has risen by 67% on a list-price basis while rising by only 42% on a net-price basis.²⁰⁸

Data released in June 2018 by HHS-OIG underscore this growing gap between list- and net-price spending.²⁰⁹ HHS-OIG reported that total reimbursements for brand name Part D drugs increased 77% from 2011 to 2015 while the utilization of these products decreased by 17%. During that period, total rebate dollars for all brand name drugs in the program more than doubled from \$9 billion in 2011 to \$23 billion in 2015. Despite the growth in rebates, HHS-OIG noted, the gap between total reimbursement and total rebates increased. When accounting for manufacturer rebates, Part D reimbursements for brand name drugs increased only 62%. Further, manufacturers paid rebates for fewer brand name drugs in the program (72% of brand name drugs in 2011 versus 61% in 2015). Thus, as these data demonstrate, some manufacturers may be raising list prices beyond an amount that accounts for downstream rebates.

At least three manufacturers have released data comparing the percentage increases in list and net drug prices.²¹⁰ Eli Lilly and Company reported that list prices for its U.S. product portfolio increased by double-digit percentages every year between 2012 and 2016. Net prices also increased in each of those years; however, those annual percent increases were less than those for Eli Lilly’s list prices.²¹¹ Johnson & Johnson’s Janssen reported a similar pattern over the same period, and experienced list price changes ranging from 7.6% to 8.5% from 2012 to 2016, respectively, and net price changes ranging from 4.3% to 3.5%.²¹² Merck & Co. reported list price changes of 9.2% to 9.6% and net price changes of 6.2% to 5.5% from 2012 to 2016, respectively.²¹³

PBMs echo this rebuttal by arguing that rebates have not risen with increasing list prices. The Pharmaceutical Care Management Association

LEGAL ATTENTION

Some arrangements between manufacturers and PBMs may implicate the Federal Anti-Kickback Statute. In February 2015, for example, DOJ entered into a \$7.9 million settlement with AstraZeneca—the manufacturer of Nexium and other pharmaceuticals—and Medco Health Solutions, a wholly-owned subsidiary of Express Scripts. DOJ alleged that AstraZeneca provided kickbacks to a PBM in exchange for maintaining Nexium’s “sole and exclusive” status on certain formularies and for engaging in related marketing activities. DOJ also asserted that AstraZeneca provided some of these kickbacks through concessions on drugs *other* than Nexium, including Prilosec.

As these allegations indicate, greater scrutiny is needed to understand how arrangements between manufacturers and PBM impact prices paid by consumers within and across product lines.

Source: Dep’t of Justice, Press Release: AstraZeneca to Pay \$7.9 Million to Resolve Kickback Allegations (Feb. 22, 2016), <https://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations>.

(PCMA))—the trade association representing PBMs—commissioned a study of the top 200 brand name drugs that found “no correlation” between rebates negotiated for products and the increasing list prices set by manufacturers.²¹⁴ The study also noted that brand name manufacturers increase list prices for products even when products maintain low rebate levels.

Implications for Beneficiaries. The implications of discounts and rebates are less clear for beneficiaries, as discussed in more detail later on in this report. Part D plans have the authority to apply discounts and rebates from manufacturers at the point of sale, which would allow patients to benefit from these price negotiations. However,

more frequently, Part D plan sponsors receive rebates and concessions after a pharmacy dispenses a product, leaving beneficiaries with cost-sharing obligations that hinge on the original list price.²¹⁵

In 2017, CMS published a Request for Information regarding the possibility of applying a portion of manufacturer rebates at the point-of-sale as a strategy to lower out-of-pocket spending for Part D enrollees. CMS explained that the price concessions received by plan sponsors and PBMs had increased by almost 24% per year between 2010 and 2015, with most of that growth attributable to manufacturer rebates that were not passed on at the point-of-sale to enrollees.²¹⁶

Pharmacies

In contrast to the financial relationships between manufacturers and PBMs, less attention has been paid to the financial relationships between manufacturers and pharmacies, perhaps due to the fewer and smaller discounts, rebates, and fees exchanged between these parties. Nonetheless, these financial arrangements influence the pricing of drugs exchanged between these parties and deserve attention.

First, the market power of a pharmacy plays a key role in these financial relationships. Chain pharmacies that serve a greater number of consumers and hold higher market share are able to negotiate more favorable financial arrangements with manufacturers. These large chains stand in contrast to smaller pharmacies, which are less able to exert the necessary leverage to negotiate substantial price concessions.²¹⁷

Pharmacies also exert greater leverage when negotiating for generic rather than brand name drugs. This is mainly because, unlike plan sponsors and PBMs, pharmacies do not control or select the brand name drug ultimately dispensed to the consumer. In contrast, for generic drugs, pharmacies select which product to stock from all available generic versions of a drug. As a result, generic manufacturers may offer discounts and

rebates to pharmacies to encourage pharmacies to stock their product for consumers. Thus, while a drug's list price may be a good indicator of the

price pharmacies pay for brand name products, pharmacies frequently pay below the listed value for generic products as a result of this leverage.

PART III: WHOLESALE DISTRIBUTORS

Wholesale distributors (also called distributors or wholesalers) principally transfer drugs from manufacturers to pharmacies or health care providers, such as hospitals or physician groups.²¹⁸ There is no legal requirement that manufacturers use distributors to send their drugs into the market.

Distributors—and particularly, McKesson, Cardinal Health, and AmerisourceBergen—touch nearly every drug sale in the United States.²¹⁹ Distributors’ revenues have grown substantially over time: distributors reported \$440.2 billion in sales for prescription and pharmacy-dispensed diagnostic products in 2016, up 8% from 2015 (\$407.5 billion) and 44.5% from 2013 (\$304.6 billion).²²⁰

Distributors negotiate complex and confidential price concessions and service arrangements with manufacturers, pharmacies, and other purchasers. These agreements are confidential which hinders market transparency. Because these arrangements often hinge on a drug’s list price, distributors benefit from rising drug costs, making it possible that these arrangements contribute to or sustain rising drug prices in the market.

THE ROLE OF DISTRIBUTORS

Distributors primarily purchase drugs directly from manufacturers and distribute them to retail pharmacies (including chain, independent, and mail-order pharmacies) and non-retail health care providers (including hospitals, long-term care facilities, and other health care providers).²²¹ Some distributors also distribute to secondary distributors, which tend to distribute products in specific geographic regions or within specialty markets.²²² According to the Healthcare Distribution Alliance (HDA)—the trade organization for drug distributors—brand name drugs, specialty drugs, and generics accounted for

65.9%, 18%, and 13.7% of distributors’ sales volume, respectively, in 2016.²²³

While drug distribution accounts for a significant portion of their services, distributors also offer inventory management, data reporting, reimbursement, repackaging, promotional and marketing services, programs to help manufacturers launch new products, and other specialized services.²²⁴ For example, McKesson offers a program to assist consumers with the prior authorization process, which enables “patient acquisition and retention” and provides efficiencies for the prescribing physician.²²⁵

Distributors also offer services and programs to pharmacy customers ranging from large chains to small specialty pharmacies. For example, McKesson offers programs to large retailers aimed at helping pharmacies manage high volumes of product to maximize their profits. These programs include a prescription refill service and forecasting software and automated replenishment technologies that are designed to reduce costs.²²⁶ For smaller independent retailers, at least two major distributors have developed national networks for independent pharmacies that are advertised as ways to improve managed care contracting, efficiency, and profitability.²²⁷

As this broad array of services highlights, distributors are responsible for much more than the distribution of the product itself. These services provide additional opportunities for distributors to generate revenue on more than simply the simple delivery of the drug to purchasers.

MARKET CONSIDERATIONS

The Big Three Distributors

The wholesale distribution industry is intensely concentrated, with the Big Three distributors—McKesson, AmerisourceBergen, and Cardinal

THE EVOLVING ROLE OF DISTRIBUTORS

The role distributors play in the drug payment and supply chain has changed dramatically in the last 20 years. Through the late 1990s, distributors used to engage in a practice known as speculative buying, where distributors bought products at low prices and large volumes assuming manufacturers would raise products' list prices as demand rose, allowing distributors to profit from price inflation.

In 2004, a large manufacturer settled with the Securities and Exchange Commission over charges that it had encouraged distributors to purchase massive quantities of its products to drive up its sales artificially. The litigation surrounding these charges led to a major transformation from the buy-and-hold model of drug distribution.

In the past two decades, distributors have reinvented their business model by charging manufacturers for the services they provide, including packing and shipping drugs as well as data management and reimbursement-related services. In turn, manufacturers have developed performance-based incentives and discounts to encourage distributors to enter services contracts with them.

Sources: Heather Won Tesoriero, "Drug Wholesalers Change Methods," WALL ST. J. (Nov. 12, 2004); Stephanie Saul, "Making a Fortune by Wagering That Drug Prices Tend to Rise," N.Y. TIMES, Jan. 26, 2005.

Health—controlling 85% to 90% of the wholesaler market.²²⁸ These firms' scale and scope of services have grown dramatically over time. In 2002, McKesson, AmerisourceBergen, and Cardinal reported revenue of \$50 billion,²²⁹ \$51 billion,²³⁰ and \$45 billion,²³¹ respectively. Over the next 15 years, revenues for these distributors doubled, tripled or quadrupled. By 2017, McKesson, AmerisourceBergen, and Cardinal reported revenues of \$208 billion,²³² \$153 billion,²³³ and \$122 billion,²³⁴ respectively.

Profitability

Wholesale distribution has grown into an industry worth more than \$440 billion, with the Big Three listed in the top 15 companies of the Fortune 500.²³⁵ Despite these enormous revenues, distributors report narrower profit margins relative to others in the drug supply chain. One estimate found that for every \$100 spent on a drug at a retail pharmacy, distributors keep roughly \$2 (\$0.32 net profit).²³⁶

Brand name and generic drugs contribute differently to distributors' profitability and growth. While brand name and specialty products drive distributors' revenue growth, distributors make a higher proportion of gross profits from transactions involving generics.²³⁷ Of \$100 spent on a drug at a retail pharmacy, distributors capture \$1 in gross profits for brand name drugs and \$8 for generic products.²³⁸ To this point, according to an estimate of profits accrued by the Big Three, generic drugs comprised 74% of total gross profits in 2017 but only 16% of drug distribution revenues.²³⁹ For this reason, distributors' profits are particularly sensitive to changes in the price of generic pharmaceuticals, as highlighted in these firms' financial reports.²⁴⁰

Specialty Distribution

While manufacturers may bypass distributors entirely and sell specialty products directly to specialty pharmacies or health care providers, distributors have handled a growing segment of the specialty distribution market. For example, AmerisourceBergen provides specialty distribution services to physicians and hospitals through AmerisourceBergen Specialty Group. The division generated revenue \$31.5 billion in revenue in fiscal year 2017, more than double the amount it did in fiscal year 2011.²⁴¹

This growing participation in the specialty market is in part the result of Big Three's acquisition of specialty distributors over past two decades.²⁴² This consolidation led AmerisourceBergen and McKesson to be responsible for over 75% of

specialty distribution revenues to physician offices and clinics by 2012.²⁴³ Distributors also acquired specialty pharmacies and networks of physician practices to participate in manufacturers' limited distribution networks for those products.²⁴⁴ For example, in 2003, AmerisourceBergen acquired a nationwide specialty pharmacy, U.S. Bioservices.²⁴⁵ In 2010, McKesson acquired US Oncology, a major cancer treatment and research network that, at the time of its purchase, included 83 cancer centers with 1,300 affiliated physicians.²⁴⁶ McKesson expanded its network of oncology pharmacies and practices in 2016 through two acquisitions totaling \$1.2 billion: Biologics, Inc.—then the largest independent oncology-focused specialty pharmacy in the country—and Vantage Oncology, a network of over 51 cancer treatment facilities.²⁴⁷

The distribution channels to specialty health care providers and pharmacies are complex and rapidly changing as the specialty market grows. Further attention must be paid to this market to understand how specialty drugs ultimately arrive at a pharmacy or with a health care provider, and how the financial arrangements that pay for these products influence cost.

KEY FINANCIAL RELATIONSHIPS

Manufacturers

As described in the previous chapter, distributors generally purchase products from a manufacturer at the Wholesale Acquisition Cost (WAC) less a discount, which varies widely depending on whether the drug is a generic or brand name product. Distributors generally negotiate larger discounts when purchasing generics.

Securities filings suggest that distributors benefit from higher list prices. As AmerisourceBergen's recently stated, "[i]f the frequency or rate of branded and generic pharmaceutical price increases slows, our results of operations could be adversely affected."²⁴⁸ Further, the Chief Executive Officer of McKesson illustrated the effect of list prices on industry profits in a 2016

earnings call when he explained that McKesson expected "to receive less compensation from branded price increases than we originally anticipated,"²⁴⁹ which lowered McKesson's profit projections.

Some financial arrangements with manufacturers may also be based in part on list price inflation. McKesson described such an arrangement in a recent financial disclosure:

[W]e have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based compensation component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases, as well as restrictions in the amount of inventory available to us, could have a material adverse impact on our gross profit margin.²⁵⁰

McKesson did not clarify further how price inflation is tied to its compensation. Nonetheless, its statement reinforces the idea that higher list prices drive up the revenues and profits distributors accrue. Further study is needed to understand how rising list prices factor into these distributor-manufacturer relationships.

Pharmacies

While the precise details of financial arrangements between distributors and their downstream customers remain largely opaque, distributors generally negotiate prices for pharmacies based on list price, including WAC or Average Wholesale Price (AWP), or the price paid by wholesale distributors for a product.²⁵¹ Like WAC, AWP is not based on actual sales data but is a wholesale price suggested by the manufacturer. Manufacturers report AWP to commercial publishers of drug prices, but AWP is not defined in statute.²⁵²

Distributors generally charge retail pharmacies a small percentage above the WAC (called WAC-plus pricing) or at a discount of AWP (estimated to be a discount of 15% to 20%).²⁵³ More recently, distributors appear to be using WAC-based pricing. The Kaiser Family Foundation estimated in 2016 that the price paid by a pharmacy for brand name drugs was WAC minus 4%.²⁵⁴ Further, the General Counsel for HDA recently testified that distributors “typically sell branded drugs to downstream customers based on WACs.”²⁵⁵

The amount distributors charged to pharmacies for generic drugs is more variable because pharmacies have a range of choices when selecting which generic drugs to stock. According to HDA, distributors may negotiate prices for generics based on WAC “or they may price generic drugs sold to downstream customers in response to the market, which includes supply of competing generic drug and considers the WACs for such generic drug products and competitors to such drug products.”²⁵⁶ Though prices likely vary based on the parties and terms of a particular agreement, without more transparency, it is impossible to identify common terms of these financial relationships.

Chain retail pharmacies, including CVS and Walgreens, are the predominant purchasers of distributors’ goods when excluding sales from specialty divisions. HDA reported that sales to chain customers (including chain drug stores, mass merchandisers and food stores, and chain warehouses) accounted for 42% of distributors’ sales volume in 2016, with chain drug stores alone accounting for nearly 30% of revenues.²⁵⁷

Arrangements between the Big Three distributors and large retail chains have evolved dramatically over the last five years. Previously, chain retailers often bypassed distributors for a large portion of their distribution and warehouse operations because these chains possessed the capability to transfer high volumes of product at low cost.²⁵⁸ More recently, pharmacy chains and distributors entered into partnerships to exert greater

purchasing power against manufacturers. For example, in 2013, AmerisourceBergen announced a 10-year venture with Walgreens Boots Alliance for the distribution of brand name and generic products, which was recently extended through 2026. This agreement made AmerisourceBergen the primary distribution source for the Walgreens Boots Alliance.²⁵⁹ This partnership generated 30% of AmerisourceBergen’s total revenue in 2017.²⁶⁰

Likewise, McKesson has an existing distribution agreement with CVS through June 2019 that is responsible for a significant portion of its revenue.²⁶¹ In its most recent annual filing, McKesson reported that sales through CVS Health accounted for 19.9% of its revenues, equal to roughly \$41.5 billion.²⁶² Further, in 2016, McKesson and Walmart announced an extension of their distribution agreement and a partnership for the sourcing of generic products that is intended to increase their buying leverage.²⁶³ Cardinal Health also has established a generic pharmaceutical sourcing program with CVS through Red Oak Sourcing.²⁶⁴ CVS accounted for 23% of Cardinal Health’s revenue in fiscal year 2017.²⁶⁵

Independent Pharmacies and Physician Practices

In addition to large retail pharmacies, distributors sell manufacturers’ products to independent pharmacies and physician practices. While direct arrangements between distributors and these smaller entities are rare, distributors frequently partner with independent pharmacies or provider practices through Group Purchasing Organizations (GPOs). GPOs contract with networks of health care providers and pharmacies to help these entities exert greater leverage against distributors or manufacturers. Because of this, distributors grant these GPOs’ members more favorable prices for drugs.²⁶⁶

Because GPOs can potentially contract with thousands of entities, forming partnerships with a GPO grants distributors access to a significant

A NOTE ON GENERIC PRICING TRENDS

Decreases in the price of generic drugs may strain distributors' profit margins. Ironically, however, distributors' vertical relationships with downstream entities such as large retail chains may have contributed to recent downward trends in generic drug pricing. Large pharmacy chains historically bypassed distributors and purchased generics drugs directly from manufacturers. When major retailers joined distributors to enhance their market power, these partnerships gave distributors access to high volumes of generic transactions between large pharmacy chains and manufacturers, increasing distributors' profits. However, these purchasing groups may have driven down generic prices overall by lowering acquisition costs.

Distributors' recent arrangements with independent pharmacies may have also exerted downward pressure on generic prices. Before distributors and GPOs entered into partnerships, distributors relied on transactions with independent pharmacies to collect high returns because these smaller buyers lacked the purchasing power of large chains. Because GPOs succeeded in making independent pharmacies more effective negotiating entities, some GPOs decided to bypass distributors altogether and buy generics directly from manufacturers. Other GPOs pressured distributors to negotiate generous contracts for the purchase of generic drugs, further driving down the cost of these pharmaceutical products.

Source: Adam J. Fein, *Cardinal Health's Unhappy Profit Surprise: The Coevolution of Pharmacy Buying Groups and Wholesaler Economics*, DRUG CHANNELS (Apr. 19, 2017).

customer base. In 2016, for example, the largest independent pharmacy GPO represented over 4,500 independent pharmacies.²⁶⁷ The vast majority of U.S. hospitals also participate GPOs.²⁶⁸

Distributors have acquired GPOs to gain greater access to pharmacies, clinics, and physician practices. Today, five of the largest GPOs focused on community physician practices are owned by one of the Big Three distributors.²⁶⁹ For example, AmerisourceBergen owns International Oncology Network, which represents over 4,800 oncologists.²⁷⁰ In turn, distributors may use the purchasing power of GPOs to negotiate with manufacturers for lower prices. Distributors may also use pharmacy GPOs as an avenue to encourage manufacturers to participate in a generic sourcing program.²⁷¹

Distributors also partner with or administer Pharmacy Services Administrative Organizations (PSAOs), which provide administrative services on behalf of independent pharmacies or represent

pharmacies in negotiations with PBMs and third-party payers. GAO reported that in 2011 and 2012, at least 22 PSAOs were in operation and represented or provided services to up to 28,300 pharmacies, the majority of which were independent.²⁷² Nine of these PSAOs were distributor-owned. In fact, the Big Three owned three of the five largest PSAOs, which represented as many as 12,000 pharmacies at the time of the 2013 GAO report.²⁷³

Legal Attention

Certain distribution arrangements have become the subject of legal attention for potentially anticompetitive practices. For example, in 2017, 45 state attorneys general filed a federal lawsuit alleging that 18 generic manufacturers, distributors, and pharmacies engaged in an anticompetitive conspiracy to increase the cost of generic drugs.²⁷⁴ The suit cited financial disclosures by McKesson, AmerisourceBergen, and Cardinal that described how their operations benefited from higher list prices.²⁷⁵

PART IV: PHARMACY BENEFIT MANAGERS

*PBMs initially operated almost exclusively as pharmacy claims processors. In the 1980s, however, these companies began to transition to entities that leveraged the number of lives they covered through their clients' networks to negotiate discounts and rebates with manufacturers and pharmacies.*²⁷⁶

Today, these middlemen have one of the most prominent roles in determining coverage and payment for drug products, despite never taking physical possession of the drug. Moreover, they have financial relationships with—or are owned by—other key entities in the drug supply chain. For these reasons, PBMs are essential in the national conversation surrounding lowering prescription drug prices.

THE ROLE OF PBMS

In the context of Medicare Part D, the core business function of a PBM is to administer the prescription drug benefit on behalf of a Part D plan sponsor. While plan sponsors are not required to contract with PBMs, many choose to do so.²⁷⁷ There are varying descriptions of the services PBMs provide, but CMS defines these services as including “contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.”²⁷⁸ In addition to the traditional claims processing function, PBMs may offer other administrative services (*e.g.*, eligibility determinations) as well as provide access to mail-order pharmacies.²⁷⁹

To furnish these services, PBMs interpose themselves between plan sponsors and other entities involved in the distribution of, or payment for, prescription drugs. PBMs negotiate directly

with manufacturers for rebates and discounts on products, and with pharmacies for product payment, dispensing fees, and other fees or incentives. In return, Part D plan sponsors reimburse PBMs through different payment terms for the costs of the drugs dispensed as well as for performing administrative services.²⁸⁰

FACTORS AFFECTING DRUG PRICING

Transparency Concerns

One of the most significant and oft-repeated assessments of PBMs is that they are not sufficiently transparent in their practices.²⁸¹ Critics contend that PBMs conceal the payment terms and rebates they negotiate so that their plan sponsor clients do not know the extent to which the savings secured by a PBM are—or are not—passed on. Further, PBMs do not disclose the fees they may be receiving from manufacturers for other services. In 2011, the Office of the Inspector General at Health and Human Services (HHS-OIG) observed that “[t]he lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs.”²⁸² This lack of transparency extends to PBMs’ relationships with other entities in the drug supply chain.

Unlike other stakeholders, PBMs feature in almost all of the key transactions that drive the price of a drug. Critics allege that PBMs exploit this role to maximize their profits through arrangements with manufacturers, plan sponsors, and pharmacies, who are not privy to the same level of information the PBM possesses when they enter into negotiations.²⁸³ Proponents of increased transparency argue that providing information about the financial transactions taking place between PBMs and the other entities in the drug supply chain would reveal the value these intermediaries provide, their current profitability, and their role, if any, in increasing prescription

drug prices.²⁸⁴ Without this information, identifying opportunities to balance the benefits PBMs offer with their potential to drive up drug prices may be impossible.

In response, representatives of PBMs have argued that their agreements offer sufficient transparency “to the extent demanded in the competitive market and in response to negotiations with individual clients.”²⁸⁵ Disclosing these data, PBMs argue, “would harm competition and could raise—rather than lower—drug prices.”²⁸⁶ In making this argument, The Pharmaceutical Care Management Association (PCMA)—the trade association representing PBMs—references, among other things, a 2004 report jointly issued by the FTC and DOJ stating that “vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms.”²⁸⁷ Whether these 2004 findings are equally applicable in today’s much changed marketplace is a question for future research and scrutiny.

Formularies

As part of their obligations in administering the plan sponsor’s pharmacy benefit, PBMs are responsible for developing a plan’s formulary, or “the entire list of Part D drugs covered by a Part D plan.”²⁸⁸ A formulary must include two drugs within each therapeutic category and class and “all or substantially all” drugs in six protected classes.²⁸⁹ Formularies are particularly important in the context of prescription drug pricing because they are a key cost-containment strategy employed by PBMs.²⁹⁰

The vast majority (97%) of Part D enrollees participate in stand-alone prescription drug plans that have formularies with five different tiers, namely “two generic tiers, a preferred brand name tier, a nonpreferred tier, and a specialty tier.”²⁹¹ Brand name and generic drugs on preferred tiers have lower cost-sharing obligations than those on non-preferred tiers. Beneficiaries and their health care are then incentivized to select products on a preferred tier. For example, CBO determined that

70% of all spending on brand name drugs in 2010 was attributable to brand name drugs on preferred tiers.²⁹² In addition, PBMs may implement utilization management tools such as prior authorization, step therapy, or quantity limits.²⁹³

Given the higher utilization of drugs on preferred tiers and PBMs’ flexibility in applying utilization-management requirements, PBMs use these formulary tools to negotiate rebates and other discounts with manufacturers. Manufacturers may offer larger rebates to have their drugs placed on a preferred tier, or to have their products be free of utilization management tools. These types of negotiations may result in lower prices for drugs and present cost savings for payers and consumers.

Implications for Pricing and Patients. Concerns have been raised that PBMs design formularies based on what maximizes revenues and profit rather than what lowers costs for patients. If rebates are based off of a drug’s list price, PBMs have an incentive to select a higher-priced drug over a lower-priced product to collect the higher rebate amount.²⁹⁴ Accordingly, PBMs may include more expensive products on formularies rather than therapeutically equivalent cheaper alternatives in order to garner the largest rebate.²⁹⁵

PBMs also have been accused of switching patients to therapeutically similar drugs for which they have negotiated more favorable rebate terms. In a practice called “therapeutic substitution,” patients are switched from one brand name drug to a generic form of a different drug in the same class or to a lower-cost brand name drug in the same class.²⁹⁶ While therapeutic substitution offers the potential for significant cost savings, at least one PBM agreed to pay \$29.3 million to settle claims that it switched patients to drugs that actually were more expensive for payers and patients, but for which the PBM had negotiated more favorable rebate terms.²⁹⁷

PBMs argue that their formulary designs, including the negotiation of substantial rebates, contribute to overall cost savings for plans. For instance, one of the largest PBMs, CVS Health,

maintains that formularies “help manage drug spend through the appropriate selection and use of drug therapy.”²⁹⁸ PCMA also emphasizes that formularies offer significant benefits because they “can minimize overall medical costs, improve patient access to more affordable care, and provide patients with an improved quality of life.”²⁹⁹ Further, some PBMs highlight that their formularies are developed by a Pharmacy & Therapeutics Committee, which reviews clinical evidence in determining what products to place on the formulary. However, there is little detail provided about how such committees reach their decisions.

Formulary designs have powerful financial consequences for consumers at the pharmacy counter, particularly because beneficiary cost-sharing is often based on the list price of a drug rather than the price net negotiated rebates. Without more transparency as to the scope and terms of the financial arrangements that PBMs have with manufacturers, it is virtually impossible to know if PBMs’ current formulary designs maximize cost savings for Part D and its enrollees or for PBMs themselves.

Rebates, Other Price Concessions, and Fees

From the perspective of plan sponsor clients, the key value of PBMs lies in their ability to leverage their market share to negotiate with manufacturers for rebates and discounts on drugs. Yet other entities within the drug payment and supply chain have cast doubt over the extent to which these arrangements lower costs for consumers.³⁰⁰

Retention of Price Concessions. PBMs may retain a portion of rebates or discounts they negotiate with manufacturers as payment for the services they provide, depending on the agreements PBMs set with plan sponsors. Critics often point to PBMs’ lack of transparency in disclosing the portion of these rebates they internalize as profits or pass on to patients or sponsors,³⁰¹ with some demanding that PBMs make these data public.³⁰² Senator Wyden

introduced the C-THRU Act to improve transparency of this process.³⁰³

Estimates suggest that for every \$100 spent on a drug at a retail pharmacy, approximately \$5 (of which \$2 net profit) goes to PBMs,³⁰⁴ with gross margins higher for generic compared to brand name products. However, PBMs’ lack of transparency “masks whether they are indeed lowering the prices paid by patients and insurers as claimed.”³⁰⁵

In response to concerns regarding rebate retention, PCMA has cited a report finding that PBMs direct over 90% of rebates to plan sponsors and noted that some plans require all rebates to be transferred to the plan.³⁰⁶ A representative of PCMA emphasized that PBMs must report “100% of rebates” to CMS under Part D.³⁰⁷ With regard to concerns about transparency, at least one PBM has articulated that it does not disclose specifics of its contracts with manufacturers because they include “confidential information,” and there is a concern that a plan sponsor “may one day become a PBM itself.”³⁰⁸

Direct and Indirect Remuneration (DIR).

Although this is the first reference to DIR in this report, these fees implicate a variety of players in the payment and supply chain, and thus will be referenced in various contexts over the course of the remainder of the report.

In general, payments categorized as a rebates or price concessions are reported as Direct and Indirect Remuneration (DIR) to CMS, regardless of whether those dollars were retained by the PBM or passed on (in whole or in part) to the Part D plan sponsor. CMS then takes DIR into account when it makes payments to plan sponsors. DIR includes “discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers” from any source—manufacturers, pharmacies, enrollees, or any other

person—that serves “to decrease the costs incurred under the Part D plan.”³⁰⁹

DIR must be reported unless payments do not directly or indirectly affect drug costs regardless of whether the plan sponsor or PBM retains some or all of the remuneration.³¹⁰ Some payments are excluded from the definition of DIR, however, including *bona fide* service fees received from manufacturers that are at or below fair market value.³¹¹

Some critics and organizations assert that PBMs designate payments from manufacturers and pharmacies as fees rather than rebates to prevent these funds from being passed on to plan sponsors.³¹² These administrative fees are significant, and can total 25% to 30% of the negotiated price concession, according to the Pharmaceutical Research and Manufacturers of America (PHRMA), the major trade group for drug manufacturers.³¹³ HHS-OIG also found in a 2011 report that PBMs collect these fees but do not always pass them on to the Part D program.³¹⁴ Of particular concern, HHS-OIG found “limited information” regarding these fees—and the services for which they were provided—in relevant contracts.³¹⁵

Categorizing rebates and other price concessions as “fees” may have important implications for patients and Part D spending. By designating price concessions from manufacturers and pharmacies as fair market value fees for services provided, PBMs may be reducing the dollars reported as DIR to CMS, preventing the Part D program and its beneficiaries from receiving the benefit of the payments from these negotiations. PBMs’ treatment of payments as fees instead of DIR may also impact reinsurance payments and risk corridor calculations for plan sponsors. Further study is needed to understand whether plan sponsors may be also benefiting from these payment categorizations.

Spread Pricing

As payment for their services, PBMs may also negotiate with plan-sponsor clients to keep the spread, defined by one PBM as the difference “between the drug price charged to plan sponsors, including Medicare Part D plan sponsors, by a PBM and the price paid for the drug by the PBM to the dispensing provider.”³¹⁶ Maximizing spread pricing can generate enormous revenues for PBMs. For example, one PBM charged a client \$92.53 for a prescription for which the PBM had accepted just \$26.91.³¹⁷

Spread pricing may drive up costs for beneficiaries and the Part D program. Other entities in the drug payment and supply chain are unlikely to benefit from this practice because they lack information about PBMs’ other financial arrangements. (For example, a plan sponsor does not know the amount paid by the PBM to the pharmacy, nor does a pharmacy know the amount at which the plan sponsor reimburses the PBM.)³¹⁸ Further, CMS does not include spread amounts in its calculation of DIR.³¹⁹ As a result, PBMs may be incentivized to set higher billed charges for the plan sponsor, driving up overall costs for plans and the Part D program.

Maximum Allowable Cost Lists. For generics and multi-source brand name drugs, PBMs may generate this spread through highly confidential “Maximum Allowable Cost” (MAC) lists, which describe the maximum payment the plan will pay for a particular drug.³²⁰

Associations representing generic manufacturers and PBMs contend that MAC lists encourage competition by incentivizing pharmacies to purchase the least expensive version of the generic drug or multi-source brand drug.³²¹ From a PBM’s perspective, MACs keep the costs of generic products down by paying the same amount for clinically equivalent products.³²²

PBMs and plan sponsors strongly oppose efforts to clarify the process for setting MAC list prices and the market factors that drive changes to these

prices. As explained by CVS Health, PBMs must be able to “maintain the confidentiality of proprietary MAC lists” in order “[t]o successfully manage prescription drug costs and help control trend.”³²³

Critics of MACs argue that PBMs use these lists to increase their spread and inflate their profits. They argue that PBMs and plan sponsors use arbitrary criteria when deciding whether to include a drug on a MAC list as well as when setting the price for the product.³²⁴ PBMs may even create multiple MAC lists with different prices to maximize their spread. The National Community Pharmacists Association (NCPA) —the trade association representing America’s community pharmacists—has supported legislation to increase transparency around these MAC lists, arguing that increased transparency would prevent unfair negotiating tactics by PBMs.³²⁵ PCMA has vigorously opposed this legislation, arguing that it would “gut the use of [MAC] lists” and lead to increased costs for federal health care programs.³²⁶

If claims about the lack of transparency are accurate, plan sponsors may not know the amount that they are charged for a generic product versus the reimbursement rate on the PBM’s MAC list. This dynamic may result in spreads that allow PBMs to benefit from higher revenues at the expense of the Part D program. To this point, a recent study concluded that PBMs make almost four times as much on generics as compared to brand drugs.³²⁷ Greater transparency from PBMs regarding these practices and arrangements is needed to fully understand the impact that spread pricing and MAC lists may have for plan sponsors, the Medicare program, and consumers.

MARKET CONSIDERATIONS

Consolidation and Concentration. Like the wholesale distributor industry, the PBM market is significantly concentrated. In 2014, three PBMs—CVS Health, Express Scripts, and OptumRx (a division of UnitedHealth Group)—served approximately 80% of the 180 million individuals who had their pharmacy benefits administered by

a PBM.³²⁸ Similar findings show these three PBMs controlled 73% of the PBM market in 2015 based on total prescription claims.³²⁹ All three companies fell within the top 22 companies on the Fortune 500 list in 2018.³³⁰

Critics argue these three entities have “monopolized control” over the industry³³¹ and created a noncompetitive market.³³² They also argue that, instead of lowering costs, PBMs’ activities result in higher drug prices that raise costs for consumers and the Part D program.³³³ These critics include manufacturers,³³⁴ which argue that PBMs demand rebates but fail to pass along savings to plan sponsors.³³⁵

PBMs maintain that the market is sufficiently competitive, with over 30 PBMs in the industry.³³⁶ The FTC has also weighed in, noting in a 2012 statement that “many competitors other than the Big Three [PBMs] compete effectively in this market.”³³⁷

PCMA contends that the large size of these organizations is the very reason they are able to negotiate effectively, explaining that they “use their substantial scale and expertise” to extract price concessions and cost savings for their customers.³³⁸ According to a 2016 analysis prepared for PCMA, PBMs will produce cost savings for Medicare Part D and its beneficiaries totaling \$257 billion between 2016 and 2025.³³⁹

Vertical Integration and Pharmacy Ownership.

The trend towards integrating different organizations within the drug payment and supply chain is perhaps most apparent when reviewing the business models of the three largest PBMs. For example, each of the three largest PBMs share some form of common ownership with a pharmacy organization, though they have varying structures. CVS Health, which began by operating stores with pharmacy departments, now runs 9,600 retail drugstores and long-term care pharmacy services.³⁴⁰ OptumRx is a division of UnitedHealth Group, which operates the largest health insurance carrier in the country, and also manages specialty and mail-order pharmacies.³⁴¹

Express Scripts is the largest stand-alone PBM and mail-order pharmacy, but does not own retail drugstores.³⁴² Pending mergers would advance the trend toward greater vertical integration.

There are two common denominators to note. First, all three PBMs are part of organizations that own specialty pharmacies: BriovaRx (OptumRx); Accredo (Express Scripts); and CVS Specialty (CVS Health). Second, all operate mail-order pharmacies, including specialty mail order pharmacies, and realize revenues from drugs dispensed through these outlets.³⁴³ According to PCMA, “PBM-managed mail service and specialty pharmacy channels typically give plan sponsors deeper discounts than retail pharmacies.”³⁴⁴

PBM’s focus on specialty pharmacies has likely been prompted by a combination of rising specialty drug use, rapidly increasing prices of these products, and the number of specialty drugs in the pipeline. PBMs argue that specialty pharmacies improve outcomes through clinical support and patient education; meanwhile, MedPAC has noted that PBM-owned specialty pharmacies may be better positioned, in some instances, to negotiate price concessions from manufacturers.³⁴⁵

PBMs have promoted mail-order pharmacies as a way to reduce costs for plan sponsors and their members. For example, PCMA and at least one PBM have cited studies showing that consumers are more likely to adhere to their medication regimen when receiving their prescriptions through mail-order pharmacies.³⁴⁶ In 2014, the FTC explained that PBMs use mail-order services as a way to lower costs and improve patient compliance, and cited a 2005 FTC study that found PBM-owned mail-order pharmacies had lower prices than mail-order pharmacies not owned by PBMs.³⁴⁷ Nonetheless, only 5% of Part D prescriptions are filled by mail pharmacies.³⁴⁸

Critics argue that PBM ownership of specialty pharmacies and mail-order pharmacies presents an inherent conflict of interest. The PBM—as an

owner of a specialty pharmacy or mail-order pharmacy—has an interest in maximizing revenue for both entities, which may be done by choosing the PBM’s specialty pharmacy or a more expensive product. In contrast, these critics argue, the PBM—as the administrator of a plan sponsor’s prescription drug benefit—should have an incentive to choose pharmacies and products that will keep costs low for a consumer and plan sponsor. Evidence suggests that vertical integration does have an impact on plans’ and consumers’ use of particular pharmacies, underscoring these concerns. One report found that in 2007, the year CVS acquired Caremark (its PBM), only 12% of CVS’s revenue was generated by Caremark, but by 2014, that number had increased to 35%.³⁴⁹

Concerns have also been raised that PBMs may be pushing enrollees towards mail-order and specialty pharmacies, even if using another pharmacy is in the best interest of the plan sponsor or the consumer.³⁵⁰ As MedPAC has observed, “the interests served by some specialty pharmacies may not be aligned with those of payers or patients.”³⁵¹ Critics contend PBMs may be more likely to switch consumers to higher-cost drugs or perform fewer generic substitutions in an effort to maximize revenues from more lucrative medications.³⁵²

They also argue that PBMs may be narrowing the network of specialty pharmacies selected to dispense specialty drugs. Several independent specialty pharmacies have filed suits alleging that they have had their network contracts terminated by a PBM over minor terms so that the PBM could steer business towards its specialty pharmacy.³⁵³ Greater transparency is needed for policymakers and the public to understand the impact of PBMs’ vertical integration on the use of specialty products from specialty pharmacies.

Future Oversight. The realm of drug delivery and reimbursement is constantly evolving and warrants continued oversight.

For example, just during the development of this report, two major mergers involving PBMs were announced: CVS Health's planned purchase of Aetna, and Express Script's merger with Cigna. The mergers, if approved, will lead to additional vertical integration within the payment and supply chain that is likely to further complicate efforts to increase transparency on prescription drug pricing.

The Aetna CVS Health merger would combine one of the largest health care insurers with an entity that operates an expansive network of retail drug stores as well as a large PBM. Immediate concerns regarding this merger have centered on its potential anticompetitive effects and the ability of these entities to restrict patient choice.³⁵⁴ With regards to drug pricing, this merger could create a larger organization better positioned to negotiate for steeper price concessions from brand manufacturers. On the other hand, this large organization could lead to higher drug prices if other insurers are not able to compete with this consolidated entity.³⁵⁵ CVS and Aetna have framed this decision as one designed to improve the consumer experience and to save money for both the consumer and the health care system.³⁵⁶

Similar concerns have been raised regarding Cigna's proposed acquisition of Express Scripts in a \$67 billion deal.³⁵⁷ While proponents of the merger argue that this deal will make Cigna a more competitive insurer in the market, others have expressed fears that the consolidated entity will restrict choice and drive up costs for consumers.³⁵⁸

The deal could also mean the end of independent major PBMs. If the CVS-Aetna and Cigna-Express Scripts acquisitions are successful, all major PBMs will share financial ties to some of the largest insurers in the country.³⁵⁹ The result would be a sector of companies that more closely mirror UnitedHealth Group, which includes both a major insurer and a PBM.

KEY FINANCIAL RELATIONSHIPS

PBMs participate in a number of financial relationships that heavily influence prescription

drug spending in the Part D program. However, little information about these relationships is publicly available. This section first focuses on PBMs' relationships with plan sponsors and then considers the financial relationship between a PBM and a pharmacy. For a discussion of PBMs' relationships with drug manufacturers, see Part II of this report.

Plan Sponsors

Plan sponsors pay PBMs for administering their pharmacy benefit. The form of this payment can vary widely. Plan sponsors may compensate PBMs for their services via spread pricing, discussed above, which permits the PBM to retain the difference between what it pays the pharmacy and what it charges the plan sponsor for a particular product. Alternatively, the parties may agree to a pass-through pricing structure in which the PBM does not retain any rebates but instead receives a flat fee for its services. The terms of these arrangements may vary given the size of the plan sponsor and the number of covered lives. PBMs may also agree to take a certain percentage of a manufacturer's discount or rebate as a fee for its services. Likewise, PBMs may earn bonus- or incentive payments for negotiating these rebates or for increasing generic utilization.³⁶⁰

Pharmacies

A PBM generally develops a network of retail and independent pharmacies, and pharmacies may contract with the PBM to join the network. The principal financial relationship involves the payment from PBMs to pharmacies for dispensing the product to a consumer.

Under a typical contract, the PBM and pharmacy set the negotiated price of the product and any other fees or incentives. The negotiated price of the product includes the ingredient cost, dispensing fee, and sales tax.³⁶¹ For brand name drugs, the ingredient cost is usually based on Average Wholesale Price (AWP) less a certain percentage. On the generic side, PBMs typically establish MAC lists and pay pharmacies according

to that pricing schedule. The exact reimbursement methodology for both categories of drugs is set by confidential contract terms and varies based on the parties.

In addition to reimbursing for the product, PBMs may pay a dispensing fee to the pharmacy. According to a 2008 HHS-OIG report, the average dispensing fee paid under Part D to community pharmacies totaled \$2.27 per prescription, with the average fee higher for generics (\$2.36) than for brand name drugs (\$2.11).³⁶² A 2009 HHS-OIG report had similar findings, with the average Part D dispensing fee for five states calculated as \$2.68 for generics and \$2.52 for brand name drugs.³⁶³ In 2015, the National Community Pharmacists Association (NCPA) —the trade association representing America’s community pharmacists— and the National Association of Chain Drug Stores (NACDS) —the trade association representing the chain community pharmacy industry— found an average dispensing cost per prescription of \$10.55 for a community pharmacy.³⁶⁴

DIR Fees. One increasingly common term of arrangements are so-called DIR fees, which are paid by a pharmacy to a PBM or plan sponsor after the point of sale and must be reported to CMS.³⁶⁵

The terms of DIR contracts vary widely, according to information collected by researchers and government agencies. For example, DIR fees may be related to a pharmacy’s performance against certain metrics identified in the contract, such as generic dispensing rates or audit error rates.³⁶⁶ DIR fees also can encapsulate payments from pharmacies to PBMs to participate in preferred networks (as described in more detail below). CMS has observed the “growing prevalence” of these arrangements³⁶⁷. It has solicited feedback, on a proposal meant to ensure that performance-based pharmacy price concessions are reflected in the negotiated price used to determine the beneficiary’s cost-sharing obligation.³⁶⁸

PBMs maintain that DIR fees lower plan premiums for beneficiaries and encourage the use of generics.³⁶⁹ A recent study commissioned by

PCMA found that consumers and the Part D program “realize savings” from point of sale price concessions and post-sale DIR—including the performance-based pharmacy DIR fees.³⁷⁰ However, the study notes that pharmacy DIR fees are a “small portion” of overall savings, which are “largely driven by manufacturer rebates.”³⁷¹

Critics argue that because DIR fees are assessed after the point of sale, they hide actual prescription drug prices paid by the plan sponsor or PBM. To this end, NCPA has requested reforms to these fees because they “mask” actual prescription drug prices.³⁷² In addition, because these fees do not lower the cost of the drug at the time of purchase, the consumer’s cost-sharing obligations are based on the higher pre-fee amount. A report commissioned by the National Association of Specialty Pharmacy (NASP) —the trade association representing the specialty pharmacy industry— explained that DIR fees may increase costs for enrollees and the Part D program through higher point of sale prices that do not reflect these concessions.³⁷³ CMS has noted that higher prices for drugs and higher levels of DIR generally increases beneficiary cost-sharing obligations but also can reduce premiums and some government costs.³⁷⁴

Gag Clauses. PBMs sometimes include contract provisions that prohibit pharmacies from proactively telling a consumer when a drug’s out-of-pocket cost is less than the consumer’s cost-sharing obligations in their prescription drug plan.³⁷⁵ Reports allege that PBMs will “claw back” the difference between what the consumer paid and what the drug costs. PBMs keep the clawed back amount as revenue.³⁷⁶

According to a survey by NCPA, more than half of surveyed pharmacists reported that this type of clause prevented them from mentioning lower-cost options to consumers 10 times or more in the preceding month.³⁷⁷ The same NCPA survey also reported that over 83% of pharmacies had seen this practice at least 10 times in the preceding month.³⁷⁸

In May 2018, CMS Administrator Seema Verma issued a letter to all Part D plan sponsors condemning these gag clauses.³⁷⁹

Pharmacy Services Administrative Organization. A pharmacy may negotiate its contract with a PBM individually or, if it is a member of a Pharmacy Services Administrative Organization (PSAO), through that organization.³⁸⁰ PSAOs provide administrative services to independent pharmacies and operate to improve their position in negotiations with PBMs and plan sponsors. There are varying reports about whether these organizations succeed in gaining additional negotiating leverage. In 2013, GAO found that more than half of the PSAOs it contacted had a successful contract negotiation with PBMs, which GAO attributed to “use of standard contract terms and the dominant market share of the largest PBMs.”³⁸¹ PCMA, however, has described PSAOs as “powerful” organizations.³⁸²

Preferred Pharmacy Networks. For PBMs administering the pharmacy benefit of a Part D

plan sponsor, any pharmacy willing to agree to the PBM’s standard terms and conditions must be allowed to participate in its network for that plan.³⁸³ PBMs may, however, designate preferred pharmacies that offer lower cost-sharing for enrollees. This trend has been increasing steadily: in 2018, nearly all Part D plans offered a preferred network.³⁸⁴ As discussed above, pharmacies often pay fees to PBMs or plan sponsors to be included in these preferred networks.³⁸⁵

PCMA cites a report that analyzed 2014 data and found that preferred networks present opportunities for consumer cost savings.³⁸⁶ In contrast, the NCPA argues that both preferred networks and mail-order pharmacies may actually increase consumer costs.³⁸⁷ Pharmacies support their argument by citing a 2013 CMS study that found, prices were “sometimes higher in certain preferred networks” as compared to non-preferred network pharmacies, even when taking into account mail and retail prescription costs that sponsors may incur.³⁸⁸

PART V: PART D PLAN SPONSORS

Insurers offered 782 Part D prescription drug plans this year, an increase of 36 more than 2017.³⁸⁹ More than 42 million Medicare recipients – roughly 70% of program participants- are enrolled in Part D plans.

ROLE OF PART D SPONSORS

Part D plan sponsors are private insurers that contract with the Medicare program to provide Part D plans to enrollees.

Part D plan sponsors must submit a bid to CMS for each prescription drug plan they offer.³⁹⁰ In this bid, sponsors provide their estimate of average monthly revenue requirements to provide prescription drug coverage to beneficiaries with an average risk profile.³⁹¹ CMS reviews the data submitted with all bids and applies a statutory formula to calculate the per-member per-month payments to plans, known as the direct subsidy. When combined with additional reinsurance subsidies for enrollees who exceed the out-of-pocket threshold, these payments subsidize premiums by about 74.5%.³⁹² For the other 25.5%, enrollees pay a base monthly premium (\$35.02 in 2018) to the plan sponsor, which may increase or decrease based on a number of factors, such as the costliness of plan or the enrollee's income.³⁹³

Medicare shares some of the insurance risk with the plan sponsor in three principal ways:³⁹⁴

First, CMS applies a risk adjustment to the direct-subsidy payments to account for the health status of a plan's enrollees as well as their expected spending.³⁹⁵

Second, if a plan's enrollees reach the catastrophic threshold, the Part D program covers 80% of drug spending above that threshold through reinsurance. The remaining amount is split between the plan (15%) and the enrollee (5%). CMS makes prospective monthly reinsurance payments to plan sponsors that are then subject to

reconciliation. These reinsurance payments to plan sponsors are based on reported reinsurance costs.³⁹⁶

Third, after the benefit year, risk corridors require CMS to limit plan sponsors' losses or profits above or below a specific threshold.³⁹⁷

For calculating both reported reinsurance costs and risk corridor costs, the plan sponsor must include only costs that are "actually paid,"³⁹⁸ which are costs incurred by the plan sponsor and net of any Direct and Indirect Remuneration (DIR).³⁹⁹

FACTORS AFFECTING DRUG PRICING

Bid Development

Plan sponsors' bids determine the payments that Medicare makes each year. For this reason, these submissions are an important first step in analyzing total Part D spending. CMS requires sponsors to "include all expected amounts that will be reported as DIR," in their annual bid submissions.⁴⁰⁰ This number must be its "best estimate of all DIR categories and amounts that they expect to report."⁴⁰¹ This estimated DIR lowers a portion of the plan's estimated liability, which reduces the price of coverage.⁴⁰² By reducing the overall spending of the plan, DIR lowers enrollees' premiums as well as Part D subsidies for premiums.⁴⁰³

Some plan sponsors have underestimated projected DIR amounts in their bids which increase consumer's costs. In 2011, the Office of the Inspector General at Health and Human Services (HHS-OIG) found that Part D sponsors underestimated DIR in 69% of bids submitted for plan year 2008, "which led to higher premiums for beneficiaries in these plans."⁴⁰⁴ Likewise, CMS recently observed that "DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts."⁴⁰⁵

CMS has found that any DIR over the projected amount serves primarily to maximize the plan sponsor's profits and not to lower premiums.⁴⁰⁶ With respect to premiums, CMS calculates the average premium based on the data in the bids. Therefore, any DIR above the bid estimate does not lower plan premiums for that year, but could mean enrollees pay premiums based on a higher cost of coverage than the plan actually incurs.⁴⁰⁷

The understated DIR also may result in the Part D program initially overpaying the plan sponsor for the cost of coverage, though Medicare recoups some of this amount through reconciliation. As part of reconciliation, plan sponsors must report DIR they received in a contract year i.e. the actual amount rather than the estimate.⁴⁰⁸ The amount stated in the DIR report is used when reconciling reinsurance payments and setting risk-corridor payments.⁴⁰⁹ While the plan sponsor and CMS share DIR “based on the share of the total Part D drug costs that each is responsible for over the course of the payment year,”⁴¹⁰ in practice the majority goes to the plan sponsor.⁴¹¹

Insurers and PBMs have both pointed to DIR as the basis for lower premiums as well as savings for the Part D program. The insurance industry's trade group, America's Health Insurance Plans (AHIP), recently testified that discounts and rebates “are passed on through improvements to benefit packages, reductions in premiums, and/or lower out-of-pocket costs.”⁴¹² Likewise, The Pharmaceutical Care Management Association (PCMA)—the trade association representing PBMs—commissioned a report estimating that DIR “will reduce the Federal Government's costs for Part D by a projected \$17.2 billion in 2017.”⁴¹³ The report also found that DIR has resulted in \$12.4 billion of savings on enrollees' premiums from the beginning of the program through 2016.⁴¹⁴ Given CMS's interest in this area, future research should assess whether this bidding process maximizes the benefits of rebates and other price concessions for consumers.

Application of Price Concessions

In addition to raising concerns about plan sponsors' estimates of DIR, CMS and others have drawn attention to how plan sponsors apply the rebates and other price concessions they receive from manufacturers and pharmacies.⁴¹⁵

Requirements. Part D requires plan sponsors to “provide enrollees with access to *negotiated prices* used for payment for covered Part D drugs,”⁴¹⁶ or the prices agreed to by the plan sponsor (or its PBM) and its network pharmacies. These prices must “take into account” price concessions and other DIR.⁴¹⁷ For the majority of price concessions, current law allows plan sponsors to elect whether to (1) apply the price concession at the point of sale or (2) report the price concession on the annual DIR report submitted after the end of the applicable year.⁴¹⁸

Sponsor Practices. In practice, however, plan sponsors seldom elect to pass along price concessions at the point of sale.⁴¹⁹ According to the HHS-OIG, only four of 258 sponsors provided rebates at the point of sale in 2008. Fewer than 1% of beneficiaries at the time were enrolled in plans offered by these sponsors.⁴²⁰

Decisions to apply concessions after the point of sale may be motivated, in part, by the structure of the Part D program. By reporting DIR at the end of the year, the plan sponsor retains the majority of the price concession (which lowers the plan's liability), while the remainder of the concession flows to the Part D program.⁴²¹

Further, as explained by MedPAC, applying rebates to aggregate benefits—rather than at the point of sale—does lower premiums and reinsurance payments.⁴²² Because beneficiaries often compare premiums when selecting a Part D plan,⁴²³ insurers may prefer to apply DIR at the end of the year in order to maintain lower premiums.

Indeed, CMS projects that the basic premium for Part D plans will decline by \$1.20 in 2018, the first decrease since 2012,⁴²⁴ even though Part D prescription drug spending continues to rise and

the Medicare Trustees expect Part D's per-capita growth rate to continue exceeding other categories of medical spending.⁴²⁵ While premium growth remains negative or minimal, this increased overall spending means patients will pay higher cost-sharing and Medicare's liability will increase.

Effects on Enrollees. This dynamic has detrimental consequences for beneficiaries, whose cost-sharing obligations are typically tied to the negotiated price at the point of sale.⁴²⁶ If plan sponsors do not apply price concessions to the negotiated price at the pharmacy counter, enrollees pay cost-sharing obligations based on a higher price that fails to reflect what the plan sponsor ultimately paid for the drug. As a result, enrollees do not receive the benefit of the significant price concessions that their plan sponsors negotiate.

This problem is particularly acute for those enrollees with coinsurance obligations because cost-sharing is based on a percentage of a drug's cost. According to one study, in 2016 more than half of medications offered in Part D had a coinsurance requirement.⁴²⁷ Plan sponsors often place specialty drugs—which are some of the market's most expensive products—on tiers that require the enrollee to pay coinsurance ranging from 25% to 33% until they reach the catastrophic phase⁴²⁸ when enrollees must pay as much as 5% coinsurance on a drug's negotiated price. As a frame of reference, in 2015 1 million enrollees in the catastrophic phase paid more than \$3,000 in out-of-pocket costs.⁴²⁹

Even for enrollees subject to a copayment (a fixed amount) instead of coinsurance, CMS takes the position that Part D plan sponsors' practice of applying concessions after the point of sale may increase copayment amounts.⁴³⁰ In sum, by not applying price concessions and other DIR at the point of sale, plans may keep enrollees' out-of-pocket costs higher. With higher cost sharing, beneficiaries may be less likely to follow—or may abandon—a treatment regimen because the prescription becomes cost prohibitive.

Drivers of Spending

Expensive medications drive overall Part D spending at a rate that may threaten the sustainability of the Part D program. Since the research and development pipeline primarily consists of expensive specialty drugs, these high-cost medications will likely continue playing a prominent role in prescription drug spending.

Some of these high-cost drugs may be accompanied with high rebates for the plan sponsor. In fact, the growth in rebates and other price concessions has resulted in an average annual *decrease* of 5% in plan liability, i.e. the insurer's financial responsibility, from 2010 to 2015.⁴³¹ Given these circumstances, further attention should be paid to how Part D manages rising costs for beneficiaries and whether the current framework incentivizes plan sponsors to encourage the use of the most effective and least expensive drugs.

Reinsurance. The reinsurance framework under the Part D program may reward plan sponsors for selecting high-cost, high-rebate drugs for their formularies over drugs with a lower point of sale price.⁴³² At least one study has found that a higher drug list price shifts cumulative Part D spending from plan sponsors and manufacturers to the Part D program.⁴³³ As a result, the current reinsurance framework also may limit a plan sponsor's incentives to contain an enrollee's spending once he or she reaches the catastrophic phase of coverage.⁴³⁴ While high-cost drug may trigger reinsurance payments for the plan sponsor in the catastrophic phase, enrollees who reach the catastrophic phase are still subject to coinsurance equal to up to 5% of the list price of the drug. For many high-cost specialty drugs, the 5% coinsurance can be substantial and potentially cost-prohibitive. By way of example, individuals without a low-income subsidy who reached catastrophic coverage averaged \$3,041 in out-of-pocket costs in 2015.⁴³⁵

Costs on the program side have been increasing dramatically as well. Between 2007 and 2015, Part

D costs for reinsurance increased steadily by an average of 20% annually. By 2015, reinsurance accounted for more than half of Part D's program spending.⁴³⁶ Consistent with these data, HHS-OIG found that Part D payments during the catastrophic phase jumped from \$10.8 billion in 2010 to \$33.2 billion in 2015,⁴³⁷ and by 2015 two-thirds of total drug spending in the catastrophic phase was attributable to high-priced drugs.⁴³⁸ More recently, the Part D program paid \$37.4 billion in reinsurance in 2017, with that expected to increase to \$39.3 billion in 2018.⁴³⁹ While plan sponsors take the position that DIR reduces reinsurance payments through the reconciliation process, CMS reports that the increase in catastrophic spending has exceeded the growth in DIR.⁴⁴⁰

Part D Coverage Gap. Total drug spending and out-of-pocket spending are calculated based on a product's list price, not the net price after rebates. As a result, utilization of high-cost drugs accelerates enrollees' entrance into the coverage gap-catastrophic phases of the Part D benefit. On the other hand, Part D plan sponsors stand to benefit more from an expensive drug than a lower cost alternative because higher-cost drugs generate higher rebates and push enrollees more quickly to catastrophic coverage. In fact, according to MedPAC, the benefits that plan sponsors gain in the form of higher rebates from high-cost drugs outmatch its 15% liability during the catastrophic phase.⁴⁴¹

Allocation of DIR. The allocation of DIR between Part D and plan sponsors may drive Part D profits higher. The current DIR formula includes a proportional split that allows Medicare to receive a share of DIR above a plan sponsor's initial bid; the plan keeps the majority.⁴⁴² A portion of DIR

are allocated to drug costs above the out-of-pocket threshold (where Part D covers 80% of costs through reinsurance), while the remainder of DIR applies to total gross drug costs below the threshold.

Plan sponsors can use their share of DIR to reduce their financial liability. This is true even in cases when the payments came in the form of rebates or other price concessions for drugs that push beneficiaries past the out-of-pocket threshold and Medicare – not the plan sponsor- is responsible for the majority of costs.⁴⁴³ Based on these findings, some have argued that the Part D program should receive a greater percentage of DIR for high-cost drugs.⁴⁴⁴

List Prices. For plan sponsors, high-cost, high-rebate drugs may ultimately lower plan liability and be financially favorable to plan sponsors' PBMs, who often retain a percentage of the rebates as fees for their services. Because high-cost medications have financial consequences for patients and the Medicare Part D program, an evaluation of how Part D could be reformed to encourage better, more cost-effective care is needed.

KEY FINANCIAL RELATIONSHIPS

As mentioned above, many of the dynamics of the financial relationships between PBMs and other entities in the drug supply web apply equally to plan sponsors who do not contract with PBMs to administer their pharmacy benefit. For a discussion of those relationships, as well as for an overview of plan sponsors' financial relationships with PBMs, see Part IV of this report.

PART VI: PHARMACIES

In 2016, 62,000 pharmacies dispensed more than 4.4 billion prescriptions to consumers.⁴⁴⁵ Pharmacies (as well as health care providers) represent the last step in the delivery of the prescription drugs by dispensing or administering these products to consumers.⁴⁴⁶ Given their direct contact with consumers, they serve an important role in ensuring consumers are able to access needed medications.

THE ROLE OF PHARMACIES

Pharmacies typically purchase drug products from wholesale distributors, though some larger retail and chain pharmacies may purchase directly from manufacturers.⁴⁴⁷ Next, the pharmacy dispenses the medication to the consumer and collects any cost-sharing obligations such as coinsurance or copayments, which the pharmacy then transfers to the Part D plan sponsor or PBM.⁴⁴⁸ The plan sponsor or PBM reimburses the pharmacy at the negotiated price,⁴⁴⁹ which includes the cost of the drug itself and any dispensing fee. While the amount of any dispensing fee varies based on the parties to the arrangement, according to a 2008 HHS-OIG report, the average dispensing fee paid under Part D to community pharmacies totaled \$2.27 per prescription, with the average fee higher for generics (\$2.36) than for brand name drugs (\$2.11).⁴⁵⁰ A 2009 HHS-OIG report had similar findings, with the average Part D dispensing fee for five states calculated as \$2.68 for generics and \$2.52 for brand name drugs.⁴⁵¹ In 2015, the National Community Pharmacists Association (NCPA)—the trade association representing America’s community pharmacists—and the National Association of Chain Drug Stores (NACDS)—the trade association representing the chain community pharmacy industry—found an average dispensing cost per prescription of \$10.55 for a community pharmacy.⁴⁵²

Like other entities involved in the distribution of prescription drugs, pharmacies generate profits for

each prescription dispensed. Of \$100 spent on a drug, pharmacies sees gross margins of 20.1% for all drugs.⁴⁵³ These profits differ significantly between brand name and generic drugs: of \$100 spent at a retail pharmacy, pharmacies keep \$3 for brand name drugs and \$32 for generics.⁴⁵⁴ Perhaps in part because of this difference, generic drugs account for the majority of prescriptions dispensed by pharmacies. One PBM calculated a generic fill rate for Part D stand-alone prescription plans of 85.8% in 2016;⁴⁵⁵ similarly, the trade association for independent pharmacies reported a rate of 84%.⁴⁵⁶

TYPES OF PHARMACIES

Retail Pharmacies

In 2015, drug spending at retail locations reached \$328 billion, representing 71.9% of total prescription spending in the United States.⁴⁵⁷ Although the use of more expensive specialty products purchased and administered by health care providers is on the rise, the majority of spending continues to take place at retail pharmacies. These pharmacies may range from small, independent pharmacies to a large chains or mass merchandisers. According to their respective trade associations, 22,041 “small business community pharmacies”⁴⁵⁸ dispense approximately 40% of retail prescriptions,⁴⁵⁹ while over 40,000 of chain pharmacies, mass merchandisers, and supermarkets, dispense 3 billion prescriptions annually.⁴⁶⁰

DIR Fees. Retail pharmacies—particularly independent pharmacies—have raised concerns about PBMs’ and plan sponsors’ use of Direct and Indirect Remuneration (DIR) fees, which are fees typically assessed against a pharmacy after the consumer pays for his or her medication. These fees can be significant: MedPAC estimates that DIR fees may have been as high as \$1 billion in 2014.⁴⁶¹

Because these fees are retroactive, they are not reflected in the cost of the drug at the time of sale. For purposes of Part D, however, a beneficiary's cost-sharing obligations as well as the calculation of his or her progression through the Part D benefit are based on the cost of the drug at the point of sale.⁴⁶² As a result, higher pre-fee prices drive a beneficiary's cost-sharing obligations and the Part D benefit calculations, which speeds up the beneficiary's entrance into the catastrophic coverage phase. NCPA argues that DIR fees, discussed in more detail in Part V, therefore increase costs for beneficiaries and the Part D program.⁴⁶³ As described earlier in this report, The Pharmaceutical Care Management Association (PCMA)—the trade association representing PBMs—responds by asserting that these DIR fees reduce premiums and program spending, citing a report estimating that all DIR—which includes DIR fees as well as other price concessions (*e.g.*, manufacturer rebates)—would save the Part D \$17.2 billion and beneficiaries \$3.2 billion in 2017.⁴⁶⁴

Most commonly, pharmacies pay DIR fees in exchange for the pharmacy's placement in a PBM's or Part D plan sponsor's preferred network. DIR fees may also be tied to performance-based goals for pharmacies. For instance, PBMs and plan sponsors may measure pharmacies based on: (1) generic dispensing rate; (2) customers' medication therapy management participation; (3) diabetes disease management programs; and (4) customers' medication adherence.⁴⁶⁵ Alternatively, these fees may serve as true-up payments related to the reimbursement the pharmacy received for the drug.⁴⁶⁶

Preferred Networks. In return for being able to participate in the preferred network, the PBM or plan sponsor may agree to steeper discounts, lower dispensing fees, or other price concessions that are labeled as DIR fees.⁴⁶⁷ Today, preferred networks are standard industry practice, with 99% of Part D plans offering a preferred network in 2018.⁴⁶⁸ Although Part D has certain “any willing pharmacy” requirements, CMS allows Part D

plans to use preferred pharmacy networks.⁴⁶⁹ Pharmacies in a Part D plan's preferred network offer lower cost-sharing obligations,⁴⁷⁰ which can reduce spending for patients and the program. In fact, a 2013 report commissioned by PCMA found that preferred networks would save the Part D program \$7.9 billion to \$9.3 billion over a ten-year period.⁴⁷¹ However, a 2013 CMS study concluded that “aggregate unit costs weighted by utilization were lower in preferred networks for the majority of sponsors with this type of network,” but that some plans had higher aggregate unit costs in preferred networks.⁴⁷²

In 2018, major chain pharmacies have varying levels of participation in plans' preferred networks.⁴⁷³ This year isn't unique - historically, larger pharmacies have shown reluctance to become part of preferred networks because the benefit of higher prescription volumes has not outweighed the sacrifice of lower margins from DIR fees.⁴⁷⁴ Given the potential savings for Part D enrollees through lower cost sharing, it is important to monitor how chain pharmacies adapt to the preferred-network structure.

Independent pharmacies are even less likely to participate in preferred networks. An analysis of the four largest Pharmacy Services Administrative Organizations (PSAOs)—which, as described in detail below, contract with PBMs and plan sponsors on behalf of independent pharmacies—revealed that their members participate as preferred pharmacies in less than half of the largest Part D plans' networks 2018.⁴⁷⁵ This lack of participation has resulted in independent pharmacies raising a number of concerns about DIR fees that are often a condition of participation in preferred networks. For instance, they have focused on the lack of transparency in the calculation of the fees, which sometimes render transactions unprofitable.⁴⁷⁶ According to NCPA, PBMs are not transparent about the criteria used to assess DIR fees;⁴⁷⁷ further, according to one study conducted by NCPA, the majority of pharmacists do not receive any claim-level information about the fees that have been deducted.⁴⁷⁸ According to

independent pharmacies, the rising DIR fees may threaten patients' access to medications because they will not be able to continue to operate if they are selling products below cost.⁴⁷⁹

Pharmacy Services Administrative Organizations. PSAOs are a lesser-known entity involved in the negotiation of reimbursement for prescription drugs. Independent pharmacies pay a fee to join PSAOs, a network of pharmacies that rely on the umbrella organization to provide certain administrative services. In return, the PSAO negotiates the pharmacies' contracts with Part D plan sponsors, PBMs, and other entities, and the PSAO also offers other administrative services.⁴⁸⁰ The PSAO uses the leverage gained by its network of members to seek more favorable contract terms for these pharmacies, though a 2013 GAO report noted that PSAOs have had limited success in these negotiations with PBMs.⁴⁸¹ Nonetheless, PCMA has highlighted independent pharmacies' participation in PSAOs in response to arguments by independent pharmacies that they do not have sufficient leverage to negotiate favorable reimbursement rates with plan sponsors and PBMs.⁴⁸²

Specialty Pharmacies

In 2016, specialty drugs constituted 42.9% of net prescription drug spending in the United States, up from 23.6% in 2006.⁴⁸³ Over one-third of research programs in Phase II clinical trials or later relate to specialty medications.⁴⁸⁴ Given the significant increase in the number of specialty medicines and research projects, the specialty pharmacy industry has enjoyed enormous success and growth, with an estimated \$78 billion in sales in 2014.⁴⁸⁵

The National Association of Specialty Pharmacy (NASP) —the trade association representing the specialty pharmacy industry— defines a specialty pharmacy as “a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies.”⁴⁸⁶ Specialty pharmacies may be independent entities, but some of the largest are owned by distributors and PBMs. In addition,

hospitals and other healthcare providers increasingly have set up their own specialty pharmacies because they have recognized the significant potential profits from this industry.⁴⁸⁷ As a result, provider-owned specialty pharmacies are the fastest-growing category in this industry.⁴⁸⁸

Conflicts of Interest. Given the common ownership of specialty pharmacies with other entities involved in the distribution of—and payment for—specialty medicines, critics have raised concerns about conflicts of interest in this industry. For example, a PBM administering the prescription drug benefit on behalf of Part D plan sponsors may also own a specialty pharmacy. This PBM would then be incentivized to steer enrollees to its pharmacy, even if doing so results in higher costs for plans and beneficiaries.⁴⁸⁹ CVS Health and Express Scripts own two of the largest specialty pharmacies in the country, suggesting these conflicts – to the extent they exist – could implicate large numbers of transactions.⁴⁹⁰

On the other hand, partnerships between specialty pharmacies and other stakeholders give the vertically integrated entity greater leverage in the drug payment and supply chain, allowing these entities to negotiate more favorable rebates from manufacturers.⁴⁹¹ A better understanding of how this vertical integration may hinder competition and drive up drug costs is warranted.

DIR Fees. Like retail pharmacies, specialty pharmacies have raised concerns about the “abuse of DIR fees” by PBMs.⁴⁹² Paying these fees may be required in order for specialty pharmacies to participate in the PBM's preferred network. However, according to NASP, the trade association for these pharmacies, performance-based fees do not take into account the unique role of specialty pharmacies because these fees “are based on wholly inapplicable performance or quality metrics on drugs, events and/or services that do not occur at the specialty pharmacy.”⁴⁹³ NASP and others have also voiced concerns that PBMs may use DIR fees as a way to force independent specialty pharmacies out of the

market because these fees undercut these pharmacies' profits. By driving out these pharmacies, NASP points out, PBMs may also be reducing competition for their internally-owned specialty pharmacy.⁴⁹⁴

Limited Distribution Networks. As noted earlier in this report, manufacturers may develop limited distribution networks of specialty distributors and specialty pharmacies to dispense certain specialty medicines.⁴⁹⁵ These arrangements may prevent testing for the development and approval of generic products.⁴⁹⁶ In cases when a manufacturer selects only one specialty distributor, pharmacies argue that they are unable to negotiate lower prices, which may result in higher costs across the board.⁴⁹⁷

In Part D, the Secretary of Health and Human Services must establish rules that require plan sponsors to secure sufficient network participation by pharmacies to ensure convenient access.⁴⁹⁸ For Part D drugs, CMS takes the following position about limiting the pharmacies that can dispense specialty medications:

Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy.⁴⁹⁹

Nonetheless, independent pharmacies contend that Part D plan sponsors and PBMs have implemented limited dispensing networks that steer enrollees to the specialty pharmacy owned by the plan sponsor or PBM.⁵⁰⁰ In addition, NASP highlighted that PBMs or plan sponsors may include contract terms requiring specialty pharmacies to stock certain limited distribution drugs that only a handful of pharmacies can access to, effectively excluding

the majority of specialty pharmacies.⁵⁰¹ Future research should explore how limited distribution networks influence beneficiary access to specialty medications, and how prices may be affected by limiting the marketplace for these products.

Mail-Order Pharmacies

Most retail chains and PBMs provide mail-order pharmacy services,⁵⁰² though the number of prescriptions dispensed by mail services has declined from 715 million in 2012 to 548 million in 2016.⁵⁰³ One of the key benefits of mail-order pharmacies is their economies of scale, which may lower costs for patients and the Part D program.⁵⁰⁴ These pharmacies typically dispense medications that treat chronic illnesses rather than those medications for acute conditions.⁵⁰⁵

Part D plans may—but are not required to—include mail-order pharmacies in their networks.⁵⁰⁶ If they do offer certain benefits through mail-order pharmacies (*e.g.*, 90 day supplies of drugs), then plan sponsors must provide reasonable access to the same benefits at retail pharmacies. However, plans may impose certain higher cost-sharing obligations on beneficiaries for obtaining these benefits in the retail setting.⁵⁰⁷ In 2013, CMS found that negotiated prices for drugs dispensed through mail-order pharmacies were higher than at retail pharmacies for certain Part D plans.⁵⁰⁸ In contrast, the FTC has argued that CMS's findings show that, overall, mail-order pharmacies generated substantial savings.⁵⁰⁹

Some observers have highlighted potential conflicts of interest arising from PBMs' or plans' ownership of some of these mail-order pharmacies.⁵¹⁰ For example, SilverScript—a Part D plan owned by CVS Health—includes in the description of its pharmacy network a significant advertisement for CVS Caremark's Mail Service Pharmacy and itemizes the financial benefits of using these mail services. From the available information on the website, CVS Caremark Mail Service Pharmacy appears to be the only available option for enrollees of this plan.⁵¹¹

Independent pharmacies and other critics have argued that PBMs and plans may decrease competition by setting terms that steer patients to the mail-order pharmacies they own, even if such terms do not produce cost savings for the patient or the plan.⁵¹² They also assert that these mail-order pharmacies do not pass on the savings they achieve from their economy of scale. More specifically, instead of charging the lower price they receive for drugs bought in large volumes, they charge the same price as that of a retail

pharmacy, which likely does not get the same volume discounts.⁵¹³ Some smaller mail-order pharmacies also maintain that they have been excluded from PBMs' networks because they compete with the PBM-owned mail pharmacy.⁵¹⁴

KEY FINANCIAL RELATIONSHIPS

Parts II through IV of this report address the key financial relationships that pharmacies hold with distributors, PBMs, and plan sponsors.

CONCLUSION

No single entity is solely responsible for the high and rising cost of drugs that consumers face in the United States.

This report shows how each business in the supply chain stands to benefit from the tangled web of financial arrangements that has developed in the drug payment and supply chains. For all the talk of bringing down costs for consumers, the evidence suggests that many companies in the supply chain may actually contribute to, or even encourage, high drug prices, drug price increases and rising consumer costs.

What's clear is that as their drug bills continue to soar, consumers are struggling to understand how they benefit from the rebates, discounts, and price concessions that have made middlemen in the pharmaceutical supply chain some of the nation's largest businesses. Seven of the 25 largest companies in the United States make most of their money in the pharmaceutical business, but none of them have any role actually manufacturing drugs. The system is bloated, filled with inefficiencies, and puts corporate profits ahead of consumers' needs.

Manufacturers are incentivized to set high launch prices to maximize profits. These launch prices can then be increased throughout a drug's lifetime, particularly when manufacturers use patent protections, exclusivity rights, and other methods to discourage the entry of generic and biosimilar competitors. When a drug occupies an exclusive corner of the market, it allows manufacturers to exert even greater leverage against downstream stakeholders in the payment and supply chains, including wholesale distributors, insurers, pharmacy benefit managers (PBMs), and pharmacies. Accordingly, manufacturers realize their largest profits from the sale of single-source brand name drugs, even after providing rebates and price concessions.

Downstream entities also benefit from high prices in a variety of ways. PBMs collect larger rebates when dealing with medications with higher list prices. Private insurers managing Part D plans face lower financial liability on expensive drugs that push beneficiaries to the final phase of the Part D benefit. Wholesale distributors have stated in no uncertain terms that their bottom line stands to suffer if branded or generic prices increase slowly.

PBMs and plan sponsors often receive rebates or concessions from manufacturers or pharmacies after the point of sale, i.e. after consumers have already paid their out-of-pocket expenses. Manufacturers argue that these rebates and price concessions drive their decisions to raise drug list prices, even though reports demonstrate that list prices are growing faster than rebate amounts. Either way, patients are left shouldering larger cost-sharing obligations, which are based on the list price of a drug.

Other opaque arrangements restrict the information consumers can access, which can also lead to higher costs. As just one example, PBMs can insert contract provisions known as "gag clauses" that prohibit pharmacies from telling their customers that they can purchase certain drugs with cash for less than the amount of their copayment required by their insurance. There is also very little understanding about the practice known as "spread pricing," which allows PBMs to extract profits from the financial transactions between health plans and pharmacies with no apparent added value. Consumers should feel confident they are paying a fair price for their drugs, not be left wondering if they are being hoodwinked. Obtaining insight into these and other practices by middlemen may prove even more difficult as consolidation increases within and across sectors in the pharmaceutical payment and supply chains.

This report should serve as a wake-up call, illustrating the need to untangle this complex tangled web of deals and arrangements.

The report reveals an urgent need for consumers and the government to more fully understand how these financial arrangements impact the drug prices and the resulting costs consumers and federal health programs pay for medications. That starts by discovering where and to whom the money is flowing.

Without action, consumers will continue struggling with the unsustainable costs of drugs and may have to increasingly forgo medications altogether. In 2016, approximately one in seven insured American adults failed to fill a prescription or skipped a dose because of the cost of a medication.⁵¹⁵ These rates rose among adults without continuous coverage, one-third of whom

did not fill a prescription or skipped doses due to cost. That same year, a quarter of adults with two or more chronic conditions cited cost as a reason for skipping their prescriptions.⁵¹⁶

Medicare and other payers also bear the financial consequences of escalating drug costs in the form of increased spending, leaving beneficiaries with higher premiums and out-of-pocket costs and taxpayers left paying the bill.

The challenges in the current drug pricing system will not resolve themselves. Without action, Americans will continue to struggle as the system's convoluted incentives drive up prices that benefit businesses up and down the supply and payment chain. This report is a first step towards understanding why and how the system is broken so work can begin to fix it.

ENDNOTES

¹ CTRS. FOR MEDICARE & MEDICAID SERVS. (“CMS”), HHS, NHE TABLE 2 (2017), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>; WORLD BANK, NATIONAL HEALTH EXPENDITURES; AGGREGATE AND PER CAPITA AMOUNTS, TABLE 2 (2016), <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=US>.

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³ The term “health care provider” for the purposes of this report includes both providers of services and suppliers as defined in Title XVIII of the Social Security Act.

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²⁹³ PEW CHARITABLE TRUSTS, *supra* note 159.

²⁹⁴ *State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary*, 114th Cong. (2015) (statement of David A. Balto) [hereinafter Balto Hearing Testimony]; *see also* Reilly Statement, *supra* note 193; Max Nisen, *Remicade Is a Litmus Test for PBMs*, BLOOMBERG BUSINESSWEEK (Aug. 17, 2017) (“There may be cases where nudging patients to a deeply discounted brand name drug may be more profitable than pushing a generic or biosimilar alternative.”).

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²⁹⁹ *Formulary Design*, PCMA (n.d.), <https://www.pcmamet.org/policy-issues/formulary-design/>.

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³⁰¹ NATIONAL ACADEMIES, *supra* note 196, at 16.

³⁰² Dayen Middleman Article, *supra* note 283 (“Health plans have no way to obtain drug-by-drug cost information to know if they’re getting the full discount.”).

³⁰³ Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017, S. 637, 115th Cong. (2017).

³⁰⁴ SOOD ET AL., *supra* note 60, at 5.

³⁰⁵ *Id.* at 8.

³⁰⁶ Press Release, PCMA, New Market Analysis Shows No Connection Between Drugmaker Pricing and Rebates (2017) (*citing* VISANTE, NO CORRELATION BETWEEN INCREASING DRUG PRICES AND MANUFACTURER REBATES IN MAJOR DRUG CATEGORIES (Apr. 2017). It is important to note, however, that at least one of the two sources cited in the Visante report evaluated only rebate arrangements for employer-sponsored plans when reaching the figure of 90%. *See* Adam J. Fein, *Solving the Mystery of Employer-PBM Rebate Pass-Through*, DRUG CHANNELS (Jan. 14, 2016), <http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html>. It is unclear if these findings also would apply to arrangements between PBMs and Part D plan sponsors.

³⁰⁷ *See The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II*, 114th Cong. (2017) (statement of Mark Merritt, President and Chief Executive Officer, PCMA) [hereinafter Merritt Hearing Statement].

³⁰⁸ OIG CONCERNS WITH REBATES REPORT, *supra* note 190, at 17.

³⁰⁹ 42 C.F.R. § 423.308.

³¹⁰ Cheri Rice Letter, *supra* note 203, at 11.

³¹¹ 42 C.F.R. § 423.501. *See* Cheri Rice Letter, *supra* note 203, at 10 (providing examples of remuneration that do not constitute DIR).

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- ³¹⁴ OIG CONCERNS WITH REBATES REPORT, *supra* note 190, at 18–19.
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- ³¹⁶ CVS HEALTH CORPORATION, ANNUAL REPORT (FORM 10-K) at Exhibit 13, 7 (Feb. 9, 2017) [hereinafter 2017 CVS FORM 10-K].
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⁴⁰⁹ 2017 MEDPAC PAYMENT POLICY REPORT, *supra* note 24, at 403.

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⁴¹⁷ *Id.* § (d)(1)(B). As of January 1, 2016, negotiated prices must include all price concessions from and additional contingent payments to pharmacies except for those that “cannot reasonably be determined at the point of sale.” 42 C.F.R. § 423.100; *see also* Cheri Rice Letter, *supra* note 203, at 5 (explaining the revised definition of “negotiated price”). Almost all price concessions, however, come from manufacturers, not pharmacies.

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- ⁴³² 2017 MEDPAC PAYMENT POLICY REPORT, *supra* note 24, at 404–05 (*citing* ADAM J. BARNHART & JASON GOMBERG, THE AIDS INSTITUTE, FINANCIAL INCENTIVES IN MEDICARE PART D 1 (2016)).
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- ⁴³⁷ OIG, HIGH-PRICE DRUGS ARE INCREASING FEDERAL PAYMENTS FOR MEDICARE PART D CATASTROPHIC COVERAGE 7 (2017).
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