

AHLA PG Toolkit

THE ROLE OF REBATES IN THE PHARMACEUTICAL INDUSTRY

July 30, 2021

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INTRODUCTION

Rebates offered by drug companies lie at the heart of the long-standing debate over drug prices. They are typically designed to align the incentives of buyers and sellers and are often an integral element of complex contracts. It is also common for rebates to be shrouded in secrecy as they are generally considered competitively sensitive information. Rebates are nevertheless central to an understanding of prices and competition in the pharmaceutical industry. This toolkit discusses where and why rebates arise in the pharmaceutical industry and some of the key features of these often poorly understood financial flows.

WHAT ARE DRUG REBATES?

Rebates are not unique to the pharmaceutical industry. Consumers generally become familiar with rebates through offers on the retail products they purchase. Rebate coupons are essentially contracts with simple terms. For example, rebate offers may state, “Send in a proof of purchase and we’ll send you a \$5.00 check,” or “Register your product with us and receive \$10.00 off your next purchase.” In effect, these designs reward customers for providing basic information about themselves to the manufacturer or incentivize them to buy more products from the company. There is a quid-pro-quo aspect to these transactions: in exchange for something of value to the company, the company is willing to compensate the consumer.

Drug rebates are conceptually similar to consumer rebates but can be complex in practice. Drug manufacturers usually offer rebates for:

1. Prompt payment
2. Volume of purchasing
3. Purchase loyalty
4. Increased breadth of purchases across a portfolio

There are typically multiple parties financially involved in the process of buying and selling prescription drugs. The supply chain and parties negotiating over pricing and market access depend primarily on whether the product is a single-source branded product or a multiple-source (generic) drug. The type of rebate and its recipient, therefore, depends on both the entity involved and the type of drug. For example, managed care rebates are generally negotiated between pharmacy benefit managers (PBMs) and branded pharmaceutical manufacturers as part of the contract governing patient access to insurance coverage for the product. Because wholesalers play little role in market access for branded products, they do not receive this type of rebate. On the other hand, prompt payment discounts are a nearly universal feature of contracts between manufacturers and direct buyers such as wholesalers and pharmacies.¹ Because these discounts are contingent on the post-purchase performance of the buyer, they are also effectively rebates.² In contrast, because health plans and PBMs do not generally purchase pharmaceuticals directly, they do not have prompt payment clauses of this type written into their contracts.³

Virtually all rebate contracts in the pharmaceutical industry are the result of negotiation, which reflects market structure on both sides of the negotiating table. Branded pharmaceutical companies face varying competitive dynamics ranging from near monopoly conditions (e.g., for a first-in-class product) to highly competitive

¹ *Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain*, THE KAISER FAMILY FOUND./THE HEALTH STRATEGIES CONSULTANCY LLC, pp. 1, 3, 9, 17–18 (Mar. 2005), https://avalere.com/research/docs/Follow_the_Pill.pdf (hereinafter *Understanding the US Commercial Pharmaceutical Supply Chain*).

² For example, *Wholesale Product Purchase Agreement*, SECURITIES AND EXCHANGE COMM’N, Section 2.2 (Jan. 1, 2018), https://www.sec.gov/Archives/edgar/data/1082554/000104746918000911/a2234069zex-10_51.htm.

³ G. Dieguez, M. Alston, and S. Tomicki, *A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices*, MILLIMAN, p. 1 (May 21, 2018), <https://www.milliman.com/-/media/Milliman/importedfiles/uploadedFiles/insight/2018/prescription-drug-rebates.ashx>.

conditions in crowded therapeutic categories. They generally negotiate pricing with PBMs or other large managed care organizations that can steer pharmaceutical demand for large numbers of beneficiaries. A relatively small handful of PBMs serve as gatekeepers to a large percentage of the insurance-covered beneficiaries in the United States. Generic manufacturers also face varying levels of competition, ranging from large numbers of suppliers vying over sales of a former blockbuster, to relatively few suppliers for low-volume generic drugs.⁴ Generic manufacturers do not typically enter into supply agreements with PBMs (apart from PBM-run mail-order operations). Instead, they generally negotiate pricing with the companies that stock their products, such as retail pharmacies and generic source programs (a generic drug one-stop-shop alternative for independent pharmacies run by wholesalers like McKesson). Like the situation with PBMs, a relative handful of pharmacy chains and wholesalers account for a significant percentage of generic drug purchases. For any given drug, whether branded or generic, relatively few suppliers and buyers account for the majority of sales. These are conditions where negotiated contracts and rebates are likely to arise and, as a consequence, prices will not generally be uniform across buyers.⁵

On the manufacturers' side, rebate contracting can mitigate the risk associated with facing a relatively concentrated set of buyers. With relatively few PBMs controlling prescription access to a majority of insured patients, there is the potential for a substantial portion of patient demand to hinge on a single contract. By incentivizing buyer commitments, manufacturers can reduce the overall demand uncertainty this demand sensitivity could induce. For purchasers, receiving rebates in exchange for steering patients toward a product can be an opportunity to leverage buying power to negotiate low prices. The rebates that result may depend on the specifics of the demand-steering mechanism employed by the payer, the type of drug, and various institutional factors. The most prominent driver of drug rebates is the availability of competing products that can act as substitutes, which could lead to a more expensive comparable product having coverage reduced or eliminated. Thus, the magnitude and prevalence of rebates are typically an indication of competitive conditions. Generally, manufacturers will offer lower prices (higher rebates) for purchasers who not only have competitive options available but are also more willing (or able) to induce patients to switch among the available options. The rebate provisions in the pharmaceutical industry that move the most money are typically those designed to reward the achievement of volume, consistency, or breadth of purchases by the buyer.⁶ These provisions go beyond simple price reductions, as the buyer "earns" these rebates by meeting certain obligations.⁷ These incentives can lead to contract structures that align the interests of manufacturer and purchaser.

It is worth noting, however, that the rebate arrangements described here would typically run afoul of the Anti-Kickback Statute (AKS) if applied to government reimbursement programs. Nevertheless, formulary rebates are an important component of Medicare Part D drug pricing because a specific AKS safe harbor has been created for these arrangements within Medicare Part D and certain other government programs.

BRANDED SINGLE-SOURCE PRODUCTS

Drug manufacturers' rebate decisions are influenced in part by how those rebates may impact a product's demand in the marketplace. For branded (single-source) pharmaceuticals, the main demand-steering mechanism that health plans or PBMs utilize is their drug "formulary." A drug formulary is a list that governs which products will

⁴ Henry Grabowski and Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, MANAGERIAL AND DECISION ECON., Vol. 28, Issue 4–5, pp. 491–502 (2007).

⁵ See, e.g., Matthew Grennan, *Price Discrimination and Bargaining: Empirical Evidence from Medical Devices*, AM. ECON. REV., Vol. 103, pp 145–177 (2013), for an examination of the economics of negotiated contracts in a life sciences context.

⁶ Katie Thomas, *Meet the Rebate, the New Villain of High Drug Prices*, N.Y. TIMES (July 27, 2018), <https://www.nytimes.com/2018/07/27/health/rebates-high-drug-prices-trump.html>.

⁷ See *Understanding the US Commercial Pharmaceutical Supply Chain*, *supra* note 1, at pp. 17–20.

be covered by the plan, the patient's out-of-pocket costs, and other conditions that might be imposed.⁸ Formularies are typically arranged in tiers by therapeutic category such that more preferred drugs are placed in lower tiers, and less preferred drugs are placed in higher tiers.⁹ In general, the patient is responsible for more of the cost for drugs in higher tiers. Varying copayments are the most common mechanism for regulating patient costs. A patient would typically find low-cost generic drugs placed in the tier with lowest copayment requirements, while they would find high-cost products for which there are lower-cost alternatives placed in a higher, more expensive tier. If the drug is not listed on the formulary or is explicitly excluded, the patient would simply not be covered for the product and face its full cost.

PBMs have a variety of other mechanisms by which to steer demand. For example, they can steer patients away from less preferred products by requiring prior authorization (PA) before agreeing to reimburse their use.¹⁰ They may also employ "step" therapy (also known as "step" edits or "fail first" policies), which requires a patient to use certain preferred medications before being allowed to use an alternative that might have been prescribed by their doctor.¹¹ In some drug classes, several products must be tried before less preferred products will be covered.

Because formularies impact patient treatment choices, PBMs employ teams of physicians and other professionals to contribute to formulary placement decisions.¹² These groups are typically known as Pharmacy and Therapeutics (P&T) committees.¹³ Economics are not the sole determinant of formulary placement; these decisions generally balance medical questions such as efficacy, safety, and comparability with the economic considerations.¹⁴ A product may be preferred due to its favorable efficacy and safety profile. Plans vary regarding the level of control they exert over treatment decisions, which can affect several mechanisms such as the number of drug exclusions, steps edits, and prior authorizations that might be imposed, as well as the structure of patient costs.¹⁵ A high-steering plan imposes more control over treatment, while low-steering plans place fewer controls. These decisions can have implications for the rebates they can negotiate with manufacturers.

Manufacturers are willing to offer rebates to PBMs and health plans for preferential formulary placement because of the power of the formulary to steer demand.¹⁶ Although at one time many health plans developed their own formularies, the role of PBMs rose because of their ability to aggregate the demand across many health plans and, thus, drive more market share in formulary negotiations with manufacturers.¹⁷ This has the potential effect of increasing demand elasticity, which can allow the PBM to negotiate lower prices. Because PBMs generally manage formularies for numerous health plans, they typically offer a variety of alternative formulary plans, ranging from

⁸ Amanda Cole, Adrian Towse, Celia S. Segel, Chris Henshall, and Steven D. Pearson, *Value, Access, and Incentives for Innovation: Policy Perspectives on Alternative Models for Pharmaceutical Rebates*, INST. FOR CLINICAL AND ECON. REV. pp. 3–4 (Mar. 2019) (hereinafter *Policy Perspectives on Alternative Models for Pharmaceutical Rebates*).

⁹ There is no consistent meaning of formulary tiers from plan to plan. While a product in "tier 2" can generally be interpreted as having better patient access than "tier 3" within a given plan, it is not generally possible to directly compare tiers across plans. Plans vary both in how many tiers they might present to their beneficiaries, and what those tiers signify.

¹⁰ See H. Grabowski and C. D. Mullins, *Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions*, SOC. SCI. MED., 45(4) (Aug. 1997), for a more complete discussion (hereinafter *Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions*).

¹¹ *Id.*

¹² *ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System*, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx>.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Ruhul Shenolikar, et al., *Sensitivity of Medication Use to Formulary Controls in Medicare Beneficiaries: A Review of the Literature*, AM. HEALTH AND DRUG BENEFITS, Vol. 4, No. 7, pp. 465–474 (2011).

¹⁶ *Policy Perspectives on Alternative Models for Pharmaceutical Rebates*, *supra* note 8, at p. 3.

¹⁷ See, e.g., April Alexander and J.P. Wieske, *Managing Prescription Drug Benefits*, PHARM. CARE MGMT. ASS'N, p. 6 (Aug. 29, 2019), <https://content.naic.org/sites/default/files/inline-files/PCMA%20Presentation%20082919%20-%20Final.pdf> (hereinafter *Managing Prescription Drug Benefits*).

low-steering/higher-cost plans to high-steering/lower-cost plans.¹⁸ Some health plans prefer more open access with fewer prior authorization restrictions and less powerful copay incentives to steer patients among products. These lower-steering formularies have less potential to generate rebates from manufacturers. Formularies with closed access and tight formulary restrictions can generate significant rebates due to their greater ability to steer patients.

Because of encompass a range of possibilities in a menu-like format. For each product covered by the contract there may be a grid spelling out a range of rebate levels associated with different formulary structures (e.g., PA or step-edit controls). Many other features may appear in these contracts, such as rewards for achieving volume or share targets or meeting goals for purchases across the portfolio of products on offer. Generally, the amount of rebate paid to the PBM is not known by either party to the rebate contract (though it is often predicted) until after the fact, when each this plan-to-plan variation, it is not unusual for contracts between PBMs and manufacturers to plan's utilization has been tallied and an accounting can be made to the manufacturer. As a result, prices inclusive of rebates are only known to both parties ex-post.

The amount of rebate passed back to the individual plans varies depending on the contracts they have with the PBM. These arrangements vary substantially, with some plans opting for fully transparent pass-through of all rebates, while others opt for a share of rebates to be passed through or fully fixed per-prescription costs (i.e., no direct rebate pass-through).¹⁹ The extent to which PBMs pass rebates along to their plan customers has been a topic of debate for many years. It has been argued that PBMs are in a position to excessively profit from retention of undisclosed rebates, although it is not apparent that PBMs actually experience outsize margins compared to other participants in the pharmaceutical supply chain.²⁰ Calls for greater PBM transparency have led to state laws requiring disclosure of certain information related to PBM contracts to state boards.²¹ This has raised concerns because cost disclosures are rarely required to achieve competitive outcomes, and may indeed facilitate tacit coordination among suppliers.²² In recent years, the market has also been evolving in ways that may address some of these concerns. For example, the share of PBM arrangements based on 100% pass-through of rebates has been increasing,²³ and several large PBMs have also been re-integrated into large national health plans.²⁴

¹⁸ For example, CVS Health (Caremark), the top PBM in the U.S. prescription market in 2018, manages multiple formularies, including standard control formulary, advanced control formulary, advanced control specialty formulary, and the value formulary. See *Market share of the top 5 pharmacy benefit managers in the US prescription market in 2018*, STATISTA, <https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/>; *Formulary Management*, CVS Health, <https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management>.

¹⁹ See Adam J. Fein, *Employers Are Absorbing Even More Manufacturer Rebates from Their PBMs*, DRUG CHANNELS (Mar. 12, 2019), <https://www.drugchannels.net/2019/03/employers-are-absorbing-even-more.html> (hereinafter *Employers Are Absorbing Even More Manufacturer Rebates from Their PBMs*).

²⁰ See, e.g., Michael Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFAIRS BLOG (Aug. 30 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180823.383881/full/>. See also *Managing Prescription Drug Benefits*, supra note 17, <https://content.naic.org/sites/default/files/inline-files/PCMA%20Presentation%20082919%20%20-%20Final.pdf>.

²¹ In fact, Maryland, South Dakota, Vermont, and the District of Columbia all “require PBMs to disclose information concerning agreements and rebate arrangements between PBM and prescription drug manufacturers.” Joanna Shephard, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Market*, Emory University Legal Studies Research Paper Series, 13–245 (2013), https://www.ftc.gov/system/files/documents/public_comments/2014/02/00006-88685.pdf (hereinafter *Is More Information Always Better?*).

²² See, e.g., John Breslin, *Legal expert issues warning over federal disclosure bills aimed at pharmacy benefit managers*, AM. PHARMACY NEWS (June 12, 2017), <https://americanpharmacynews.com/stories/511125630-legal-expert-issues-warning-over-federal-disclosure-bills-aimed-at-pharmacy-benefit-managers>, and *Is More Information Always Better?*, supra note 21.

²³ *Employers Are Absorbing Even More Manufacturer Rebates from Their PBMs*, supra note 19.

²⁴ See, e.g., Adam J. Fein, *CVS, Express Scripts, and the Evolution of the PBM Business Model*, DRUG CHANNELS (May 29, 2019), <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>.

The level of rebates offered by manufacturers to PBMs varies greatly between products and categories. Essential treatments with no close therapeutic alternatives provide little scope for PBMs to seek competitive rebate bids from manufacturers of substitute products, resulting in low or nonexistent rebates.²⁵ In crowded therapeutic classes—where products are viewed as close substitutes (e.g., allergy or gastric medications)—rebates may be substantial. A notable example of the competitive negotiation dynamics driving rebates among single-source products was the new class of Hepatitis C (Hep-C) cures first approved in 2013.²⁶ Sovaldi, one of these drugs, arrived as a breakthrough drug. Because it was the first product to cure Hep-C, it had the potential to avert costs of hundreds of thousands to millions of dollars in medical costs per patient over their lifetime. Despite its cost-saving potential and innovation, Sovaldi became frontpage news for its launched list price, which was roughly \$88,000 per course of treatment.²⁷ Although even at this list price the product may have been cost-effective (treating Hep-C patients is expensive), many payers requested rebates to cover this product and soften the financial blow of treating the substantial number of existing Hep-C patients.²⁸ Furthermore, some payers anticipated competitive effects of alternatives in the pipeline and waited for that competition to bring prices down, or used the prospect of future competition to negotiate larger current rebates. These dynamics led to substantial rebates—some of which exceeded 50% within a year of Sovaldi’s launch.²⁹ As therapeutic alternatives entered the market and payers were able to leverage the competition among products, the price (net of rebates) for the Hep-C cures continued to fall.³⁰

Pharmacies do not generally receive rebates from single-source branded manufacturers because they do not possess the ability to steer patients toward one branded product over another. This is due in part to the fact that there is no mechanism allowing the pharmacy to make this switch without authorization from the prescriber. Although in principle the pharmacist could call a doctor and ask for approval to make such a switch, they also have no control over the formulary that drives patients’ costs, which is governed by the insurance plan.³¹ As a result, pharmacies have historically not played this role, although they often work with the plan, patient, and doctor to obtain a prescription for preferred on-formulary options if they exist. As a result, most prescriptions are filled in accordance with health plan formularies.³²

Manufacturers have a variety of ways to directly affect out-of-pocket costs for patients. These can either result from or affect their rebate negotiations with plans. Copay coupons, for example, can be used to offset the relatively high copayment a patient might experience on a plan for which a prescribed drug is not the preferred option.³³ This can alter the specific copay incentives that the health plan put in place to guide the patient toward the plan’s

²⁵ There are circumstances where a PBM may nevertheless seek to obtain rebates from a manufacturer by threatening to place a product in a high copay tier if the P&T Committee expresses skepticism about the overall merits of the product. Payers have also been known to erect formulary obstacles to a new therapy without close substitutes if there is a viable substitute in the pipeline. In this instance, they may be unwilling to lock themselves into a high-cost contract that may preclude taking advantage of forthcoming competitive alternatives.

²⁶ K. Doheny, *New Oral Hepatitis C Drugs: FAQ*, WebMD (Dec. 9, 2013), <https://www.webmd.com/hepatitis/news/20131126/new-hepatitis-c-drugs#1>.

²⁷ A. Pollack, *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to \$10.3 Billion*, N.Y. TIMES (Feb. 3, 2015), <https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html>.

²⁸ *Id.*

²⁹ Rebates exceeded 50% for certain Medicaid programs and the Department of Veteran Affairs. *Id.*

³⁰ *Id.*

³¹ *Policy Perspectives on Alternative Models for Pharmaceutical Rebates*, *supra* note 8, at p. 3.

³² *Pharmacy Plan FAQs*, BLUE CROSS BLUE SHIELD, <https://www.bcbst.com/manage-my-plan/pharmacies-and-prescriptions/pharmacy-plan-FAQs.page> (accessed Dec. 12, 2019); *Frequently asked questions about pharmacy coverage*, AETNA, <https://www.aetna.com/faqs-health-insurance/pharmacy-faqs.html> (accessed Dec. 12, 2019); *Drug formulary*, KAISER PERMANENTE, <https://wa.kaiserpermanente.org/html/public/pharmacy/drug-formulary>, (accessed Dec. 12, 2019).

³³ Other cost offsets that manufacturers offer to patients include bridging programs, which, for example, may support the cost of treatment until the patient’s deductible limit has been reached and coverage begins. Another type of program is the needs-based patient assistance programs that may be made available for patients not qualified for state or federal programs, but who face economic hardship covering their prescription drug costs.

preferred option, which can lead to higher costs in the long run.³⁴ Plans may sometimes respond to copay coupons by forbidding their use by beneficiaries, although coupons are generally popular with patients, so this is not always considered an option. Formulary exclusion decisions have been made on this basis, however, and for the manufacturer this can drive up the cost of patient expense offsets and reduce their ability to switch patients to their product. This back and forth between manufacturer and payer can feed back into rebate and formulary negotiations. Because copayment barriers are frequently responsible for patients abandoning treatment, copay coupons have also been shown to have a beneficial effect on treatment adherence.³⁵ There is no AKS safe harbor for copay coupons and other direct supports from manufacturers to patients, so their use is prohibited under Medicare Part D and other federal programs.

SPECIALTY PRODUCTS

Specialty drug products do not have a fixed definition, but they are typically characterized by their high cost and complexity.³⁶ With a few exceptions, these products have historically been administered by infusion or injection in a clinic or hospital setting. Modern biologics, which are also generally considered specialty products, are frequently self-administered by patients via subcutaneous injection.

In the clinical setting, it is the provider who not only makes the choice regarding treatment but also generally acquires and stocks the pharmaceutical products used in the practice. Subsequently, medical providers bill the patient's insurance company based on the implemented treatment.³⁷ Health plans and PBMs have not typically been involved in managing those costs in the way pharmacy costs are managed.³⁸ Because of this business arrangement, doctors possess a strong ability to steer patients among alternative therapies without interference from insurance companies. Pricing and rebate strategies for these products primarily targeted these doctors. For example, bundled rebates for doctors purchasing portfolios of immunization products have long been a feature in the marketplace. Companies offering competing portfolios of these products have used rebates to steer doctors to their alternatives.³⁹

However, in recent years, the increasing reimbursement of high-cost specialty drug products has given rise to rebate programs directly addressing these products. In fact, these products have become the fastest-growing cost center for insurance companies. Once accounting for less than 10% of total pharmaceutical reimbursement, specialty products now account for almost half of drug spending by health plans, even though they only account for 2% of prescriptions.⁴⁰ Modern biologic treatments are driving much of this disruption. Biologics are complex,

³⁴ These discount coupons are provided by manufacturers directly to patients to offset a portion of their out-of-pocket costs. Sometimes provided at the pharmacy point of sale, they can have the effect of incentivizing a patient to ask their doctor to switch to the alternative with a copay coupon, if it exists. The pharmacy has little direct role in the ultimate prescribing decision, however, which is in the hands of the doctor, subject to the financial incentives placed on the patient.

³⁵ See, e.g., Arpamas Seetasith, et al., *The impact of copay assistance on patient out-of-pocket costs and treatment rates with ALK inhibitors*, J. OF MED. ECON., Vol. 22, pp. 414–420 (2019),

<https://www.tandfonline.com/doi/pdf/10.1080/13696998.2019.1580200?needAccess=true>.

³⁶ Alan Lotvin, *What's Special About Specialty?*, CVS HEALTH, <https://cvshhealth.com/thought-leadership/whats-special-about-specialty>.

³⁷ Adam J. Fein, *Follow the Vial: The Buy-and-Bill System for Distribution and Reimbursement of Provider-Administered Outpatient Drugs*, DRUG CHANNELS (Oct. 14, 2016), <https://www.drugchannels.net/2016/10/follow-vial-buy-and-bill-system-for.html>.

³⁸ This may be due in part to the reality that clinics do not have electronic systems that can instantaneously adjudicate medical claims, which are generally more complex than pharmacy claims. As a result, for many payers and providers it would be difficult to manage formulary and patient payment responsibilities prior to treatment.

³⁹ K. W. Caves and H.J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines*, SSRN (Aug. 11, 2011), <https://ssrn.com/abstract=1908306>.

⁴⁰ *Express Scripts Drug Trend Report (2009, 2018)*, EXPRESS SCRIPTS, <https://www.express-scripts.com/corporate/articles/previous-drug-trend-reports>.

large-molecule drugs used to treat chronic diseases such as rheumatoid arthritis or Crohn’s disease.⁴¹ As a result, payers became more aware of the need to manage these costs more directly.⁴²

Self-administered biologics that can either be picked up at a pharmacy or delivered to the patient via mail-order are generally managed by PBMs in much the same way that non-specialty pharmaceuticals are managed. Many PBMs have a “specialty” tier for such products. These tiers may include a special set of reimbursement rules, including routine prior authorizations, quantity limits, and step edits. Negotiated rebates are an important feature of pricing for these products to the extent that competitive conditions dictate. Even without devising full-blown formularies, insurers have nevertheless targeted specific high-cost specialty products. In the early example of human growth hormone—a drug that in 1997 had a price tag around \$25,000 a year—PBMs required prior authorization. This served as a hurdle for its use and ensured it would be limited to only approved indications.⁴³

Products administered in a clinical setting have followed a somewhat different path. PBMs do not generally factor into these negotiations as they do not contract with doctors. Nevertheless, the interaction between insurers and doctors driven by the growth of high-cost biologics has led plans to exert a degree of leverage over the doctors’ choices. Insurance companies have the option to not reimburse certain treatments if deemed unnecessary.⁴⁴ They can also require that patients be stepped through lower-cost therapies before being approved for high-cost therapy.

With increasing recognition that insurance companies aggressively monitor payments for specialty therapies, drug companies have responded with rebate programs embedded with economic tools to steer prescribing. These programs are similar to the rebate schemes of PBMs. Referred to as managed care rebate programs, drug manufacturers incentivize insurance companies to use their drugs in favor of alternative therapies. The mechanics of these programs involve denials of coverage for other therapies or require “fail-first” provisions, which favor products that receive higher manufacturer rebates.⁴⁵

As with PBM rebates, managed care rebates are only relevant in therapeutic categories in which the threat of exclusion is credible due to the existence of viable alternatives. For example, such rebates have been utilized in the context of biosimilar drugs to steer demand toward branded products in the face of competition from close substitutes.⁴⁶ As in the PBM context, these rebates may be tied to a preferred or exclusive coverage position relative to competitors or market share achievement, or bundled with purchases of other products in the company’s portfolio.

As with non-specialty products, there are interactions between specialty drug rebate programs and subsidy programs directed at patients. It is standard in many specialty pharmacy coverage plans to require a coinsurance

⁴¹ *What Are “Biologics” Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2018), <https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers>; *Biologics for Treating Rheumatoid Arthritis*, WebMD, <https://www.webmd.com/rheumatoid-arthritis/biologics#1>.

⁴² A. Roy, *Biologic Medicines: The Biggest Driver Of Rising Drug Prices*, FORBES (Mar. 8, 2019), <https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#62660dcf18b0>.

⁴³ *Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions*, *supra* note 10.

⁴⁴ M. Bihari, *Medical Necessity Definition in Health Insurance*, VERYWELL HEALTH (May 8, 2019), <https://www.verywellhealth.com/medical-necessity-1738748>.

⁴⁵ R. K. Nayak and S. D. Pearson, *The Ethics of ‘Fail First’: Guidelines And Practical Scenarios For Step Therapy Coverage Policies*, HEALTH AFFAIRS (Oct. 2014), <https://doi.org/10.1377/hlthaff.2014.0516>.

⁴⁶ W. Winegarden, *Impediments to a Stronger Biosimilars Market: An Infliximab Case Study*, PACIFIC RESEARCH INST. (June 2018). As noted later, the precise form of these rebates in some circumstances have raised concerns about so-called “rebate walls” that may also raise antitrust concerns.

payment from patients.⁴⁷ Given the high cost of specialty products, this coinsurance burden can be quite substantial. For example, according to a recent study, patients on Affordable Care Act (ACA) Bronze plans in 2016 experienced a 37% average coinsurance fee on Humira Pen, resulting in a monthly out-of-pocket cost of \$1,942.15.⁴⁸ Annualized, this figure exceeds \$23,000.⁴⁹ Drug companies may use coupons, bridging programs, or needs-based patient support programs to help patients afford these substantial out-of-pocket costs. Rebates and patient subsidies often work in tandem to steer both patients and health plans to a therapy. Patient subsidies also have been demonstrated to improve health outcomes. Patients tend not to forego or skip treatments when their costs are lower.⁵⁰ Doctors are also more likely to receive payment when patients receive support.⁵¹ All of these factors may impact providers' treatment decisions. As with non-specialty products, patient subsidies are not allowed under federal programs such as Medicare Part D.

GENERIC PRODUCTS AND BIOSIMILARS

Rebates also exist for generic drug products, although they are used in ways that differ markedly from those previously described. Primarily, this is due to the inability of PBMs and insurance companies to steer the choice regarding which generic supplier's product will be used to fill a prescription.⁵² The role of the PBM is generally limited to incentivizing the use of generic alternatives by offering low copayment options to patients. Additionally, PBMs may use reimbursement policies that elevate pharmacies' profit percentages relative to branded drugs to incentivize brand-to-generic switches.

In generic drug markets, retail pharmacies and drug wholesalers generally play the role of determining which generic supplier's product will be used to fill prescriptions. When there are multiple equivalent Food and Drug Administration (FDA)-approved generics available, the pharmacy will be in position to receive competitive bids

⁴⁷ *Difference between Coinsurance, Deductible, Out-Of-Pocket Limit, Copayment, and Premium*, SAFEPOL, <https://www.safepol.com/health-insurance/faqs/difference-between-coinsurance-deductible-out-of-pocket-limit-copayment-and-premium/>; *US average coinsurance rate 20 percent*, UPI (Mar. 27, 2013), https://www.upi.com/Health_News/2013/03/27/US-average-coinsurance-rate-20-percent/28831364411100/, *Coinsurance*, HealthCare.gov, <https://www.healthcare.gov/glossary/co-insurance/>.

⁴⁸ Infostat, *In The Fourth Year of Affordable Care Act Coverage, Specialty Drug Out-of-Pocket Costs Remain A Problem For Consumers*, HEALTHPOCKET (Sept. 5, 2018), <https://www.healthpocket.com/healthcare-research/infostat/2017-obamacare-drug-out-of-pocket-costs#.XfkAOCB7kUE>.

⁴⁹ According to the U.S. Census Bureau, median household income in the United States was \$60,309 in 2016; this means the annual cost to the patient for this drug would be more than 38% of median household income. See Kayla Fontenot, Jessica Semega, and Melissa Kollar, *Income and Poverty in the United States: 2017*, U.S. CENSUS BUREAU (Sept. 12, 2018), <https://www.census.gov/library/publications/2018/demo/p60-263.html>.

⁵⁰ Interestingly, these benefits kick in at very low-cost levels. Research shows that even \$50 versus \$25 copayment requirements can have a substantial impact on treatment adherence. See, e.g., Chernew, Michael, et. al., *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment*, HEALTH AFFAIRS, Vol. 27, No. 1 (Jan./Feb. 2008); Eaddy, et. al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes—A Literature Review*, PHARMACY & THERAPEUTICS, Vol. 37(1) (Jan. 2012); Xu, Liou, et. al., *Drug Copay and Hospitalizations in Elderly Patients with Type 2 Diabetes*, DIABETES, Vol. 67 suppl. (July 2018).

⁵¹ As a rule, doctors are responsible for collecting the amounts that patients are responsible for paying, so they face the risk of non-payment. Sarah Weiner, *I Can't Afford That!*, J. OF GEN. INTERNAL MED., Vol. 16, No. 6 (2001).⁵² Although in principle a PBM could write a contract with a pharmacy that stipulates which generic manufacturers will be used to supply products to fill prescriptions, in practice they do not. This would likely be difficult to administer for thousands of smaller pharmacies without access to physical supply chain management, which PBMs generally do not control. Large chain pharmacies and wholesalers have supply chain access but have no obvious incentive to share this core part of their business with PBMs.

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from a variety of generic suppliers. Large pharmacy chains can steer purchases to a single manufacturer, often effectively auctioning access by putting generic supply contracts up for bid.⁵³ These competitive conditions often drive the net price of generic drugs to a fraction of the price of the reference brand product. The negotiated net prices for generic drugs may result from a combination of upfront discounting off list price (wholesale acquisition cost, WAC) or rebates tied to performance. Pharmacy rebates can, for example, be linked to achieving quantity thresholds or to meeting purchase requirements across a portfolio of generic products offered by the manufacturer.⁵⁴ Because these prices are the result of private negotiations, they are rarely made public. They can also vary substantially from customer to customer.

Retail drug stores are not the only entities that receive rebates and discounts from generic manufacturers. Large drug wholesalers such as AmerisourceBergen, Cardinal Health, and McKesson also have rebate contracts with generic drug suppliers.⁵⁵ These businesses distribute products from manufacturers to their ultimate buyers—retail pharmacies. Typically, larger pharmacies and chains negotiate pricing directly with the manufacturer, while relying on wholesalers to move products from the manufacturing plants to their pharmacy locations or warehouses. The wholesaler plays no direct role in the negotiation of pricing and rebates for these pharmacies.⁵⁶ The wholesaler will pass contracted discounted prices for these customers via a system of “chargebacks.”⁵⁷ In this system, the pharmacy pays the wholesaler the discounted price it negotiated with the manufacturer.⁵⁸ Since the wholesaler typically pays WAC minus a small prompt pay discount for its stock, it must bill the manufacturer for the difference between that and the pharmacy’s contracted price to true-up the transaction. Any contracted rebates pass directly between manufacturer and pharmacy, bypassing the wholesaler.⁵⁹

Frequently, small chain or independent pharmacies do not directly negotiate discounted generic drug prices with manufacturers. Instead, it can be advantageous for them to outsource this function to others since this process can consist of negotiating prices for thousands of generic drug products with dozens of manufacturers and frequent updates as competitive conditions change. To fill this niche, wholesalers offer what are called “source programs” that provide a generic drug acquisition service to independent pharmacies.⁶⁰ These programs are marketed as one-stop shops for generic drugs for the participating pharmacies. They also allow wholesalers to aggregate the volume of many smaller purchasers and consequently access better discounting than individual pharmacies could achieve. A portion of these savings are passed on to participants. Therefore, wholesalers can steer purchases of generic drugs from one manufacturer to another, and this allows them to receive discounts and rebates like those obtained by large chain pharmacies.⁶¹

Biosimilar drugs are economically distinct from generic drugs in important ways. Therefore, their rebates differ as well. Biosimilars are biologic drugs that have been approved under an abbreviated FDA approval pathway set forth in the 2009 Biologics Price Competition and Innovation Act (BPCIA), which was intended to speed up market competition.⁶² Biologics, however, are distinct from other drugs in that they are not chemically synthesized, but

⁵³ *Understanding the US Commercial Pharmaceutical Supply Chain*, *supra* note 1, at p. 17.

⁵⁴ R. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, HEALTH AFFAIRS, Vol. 20, No. 2 (Mar./Apr. 2001), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.20.2.115>.

⁵⁵ Adam J. Fein, *2018 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM.

⁵⁶ Adam J. Fein, *The 2018–19 Economic Report on Pharmaceutical Wholesales and Specialty Distributors*, DRUG CHANNELS (Oct. 2018), https://drugchannelsinstitute.com/products/industry_report/wholesale/ (hereinafter *The 2018–19 Economic Report on Pharmaceutical Wholesales and Specialty Distributors*).

⁵⁷ *Understanding the US Commercial Pharmaceutical Supply Chain*, *supra* note 1.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Choosing a Wholesaler: How Independent Pharmacies Can Make the Most of Their Primary Wholesaler Relationship*, PHA HEALTH (June 15, 2017), <https://www.pbhealth.com/choosing-wholesaler-independent-pharmacies-can-make-primary-wholesaler-relationship/>.

⁶¹ *The 2018–19 Economic Report on Pharmaceutical Wholesales and Specialty Distributors*, *supra* note 56.

⁶² *Biosimilars*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>.

rather are derived from a variety of processes that result in substantially larger and more complex molecules.⁶³ Because of their complexity, the chemical makeup of these large molecules cannot be fully characterized by modern scientific tools. The result is that the FDA cannot yet deem a biosimilar to be chemically identical to its reference biologic product in the same way that it can with generic small molecule drugs. This is why they are called *biosimilars* rather than *biogenerics*.⁶⁴ As a result, pharmacies do not have authority to substitute a biologic with a biosimilar without physician involvement. Because doctors alone can make this choice, biosimilars are more analogous to branded products than to generics, and in fact are generally marketed to physicians using trademarked brands. As a result, rebates for biosimilars mirror the rebates of branded specialty products. Either the prescribing doctor, a pharmacy benefit manager, or a health plan could receive rebates depending on the type of product (self-administered vs. office-based) and other circumstances. In the case of biosimilars, rebates are likely to be prevalent given the competitive conditions implied by their presence in the market.

MEDICAID (OBRA) REBATE PROGRAM

Medicaid has its own set of drug rebates, known as the Medicaid Drug Rebate Program (MDRP), which was created in 1990 under the Omnibus Budget Reconciliation Act (OBRA) and substantially updated as part of the ACA.⁶⁵ Under the MDRP, most rebates are statutorily determined and are automatic for all Medicaid prescriptions.⁶⁶ The MDRP is essentially a “pay-to-play” system where participation is a requirement for a drug to be reimbursable under state Medicaid programs and no steering is involved. Many states have supplemental rebate programs where additional rebates may be tied to listing on a state Medicaid Preferred Drug List (PDL).

The MDRP statutory rebates are intended to ensure that state Medicaid programs get access to the lowest prices available on the market.⁶⁷ The formula for these rebates depends on whether the drug is generic or branded.⁶⁸ For brand-name drugs, the current base rebate is either 23.1% of the average manufacturer price (AMP) or the difference between the AMP and the best price (BP), whichever is greater.⁶⁹ The generic drug base rebate formula is a flat 13% of the AMP with no reliance on best price. Both AMP and BP are statutorily defined price measures that manufacturers participating in the MDRP must regularly report to the Centers for Medicare & Medicaid Services. These calculations are generally restricted to sales to entities in the retail class of trade and exclude prices to certain other federal programs such as 340B covered entities.⁷⁰

⁶³ *Biosimilar and Interchangeable Products*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>.

⁶⁴ The FDA has not yet approved any biosimilar as “substitutable” the way it commonly does for generic small molecule drugs. Boehringer Ingelheim has applied to the FDA for an “interchangeable” designation for its biosimilar of Humira, Cyltezo. A decision is expected in the fourth quarter of 2021. *Cyltezo Is a Contender for First Interchangeable to Humira, Boehringer Ingelheim Says*, <https://www.centerforbiosimilars.com/view/cyltezo-is-a-contender-for-first-interchangeable-to-humira-boehringer-ingelheim-says>.

⁶⁵ *Understanding the Medicaid Prescription Drug Rebate Program*, KAISER FAMILY FOUND., <https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/> (hereinafter *Understanding the Medicaid Prescription Drug Rebate Program*).

⁶⁶ *Id.*; *Medicaid Drug Rebate Program*, MEDICAID, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ These exclusions were updated in a final rule in 2016, which was released to implement changes to the MDRP by the ACA and address other MDRP issues. See *CMS Publishes Final Rule Regarding Medicaid Drug Rebate Program*, COVINGTON & BURLING LLP (Feb. 1, 2016), https://www.cov.com/-/media/files/corporate/publications/2016/02/cms_publishes_final_rule_regarding_medicaid_drug_rebate_program.pdf.

In addition to the base rebate, there is a price protection component that limits drug price inflation to be no more than consumer price inflation.⁷¹ This rebate calculation is calculated as the “difference between the drug’s current quarter AMP and its baseline AMP adjusted to the current period by the Consumer Price Index for All Urban Consumers.”⁷² The baseline AMP refers to the price of the product at an initial point in time, usually when the product was introduced. This formula ensures that if a drug’s price rises at a faster rate than inflation, the manufacturer is required to “rebate the difference to Medicaid.”⁷³ This rebate is additional to the base rebate formula. Because the inflation adjustment is effectively cumulative, it can be quite substantial for products that have a long history of sales and price growth greater than general inflation—in some cases it could cause the total Medicaid rebate to exceed 100% of AMP.⁷⁴ The total rebate is capped at 100% of AMP. According to the Department of Health and Human Services Office of Inspector General (OIG), the inflation protection component of the Medicaid rebate accounted for over half of total Medicaid rebate receipts from manufacturers by 2012.⁷⁵ OIG also found that average statutory rebates received by Medicaid exceeded the privately negotiated rebates received by Medicare under Part D.⁷⁶

Many states also have supplemental rebate programs through which their Medicaid programs can negotiate additional rebates with manufacturers in exchange for placement on their PDL.⁷⁷ Excluding a medication from a formulary and thus making it non-payable is not permitted through the supplemental rebate program. This limits the ability of a Medicaid program to steer utilization. However, a PDL can still be created through Medicaid programs offering a preferred position in exchange for the supplemental rebate.⁷⁸ This supplemental rebate program allows medication to be dispensed without prior authorization, which often makes these drugs preferred by prescribers.⁷⁹ Furthermore, supplemental rebates can be negotiated individually by state Medicaid programs or the state programs can join “multi-state pools,” which increase bargaining power.⁸⁰ Supplemental rebate programs are typically small given their limited ability to steer.

The MDRP can also have significant effects on commercial programs and manufacturers. The Most-Favored-Nation aspect of the best price provisions in the Medicaid program can inhibit discounting beyond the 23.1% of AMP statutory rebate. For example, offering a discount to a single commercial entity that lowers the best price to an amount below the statutory 23% less than AMP can trigger the best-price provision and cause all Medicaid prescriptions to also be discounted by that amount.⁸¹ This spillover effect can have a significant deterrent effect on discounting decisions, and is frequently dependent in part on the volume of Medicaid business implicated. It has

⁷¹ *Understanding the Medicaid Prescription Drug Rebate Program*, *supra* note 65.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin (OEI-03-13-00650)*, DEP’T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., at p. 8 (2015), <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

⁷⁶ *Id.*

⁷⁷ Kathleen Gifford, Anne Winter, Linda Wiant, et. al., *How State Medicaid Programs Are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, KAISER FAMILY FOUND. (Apr. 29, 2020), <https://www.kff.org/report-section/how-state-medicicaid-programs-are-managing-prescription-drug-costs-payment-supplemental-rebates-and-rebate-management/>.

⁷⁸ Marcus Bachhuber, *How Do State Medicaid Programs Determine What Substance Use Disorder Treatment Medications Need Prior Authorizations? An Overview for Clinicians*, ADDICTION SCI. & CLINICAL PRACTICE, Vol. 15, No. 1 (June 29, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7325260/>.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Fiona Scott Morton, *The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules*, NBER Working Paper Series, Working Paper 5717 (1996).

also been argued that the best-price provision may inhibit the use of value-based or alternative purchasing agreements to manage the high cost of new therapies.⁸²

CONCLUSION

Understanding rebate arrangements is fundamental to grasping pharmaceutical prices in the United States. In many instances, neither the level nor the trend of drug prices can be fully appreciated without an understanding of rebate flows. Competition among pharmaceutical products is often manifest in private contract mechanisms and the rebates they stimulate. Because of their proprietary nature, most publicly available sources of drug pricing information do not include rebates and, therefore, can be a poor barometer of competition.

There are many important questions about the efficiency and equity of the managed care rebate system, and there have been many calls to change it. These calls stem partly from the lack of transparency of the system's inner workings, and concerns about whether incentives are properly aligned among parties. For example, concerns have been raised regarding the extent to which the benefits of rebates flow through to health plans and, consequently, to premiums paid by patients. Uninsured or underinsured patients may also have no immediate pathway to participate in payer-negotiated rebates when they do not appear at the point of sale. Rebates have also been alleged in certain instances as a means of pharmaceutical manufacturers to foreclose competitors.

Changing these dynamics can be complicated. Existing contract structures, legal arrangements, and the business models they reflect have evolved over decades. A multitude of entities would be impacted, including manufacturers, wholesalers, pharmacies, PBMs, insurance companies, employer health plans, patients, and government entities. Well-meaning proposals such as price transparency laws can have unintended and sometimes anticompetitive results. Changing the rules for how and where discounting can occur within the distribution chain could have even more complex and far-reaching implications. Given the centrality of rebate contracts to the basic operation of competition in this industry, great care is needed to avoid unintended adverse consequences.

⁸² Edwin Park and Andrea Noda, *Alternative Drug Purchasing Arrangements Do Not Justify Raising The Prices Medicaid Pays For Brand*, HEALTH AFFAIRS (Apr. 3, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200325.649781/full/#:~:text=The%20intent%20of%20the%20best,taxpayers%20sharing%20in%20the%20savings>.