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Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)

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SUMMARY

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Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)

U.S. pharmaceutical manufacturers fund a variety of programs to help consumers defray the cost of prescription drugs. Industry assistance includes drug discount coupons as well as free drugs or insurance cost-sharing payments for individuals with lower incomes or high drug expenses. According to one analysis, 95% of brand-name drugs offer manufacturer assistance and 75% of cost sharing in commercial insurance plans is offset by manufacturers. In addition, nonprofit patient assistance programs (PAPs) offered by drug manufacturers and independent charities dispense billions of dollars in assistance annually, placing some among the nation's largest charitable organizations.

Drug manufacturers say the generous aid is evidence of their commitment to patients who cannot afford a prescribed course of medication. Many manufacturer programs are designed to reduce consumer cost sharing for high-cost specialty drugs used to treat cancer, hepatitis C, Crohn's disease, and other serious and chronic conditions. Industry analysts and the Department of Health and Human Services' Office of Inspector General say that the programs also are used to bolster manufacturer prescription drug sales and prices and can increase costs for government and commercial health payers. For example, an insured consumer may use a manufacturer coupon to buy a more expensive brand-name drug even if a lower-cost generic is available. Although the coupon reduces the consumer's cost-sharing obligation for the drug, it may not cut the price paid by the consumer's health care plan.

Federal statutes, including the federal anti-kickback statute, limit the use of coupons and manufacturer donations in conjunction with federal health care programs, such as the Medicare Part D prescription drug benefit. The anti-kickback statute in Section 1128B(b) of the Social Security Act generally prohibits the knowing and willful offer or payment of remuneration to induce a person to buy an item or service that will be reimbursed by a federal health care program. In the private sector, health plans have made major changes in drug plan benefit design during the past several years specifically to blunt the impact of manufacturer assistance offers. Some health payers have barred enrollees from redeeming coupons for certain drugs or do not count the value of the manufacturer assistance toward an enrollee's annual plan out-of-pocket spending requirements. Another approach for health plans is to require enrollees to apply for manufacturer assistance for expensive drugs and then to increase the plan's enrollee out-of-pocket cost-sharing requirement to maximize the amount of manufacturer assistance collected by the payer.

During the past several years, the U.S. Department of Justice has stepped up enforcement of relevant laws governing manufacturer cost-sharing assistance and has collected billions of dollars in settlements with pharmaceutical companies and patient assistance organizations for allegedly steering Medicare Part D beneficiaries to specific drugs.

This paper provides an overview of coupons and patient assistance programs, federal regulation, the commercial marketplace, and federal enforcement efforts.

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Introduction

U.S. pharmaceutical manufacturers spend billions of dollars annually on special assistance programs to defray the consumer cost of prescription drugs for both insured and uninsured individuals. Many manufacturers offer prescription drug discount coupons that reduce or eliminate required out-of-pocket payments for consumers, including insurance deductibles, co-payments, and coinsurance.[1] Likewise, pharmaceutical manufacturers, along with some state governments and independent charities, operate patient assistance programs (PAPs) that provide free drugs or financial aid to help eligible individuals pay for prescription drugs based on factors including income, medical necessity, and health insurance status. Many PAPs are set up as 501(c)(3) nonprofit foundations or charities.[2] Pharmaceutical companies may qualify for federal tax deductions for the donation of inventory through their own manufacturer PAPs or for donating to independent charity PAPs.

There are restrictions on the use of pharmaceutical assistance. Drug coupons may not be used in conjunction with federal programs such as the Medicare Part D prescription drug benefit, because the coupons may implicate, among other things, the federal anti-kickback statute.[3] Manufacturer-sponsored PAPs may not offer cost-sharing assistance to enrollees in Medicare Part D and other federal programs. However, PAPs operated by independent charities (which are allowed to receive cash donations from drug companies) may assist beneficiaries in federal programs, if the PAPs comply with certain conditions.[4]

Pharmaceutical assistance programs, including PAPs and coupons, have increased in value and scope in recent years. According to one analysis, 95% of brand-name drugs offer manufacturer assistance and 75% of cost sharing in commercial insurance plans is offset by manufacturers.[5] A study of retail pharmacy data found that manufacturer coupons offset $12 billion in consumer prescription drug spending in 2019, an increase from $8 billion in 2013.[6] More recent data show $14 billion in coupon use for commercially insured patients in 2020, which also includes the use of prepaid debit cards.[7] An analysis of proprietary Internal Revenue Service (IRS) data found that giving by selected large drug manufacturer PAPs has risen substantially since the early 2000s, with 10 drug manufacturers providing $1.6 billion in aid in 2014,[8] accounting for 85% of all

[1] See text box entitled "Common Insurance Terms."

[2] See "What Is a 501(c)(3) Organization?"

[3] See, generally, CRS Report RS22743, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*. Anti-kickback statute (Section 1128B(b) of the Social Security Act) prohibits the knowing and willful offer or payment of remuneration to induce a person to buy an item or service that will be reimbursed by a federal health care program.

[4] HHS OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons," September 2014, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.

[5] IQVIA, "Trends to Watch through 2023: Copay Accumulator Adjuster Programs," March 21, 2022, at https://www.iqvia.com/locations/united-states/blogs/2022/03/trends-copay-accumulator-adjuster-programs.

[6] IQVIA, "Medicine Spending and Affordability in the United States," August 2020, pp. 6, 9, at https://www.iqvia.com/insights/the-iqvia-institute/reports. The figures do not include prepaid debit cards, also offered by manufacturers. IQVIA provides a range of services including health care data analytics, management consulting, and product launch services. The company has compiled extensive pharmaceutical data sets from physician prescription and pharmacy claims information. Although most of the data are proprietary, IQVIA releases some reports to the public. The Department of Health and Human Services (HHS) uses IQVIA data in estimating national prescription drug spending.

[7] IQVIA, "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025," 2021, p. 46, at https://www.iqvia.com/insights/the-iqvia-institute/reports.

[8] Austin Frerick, "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity," *Tax Notes*, November 28,

pharmaceutical charity deductions and one-sixth of all U.S. corporate charity deductions that year.[9] The largest drug manufacturer PAP in that study contributed more than $853 million in 2014, but a Congressional Research Service (CRS) review of more up-to-date IRS financial filings by selected manufacturer PAPs shows that, in 2019 and 2020, a number provided well over $1 billion each in annual assistance.[10] An outside analysis of charitable giving included five charitable PAPs in the 2021 list of top 100 U.S. nonprofits (ranked by revenue).[11]

Pharmaceutical manufacturers say the assistance programs are evidence of their commitment to ensure that prescription drugs remain affordable. They note that although more people have gained insurance since the 2010 Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) took effect, a number of insured consumers have difficulty meeting required prescription co-payments, deductibles, and other out-of-pocket costs. That appears to be especially the case for people in high deductible health plans (HDHP) and those prescribed high-cost *specialty drugs*.[12] However, recent studies indicate that coupons are also widely redeemed for relatively less expensive therapies, such as diabetes treatments, for which there is market competition.[13]

There is evidence that coupons may be a useful tool for improving enrollee adherence to prescriptions and improving health outcomes—possibly at the expense of higher health plan premiums.[14] Industry internal documents and public statements have indicated that manufacturers and drug marketers also view PAPs as a crucial tool for creating brand loyalty, supporting higher list prices, and developing markets for new drugs.[15]

2016, at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2874391.

[9] See "How Are PAP Donations Valued?"

[10] CRS research based on IRS Form 990s for tax years 2018-2020. See "Pharmaceutical Assistance Programs".

[11] *The NonProfit Times*, "The 2021 NPT 100: Donors Stood Tall, Led With BIG Gifts," November 3, 2021, https://www.thenonprofittimes.com/report/the-2021-npt-100-donors-stood-tall-led-with-big-gifts/. The NPT 100 is a report by The NonProfit Times—a business publication on nonprofit management—on the largest nonprofits in the United States that derive at least 10% of revenue from public support. The organizations were ranked by total revenue.

[12] High deductible health plans (HDHP) refer to health plans with large out-of-pocket (OOP) spending requirements that must be met before coverage commences. Certain HDHPs help provide eligibility to establish and contribute to a health savings account (HSA). To be considered an HSA-qualified HDHP, a health plan must meet several tests: it must have a deductible above a certain minimum level, it must limit total annual out-of-pocket expenditures for covered benefits to no more than a certain maximum level, and it can provide only preventive care services and (for plan years beginning on or before December 31, 2021) telehealth services before the deductible is met. See CRS Report R45277, *Health Savings Accounts (HSAs)*.

[13] Massachusetts Health Policy Commission, "Prescription Drug Coupon Study: Report to the Massachusetts Legislature," July 2020, p. 11, at https://archives.lib.state.ma.us/handle/2452/829870.

[14] Massachusetts Health Policy Commission, "Prescription Drug Coupon Study: Report to the Massachusetts Legislature," July 2020, p. 14, at https://archives.lib.state.ma.us/handle/2452/829870. According to the study, drug coupons increased utilization and spending for a number of drugs that have lower-cost generic alternatives that would be clinically appropriate for many patients, with implications for higher premiums. However, in cases where patients with commercial insurance could not afford clinically necessary medication, coupons provide financial relief and likely improve adherence, leading to better clinical outcomes. See also Catherine Starner et al., "Specialty Drug Coupons Lower Out-Of-Pocket Costs and May Improve Adherence At The Risk Of Increasing Premiums," *Health Affairs*, vol. 33, no. 10 (October 2014), pp. 1761-1769.

[15] HealthWell Foundation, "When Health Insurance Is Not Enough: How Charitable Copayment Assistance Organizations Enhance Patient Access to Care," 2012, at https://www.healthwellfoundation.org/wp-content/uploads/legacy/files/HWF-white%20paper%20for%20printing.pdf. Senate Committee on Finance, "The Price of Sovaldi and its Impact on the U.S. Health Care System," December 1, 2015, link at https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.

Although a drug discount coupon may reduce the amount an insured consumer must pay out of pocket for a drug, it generally does not reduce the price charged to an insurer or government program for the drug. The same is true with cost-sharing assistance offered through certain PAPs.[16] More broadly, when consumers are relieved of cost-sharing obligations, there may be less market constraint on drug prices.

However, it is increasingly difficult to describe the impact of coupon and PAP support on drug sales, health payer spending, and enrollee prescription adherence because health care payers and insurers have begun to redesign their health plan benefits to maximize the amount of manufacturer prescription assistance dollars that the payers can collect—while sometimes reducing the enrollee benefit of the programs. For example, some private health insurance plans now employ so-called accumulator programs that allow enrollees to use manufacturer assistance to reduce the dollar amount of their cost-sharing for a given drug, but do not allow the manufacturer assistance to count against the enrollee's deductible and/or annual out-of-pocket maximum requirements. ("Insurance Market Response to Coupons/PAPs") Recent federal regulations have bolstered these market changes by allowing insurers to use coupon accumulators in certain ACA-regulated health plans. ("2020 HHS Rules on Co-payment Assistance")

Evidence of fraud on the part of manufacturers and PAP operators has been an additional development. During the past several years the Department of Justice has stepped up enforcement of relevant laws governing manufacturer cost-sharing assistance and has collected billions of dollars in settlements from pharmaceutical companies and patient assistance programs charged with steering Medicare Part D beneficiaries to specific drugs. ("Justice Department Action on Prescription Drug Aid Programs")

This report will provide an overview of spending and coverage for prescription drugs, coupon and PAP offers and legal considerations, insurers' responses to coupon programs, federal regulation and enforcement and information on real world impact of the pharmaceutical assistance.

[16] HHS Office of Inspector General (OIG), "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons," September 2014, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.

Common Insurance Terms

Brand-Name Drug: The Food and Drug Administration defines a *brand-name drug* as a drug marketed under a proprietary, trademark-protected name.

Coinsurance: The percentage share that an enrollee in a health insurance plan pays for a product or service covered by the plan. An insurer could charge 10% coinsurance for a $100 prescription drug, meaning the consumer's out-of-pocket cost would be $10.

Co-payment: A fixed dollar amount that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer could charge a $20 co-payment for a physician visit or a $5 co-payment for a prescription drug.

Deductible: The amount an enrollee is required to pay for health care services or products before his or her insurance plan begins to provide coverage. An enrollee in an insurance plan with a $500 deductible would be responsible for paying for the first $500 in health care services. In some insurance plans, the deductible does not apply to certain services, such as preventive care. Insurance plans vary regarding whether beneficiaries must meet a deductible for prescription drug coverage.

Formulary: A list of prescription drugs covered by an insurance plan. In an effort to control costs, insurers are imposing closed or partially closed formularies, which include a more limited number of drugs than traditional formularies.

Generic: A generic drug is identical to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

High Deductible Health Plan (HDHP): High deductible health plans are health plans that require enrollees to meet large out-of-pocket spending requirements before coverage commences. Certain HDHPs are eligible for special health savings accounts (HSA). To be considered an HSA-qualified HDHP, a health plan must: have a deductible above a certain minimum level, limit total annual out-of-pocket expenditures for covered benefits to no more than a certain maximum level, and provide only preventive care services and (for plan years beginning on or before December 31, 2021) telehealth services before the deductible is met.

Out-of-Pocket Costs: The total amount an insured consumer pays each year for covered health care services that are not reimbursed by an insurance plan. Out-of-pocket costs can include deductibles, co-payments, and coinsurance.

Out-of-Pocket Maximum: The maximum amount an enrollee must pay before his or her health insurance plan covers 100% of health benefits. Certain costs, such as premiums, generally do not count toward an out-of-pocket maximum, or cap.

Pharmacy Benefit Managers (PBMs): Intermediaries between health plans and pharmacies, drug wholesalers, and manufacturers. PBMs perform functions such as designing drug formularies, negotiating prices, and administering prescription drug payment systems on behalf of health plans.

Pharmacy Network: A group of retail, mail-order, and specialty pharmacies that contract with PBMs and health insurers to dispense covered drugs at set prices. Network pharmacies also may provide other services under contract, such as monitoring patient adherence to drugs.

Premium: The amount an enrollee pays for health insurance coverage. Many plans charge monthly premiums, but premiums also can be assessed on a quarterly or annual basis.

Specialty Drug: There is no one set definition of specialty drugs, although insurers and other health care payers often characterize them as prescription products requiring extra handling or administration that are used to treat complex diseases, such as cancer. High cost can trigger a specialty drug designation. Biologics, or drugs derived from living cells, often are deemed to be specialty drugs.

Tiered Pricing: Insurers use tiered cost sharing for formulary drugs, meaning that patients face lower co-payments or coinsurance for less expensive generic drugs and certain brand-name drugs designated by the plan as preferred drugs, based on the price the plan has negotiated with the manufacturer and the effectiveness of the product. At the same time, patients are charged higher co-payments or coinsurance for more expensive drugs (including specialty drugs) or drugs that the plan deems to be less effective.

Underinsured: Refers to people who have insurance but still have financial difficulty paying for prescription drugs or medical treatments.

Consumer Out-of-Pocket Prescription Drug Costs

During the 1990s, manufacturers expanded their pharmaceutical assistance programs, including direct aid to consumers and discount coupons, in response to public concern about rising drug prices and lack of coverage.[17] The programs have continued to grow despite a broad expansion of health insurance drug coverage and the widespread adoption of low-cost generic drugs.[18] Millions of consumers gained prescription drug coverage through Medicare Part D (Medicare Prescription Drug, Improvement, and Modernization Act of 2003; P.L. 108-173) and the 2010 ACA.[19] The ACA, among other things, capped total annual out-of-pocket spending in many commercial health plans, including drug spending; expanded coverage through the health insurance exchanges and state-federal Medicaid program; eliminated cost sharing for contraceptives in many health plans; and reduced annual cost sharing for Part D enrollees by closing the coverage gap or "doughnut hole."[20]

In 1990, consumer out-of-pocket spending—cash payments, health plan deductibles, coinsurance, and co-payments—for filled prescriptions made up 57% of U.S. retail drug spending, whereas commercial payers and taxpayer-financed health programs accounted for about 43%, according to federal data. However, in the ensuing years, commercial payers and taxpayer-financed health programs have covered a growing share of the nation's retail prescription drug bill. According to the National Health Expenditure (NHE) data, out-of-pocket spending declined to 13.3% of retail drug spending in 2020, versus about 86.7% for these other payers.[21] Going forward, out-of-pocket (OOP) spending is projected to decline to 10.4% of outpatient drug spending by 2030. (**Figure 1**)

Looked at on a per capita basis, the NHE data show that average per person, out-of-pocket spending for retail prescription drugs fluctuated from $153 in 2014 to $141 in 2020. Out-of-pocket spending is forecast to increase gradually to $169 by 2030.[22] However, because cost sharing is not projected to increase as fast as total drug spending, OOP expenditures are forecast to drop as a share of per capita drug spending.

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[17] Tom Norton, "The Vanishing Rx Patient Assistance Programs?" *Pharmaceutical Executive*, November 6, 2013, at http://www.pharmexec.com/vanishing-rx-patient-assistance-programs; Government Accountability Office (GAO), "Drug Company Programs Help Some People Who Lack Coverage," November 2000, at https://www.gao.gov/products/gao-01-137; Saul Weiner, Jill Dischler, and Cheryl Horvitz, "Beyond Pharmaceutical Manufacturer Assistance: Broadening the Scope of an Indigent Drug Program, *American Journal of Health System Pharmacists*, vol. 58, no. 2 (2001), at https://academic.oup.com/ajhp/article-abstract/58/2/146/5149905.

[18] Austin Frerick, "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity," *Tax Notes*, November 28, 2016, at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2874391.

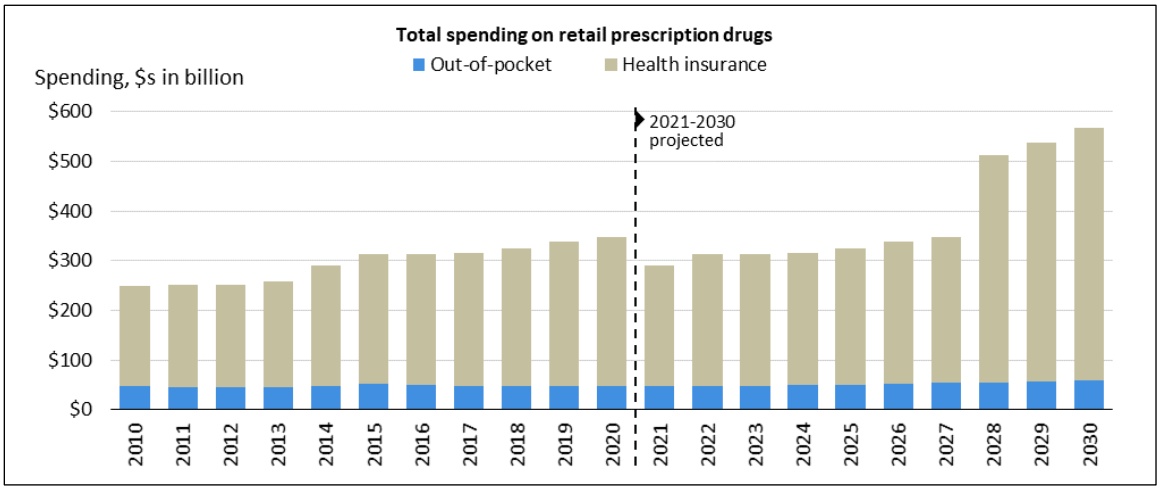
[19] See CRS In Focus IF10287, *The Essential Health Benefits (EHB)*. The ACA requires insurers to provide drug benefits as part of qualified individual and fully-insured small-group health plans and provides incentives for states to expand enrollment in Medicaid. Although prescription drug coverage is an optional Medicaid benefit, all states include drug coverage. Medicare Part D was implemented in 2006. The ACA exchanges and incentives for Medicaid expansion took effect in 2014.

[20] CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

[21] "National Health Expenditure Data: Historical," Table 16, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical. The NHE accounts estimate how much consumers pay each year to fill retail prescriptions including cash purchases and insurance deductibles, co-payments, and coinsurance. Insurance premiums are not included in out-of-pocket spending.

[22] National Health Expenditure Data: Historical," Table 16, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical. CMS, "National Health Expenditure Projections 2021-2030," Table 11, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.

Figure 1. Total Out-Of-Pocket Spending as a Share of Retail Drug Spending



Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure (NHE) Data: Historical and Projected.

Notes: Out-of-pocket spending includes cash payments, deductibles, co-payments, and coinsurance but does not include insurance premiums. Consumer out-of-pocket spending rose from $22.9 billion in 1990 to $46.5 billion in 2020 and is projected to reach $59 billion in 2030.

It may seem paradoxical that manufacturer assistance has increased while average out-of-pocket spending has moderated. There appear to be several reasons for continued growth of manufacturer aid.

- Individual consumers can face significant out-of-pocket drug costs depending on whether they have insurance coverage, the design of their health plan, and their specific diagnosis and prescribed medications. (See "Distribution of Prescription Drug Cost Sharing.")
- The growth of independent charity PAPs in the early 2000s created a way for manufacturers to aid consumers enrolled in Medicare Part D without violating federal anti-kickback statutes. (See "Restrictions on Coupon Use.")
- Manufacturers and drug marketers view PAPs and discount coupons as important tools for creating brand loyalty, supporting drug prices, and developing markets for new drugs. (See "Financial Impact of Coupons and PAPs.")

Coupon and PAP Assistance in Pharmaceutical Spending Data

Manufacturer coupons and patient assistance program (PAP) assistance generally are not broken out in data sets on prescription drug spending, making it difficult to determine how the aid affects out-of-pocket costs and other measures of drug spending. For example, the NHE data compiled by the Centers for Medicare & Medicaid Services (CMS) are adjusted to account for pharmaceutical manufacturer rebates to private payers and government programs including Medicaid, the State Children's Health Insurance Program, Medicare, and Department of Defense health programs. However, the NHE data only include manufacturer coupons and PAP payments when the source data reporting to CMS includes that information.

In the commercial market, analysis and consulting firm IQVIA has extensive prescription drug spending data sets of physician, hospital and pharmacy transactions as well as information on coupon programs. IQVIA is also a consultant to manufacturers and health plans, and operates subsidiaries that help manufacturers operate their prescription drug discount programs. (IQVIA, Global Compliance, at https://www.iqvia.com/solutions/integrated-global-compliance.)

Sources: CRS, CMS, and IQVIA.

Distribution of Prescription Drug Cost Sharing

Lower-cost generic drugs accounted for about 90% of filled prescriptions in 2020, but only 18% of total drug spending, according to the Association for Accessible Medications.[23] The majority of drug spending is concentrated in prescriptions for brand-name drugs, particularly high-cost specialty drugs for cancer, rheumatoid arthritis, and other serious ailments.[24] For example, a Congressional Budget Office (CBO) study found that net spending on specialty drugs in Medicare Part D rose from $8.7 billion in 2010 to $32.8 billion in 2015. Net spending on specialty drugs in Medicaid roughly doubled from 2010 to 2015, rising from $4.8 billion to $9.9 billion. In 2015, brand-name specialty drugs accounted for about 30% of net spending on prescription drugs under Medicare Part D and Medicaid, but were only about 1% of all prescriptions dispensed in each program. A number of drugs now in the development pipeline are specialty biologics, which often have a high introductory price and initially may not have many lower-cost alternatives.[25]

Given the trends in drug development and spending, health payers have worked to closely manage drug utilization through use of formulary tiered pricing, prior authorization, and other practices. In tiered plans, enrollees may be charged coinsurance, as opposed to flat co-payments, for more expensive or less preferred drugs. For example, a consumer may pay a $10 co-payment for a generic drug on a formulary low-cost price tier; the same consumer may be charged 30% coinsurance for an expensive specialty drug on a high-priced tier.

The use of health plan price tiers specifically for high-priced drugs has been increasing, imposing a greater financial burden on consumers who use higher-priced drugs.[26]According to the Kaiser Family Foundation, in 2021, 49% of covered workers at large firms were in a health plan with at least one cost-sharing tier just for specialty drugs. The average specialty drug co-payment was $101 and the average coinsurance was 27%.[27] Part D enrollees prescribed expensive drugs may face an annual deductible and cost sharing of up to 50% for certain non-preferred drugs.[28]

Many health plans, including Medicare Part D plans, base coinsurance on the list price of a drug, rather than the plan's net price (the price after rebates and other discounts). Basing cost-sharing, such as coinsurance, on the higher list price also serves to increase enrollee costs.[29] Also, enrollees in certain health care plans with deductible requirements for prescription drugs can face out-of-pocket costs for a therapy before coverage begins.[30] More generally, enrollment in HDHP

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[23] See Association for Accessible Medications, 2021 Generic Drug & Biosimilars Access & Savings in the U.S., at https://accessiblemeds.org/resources/blog/2021-savings-report.

[24] Stacie Dusetzina, "Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–14," *Health Affairs*, vol. 35 no. 7 (July 2016), pp. 1241-1246. Congressional Budget Office (CBO), "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid," March 19, 2019, at https://www.cbo.gov/publication/54964.

[25] Food and Drug Administration (FDA), "Novel Drug Approvals for 2021," p. 12, at https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021. The FDA approved 50 novel new drugs in 2021. From 2012 through 2021, the FDA's Center for Drug Evaluation and Research has averaged 43 novel drug approvals per year.

[26] Kaiser Family Foundation, "2021 Employer Health Benefits Survey," Section 9, at https://www.kff.org/health-costs/report/2021-employer-health-benefits-survey/. The Kaiser data indicate that more plans are imposing separate price tiers for specialty drugs or other high-cost drugs.

[27] Ibid.

[28] CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

[29] HHS OIG, "High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage," January 2017, OEI-02-16-00270, at https://oig.hhs.gov/oei/reports/oei-02-16-00270.asp.

[30] Deductible requirements vary among plans. For example, most Medicare Part D plans impose an annual deductible

plans has been rising, with 31% of individuals covered by large employer-offered insurance enrolled in HDHP plans in 2021.[31]

The result of these parallel trends—expanded insurance coverage coupled with higher cost sharing for more expensive drugs—appears to have been a decline in average out-of-pocket spending but potentially high spending for enrollees who have chronic conditions or may be prescribed high-cost drugs. Manufacturer coupon offers and PAP assistance grants are designed to blunt health plan cost-sharing requirements by covering a portion of enrollee out-of-pocket costs. The following sections examine different forms of manufacturer assistance—discount coupons, manufacturer PAPs, and independent charity PAPs.

Manufacturer Co-payment Coupons

Pharmaceutical firms offer co-payment coupons or cards to help consumers reduce out-of-pocket costs, such as co-payments and coinsurance. While individual coupon offers may be for a limited period, such as six months or one year, manufacturers may allow patients to re-enroll.[32]

For a sense of how a coupon works, consider a pharmaceutical manufacturer that sells a brand-name drug to a commercial payer for $1,000 for a 30-day supply.[33] The payer places the drug on a price tier that imposes 25% enrollee coinsurance up to the plan's annual out-of-pocket maximum. To support sales of the drug, the manufacturer offers a coupon that limits out-of-pocket costs to $100 per 30-day refill for a 12-month period. In the absence of the manufacturer coupon, an enrollee would pay $250 out of pocket each time he or she went to a pharmacy to buy a 30-day supply of the drug (25% of the $1,000 price), until the annual out-of-pocket maximum was reached. With a coupon, the consumer would pay $100 per fill and the manufacturer would cover the remaining $150 of the required coinsurance up to the maximum subsidy amount.

Many co-payment coupons include disclaimers stating that they cannot be used by enrollees in federal health programs, including Medicare, Medicaid, and the Veterans Health Administration. (See "Restrictions on Coupon Use.") Some coupons are expressly for use outside of insurance coverage, meaning without submitting an insurance claim.

(capped at $480 in 2022). Most workers covered by insurance offered by large employers that includes general deductibles do not have to meet the deductible before drug coverage begins. Kaiser Family Foundation, "2021 Employer Health Benefits Survey," Section 7, Figure 7.27, at https://www.kff.org/report-section/ehbs-2021-section-7-employee-cost-sharing/. Workers covered by HDHPs may have higher costs. An IQVIA analysis of U.S. sample prescription drug claims data found that in 2019, brand-name drug claims in health plans' deductible phase made up less than 1% of all claims, but nearly 15% of out-of-pocket spending. IQVIA defined deductible claims as those where the patient would pay more than 50% of the claim, and the primary patient payment was greater than $250. IQVIA, "Medicine Spending and Affordability in the United States," August 2020, medicine-spending-and-affordability-in-the-united-states.pdf (iqvia.com).

[31] Kaiser Family Foundation, "2021 Employer Health Benefits Survey," Section 5, at https://www.kff.org/report-section/ehbs-2021-section-5-market-shares-of-health-plans/.

[32] For example, see "Aimovig® Copay Card Terms and Conditions," at https://www.aimovigcopaycard.com/tcs. Aimovig, manufactured by Amgen Inc., is a treatment for migraine headaches.

[33] Insurers and PBMs negotiate rebates and discounts from manufacturers on the drugs that they purchase for health plans or distribute through their own mail-order and specialty pharmacies. These rebates and discounts are separate from those that manufacturers offer consumers through coupons and other assistance programs. Overall drug pricing also includes payments to pharmacies that dispense the drugs and other costs and markups along the supply chain, but those costs have not been included to simplify the transaction.

Coupon Processing

When an insured consumer's prescription is presented at a pharmacy (either in person or through an electronic e-prescribing transaction), the pharmacist uses an electronic routing system to submit a claim to the pharmacy benefit manager (PBM) or health plan that manages the consumer's specific pharmacy benefit.[34] The PBM or plan processes the initial drug claim and determines the patient's cost-sharing obligation. The electronic processing system then submits secondary claims to other payers. Secondary payments can include another insurance policy held by the individual or a manufacturer coupon. If a coupon is presented for coverage, the PBM or plan system, using special codes, will route a coupon to a manufacturer for payment.[35] After all payments are processed, the consumer covers the remaining co-payment, if any.

In certain instances, manufacturer discounts are not processed through the electronic system, such as offers that take the form of a rebate or discount after the point of sale. In this case, a consumer may make the required co-payment imposed by his or her primary insurance plan when filling a prescription, then send the pharmacy receipt and rebate offer to the manufacturer to secure the promised discount.[36]

Consumers may use a coupon and pay cash for a drug that is not covered by their insurance plan, that is less expensive outside their insurance coverage, or if they do not have insurance.

Prescription Drug Discount Coupon Distribution

Coupons can be printed in a magazine or advertising supplement, offered electronically—such as a discount offer on a website—or presented as a debit-type card. Manufacturers can directly offer coupons and/or work through vendors.[37] Coupons loaded on smartphones can provide automatic reminders to a consumer to refill a prescription. Manufacturer coupons and other discount offers may be offered via special programs on physician electronic prescribing systems.[38] Manufacturers may offer starter cards that patients can use to receive an initial fill of a prescription at no cost while they wait for a coverage decision from their health plan.

A portion of pharmaceutical assistance consists of special coupons and discount cards that reduce a drug's retail price, but are not designed to be applied to health plan co-payments. The rise of digital platforms has made these services easier to use.[39]

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[34] National Council for Prescription Drug Programs, "Background and Guidance for Using g the NCPDP Standards for Digital Therapeutics," August 2021, at https://www.ncpdp.org/NCPDP/media/pdf/Background-and-Guidance-for-Using-the-NCPDP-Standards-for-Digital-Therapeutics.pdf?ext=.pdf

[35] HHS OIG, "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs," September 2014, at http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf.

[36] Ibid.

[37] For example, see Abbvie, "Join the Before Breakfast Club," offer for Synthroid assistance, at https://www.synthroid.com/support/before-breakfast-club. Abbvie offers discounts to both insured and uninsured consumers for the drug, used to treat hyperthyroidism.

[38] GoodRx Announces Agreement with Surescripts to Provide Real-Time Drug Discount Pricing in Electronic Health Records, August 5, 2021, at https://investors.goodrx.com/news-releases/news-release-details/goodrx-announces-agreement-surescripts-provide-real-time-drug.

[39] One example is digital health company Goodrx, which allows consumers to access discount offers for drugs, including both generic and brand drugs, without insurance. In addition, GoodRx has a telehealth service to help consumers obtain prescriptions and has agreements with certain companies to provide GoodRx discounts as an employee benefit. GoodRx revenues come from prescription transaction fees, subscriber fees, and payments from drug manufacturers and telehealth providers. According to the GoodRx quarterly letter to shareholders from May 2022, the

Some pharmacies, nonprofit organizations, and PBMs also offer their own prescription drug cards or programs, which generally may not be used with government benefits or private insurance.[40]

Scope of Coupons and Discounts

There are no comprehensive public data on co-payment coupon distribution and use. Manufacturers, consulting firms, PBMs, and various websites that serve as online clearinghouses for coupon offers release some information, but it is difficult to gauge the overall market.

According to IQVIA, retail pharmacy data show that manufacturer coupons (excluding prepaid debit cards) offset $12 billion in consumer prescription drug spending in 2019, an increase from $8 billion in 2013.[41] A more recent IQVIA analysis found that coupons for commercially insured patients reached $14 billion in 2020 – including the use of prepaid debit cards.[42] Coupon usage for branded drugs used by commercially covered patients in some therapy areas was high: 47% for drugs in the mental health category and 80% for immunology drugs. In another example, the Pharmaceutical Research and Manufacturers of America (PhRMA) cite research that 70% percent of patients taking innovative medicines to treat multiple sclerosis in 2019 used cost-sharing assistance.[43]

Other studies indicate that coupons are not just important for specialty or single-source drugs, but for widely used products where there is market competition. A 2020 Massachusetts study of drug coupon use in the state found the top category of coupon use was drugs for treating diabetes, which represented 20% of all coupon volume. Antivirals, largely for HIV treatment and prevention but also for conditions such as Hepatitis C, were the second largest category with 11% of all coupons. The study suggested that coupon availability was "associated with moderately higher utilization of branded drugs relative to use of generic close therapeutic substitutes, and that coupon availability is associated with higher total spending."[44]

company acquired vitaCare in April 2022, a pharmacy services platform that helps facilitate access to drugs, including manufacturer savings programs.

[40] For example, see the CVS Caremark description of National League of Cities Prescription Discount Program, at http://nlc.org./nlc-prescription-discount-program; and OptumRx, at http://www.myprescriptiondrugsavings.com/welcome.aspx.

[41] IQVIA, "Medicine Spending and Affordability in the United States," August 2020, p. 6 and p. 9. The figures do not include prepaid debit cards, also offered by manufacturers. Available for download at https://www.iqvia.com/insights/the-iqvia-institute/reports.

[42] IQVIA, "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025," May 2021, p. 46. Available for download at https://www.iqvia.com/insights/the-iqvia-institute/reports. Savings programs include coupons, e-coupons, prepaid debit cards, and average 50% of brand prescriptions in some of the highest overall spending specialty therapy areas, compared to 33% of leading traditional medicine therapy areas.

[43] PhRMA vs. Becerra, et al., Civil Action No. 1:21-cv-1395, May 2021. The legal filing includes information on multiple sclerosis drugs from an IQVIA Analysis for PhRMA, U.S. Market Access Strategy Consulting Analysis (2020). According to the filing, the study also said that patients taking diabetes medicines would have paid more than twice as much out of pocket if they were prevented from using cost-sharing assistance. PhRMA is the main trade association for the pharmaceutical industry.

[44] Massachusetts Health Policy Commission, "Prescription Drug Coupon Study: Report to the Massachusetts Legislature," July 2020, p. 3, at https://archives.lib.state.ma.us/handle/2452/829870.

Restrictions on Coupon Use

Federal Programs

There are limitations on use of co-payment coupons in conjunction with federal health care programs, including Medicare, Medicaid, TRICARE military insurance, and Veterans Health Administration programs. One limitation is based on the federal anti-kickback statutes,[45] which cover various types of remuneration—including kickbacks, bribes, and rebates—whether made directly or indirectly, overtly or covertly, in cash or in kind.[46] Pharmaceutical companies may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by federal health care programs.

Retailers and other entities that submit claims to federal agencies for items or services resulting from a violation of anti-kickback statutes may also face civil monetary penalties and damages under the False Claims Act.[47]

Federal Employees Health Benefit Program and Qualified Health Plans

Private health plans sold to federal workers through the Federal Employees Health Benefit (FEHB) Program are not considered federal health care programs for purposes of the anti-kickback statute. Enrollees in these plans may use drug discount coupons or pharmacy incentive programs in concert with their insurance benefits.[48]

Regarding qualified health plans,[49] former HHS Secretary Kathleen Sebelius in an October 2013 letter to Representative James McDermott said the HHS did not consider qualified health plans, as well as tax subsidies and cost-sharing assistance, to be federal programs.[50]

Purchases and Donations "Outside" a Government Benefit

There may be cases in which an individual covered by a federal health plan goes "outside" his or her benefit to purchase prescription drugs. For example, a Medicare Part D beneficiary may

[45] Section 1128B(b) of the Social Security Act.

[46] The HHS OIG in December 2016 issued final regulations to create safe harbors from the anti-kickback statute for certain Part D program activities. The rules provide protection for pharmacy waivers of cost sharing for financially needy Medicare Part D beneficiaries and for mandatory manufacturer discounts in the Part D coverage gap. The final rules are at 81 *Federal Register* 88368, December 7, 2016, at https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf. For the proposed rules, see HHS OIG, 42 C.F.R. Parts 1001 and 1003, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing," 79 *Federal Register* 59717, October 3, 2014, at https://www.federalregister.gov/articles/2014/10/03/2014-23182/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the#h-4.

[47] 31 U.S.C. §§3729-3733. See also 42 U.S.C. §1320a-7b(g).

[48] See 42 U.S.C. §1320a-7b(f)(1). See also Office of Personnel Management, "Frequently Asked Questions: Insurance," at https://www.opm.gov/faqs/QA.aspx?fid=fd635746-de0a-4dd7-997d-b5706a0fd8d2&pid=c8263db8-cf0e-4144-9e8a-13a1ef38c084.

[49] A qualified health plan is an insurance plan that is certified by an exchange, provides essential health benefits, follows established limits on cost sharing (such as deductibles, co-payments, and out-of-pocket maximum amounts), and meets other requirements. See https://www.healthcare.gov/glossary/qualified-health-plan/. Qualified health plans are sold in the non-group (individual) and small-group markets inside and outside exchanges.

[50] Letter from Kathleen Sebelius, HHS Secretary, to Rep. McDermott, October 2013, at https://www.health-law.com/media/news/85_The-Honorable-Jim-McDermott.pdf.

choose to pay cash for a drug at a retail pharmacy if doing so is cheaper than buying the drug through his or her Part D plan.

Although a Part D enrollee may use a coupon to purchase a drug outside the program, only the actual price paid for the drug—minus all discounts—counts toward Part D annual out-of-pocket spending limits.[51]

2014 HHS Office of Inspector General Report

A 2014 report from the HHS OIG said that pharmaceutical manufacturers did not have consistent, effective safeguards to prevent Medicare Part D beneficiaries from using co-payment coupons along with program benefits.[52]

Some beneficiaries might not be aware of the ban on coupons. According to the report, not all manufacturer offers carried a disclaimer stating that the coupons, rebates, or other incentives may not be used by individuals enrolled in federal health care programs or in conjunction with federal benefits. The report noted that manufacturers that redeem coupons through PBM electronic claims systems have set up edits at the point of sale designed to identify individuals who may be enrolled in federal programs such as Medicare. For example, when an enrollee submits a coupon with a prescription, and when it is submitted to a manufacturer as a secondary payer, the manufacturer may check for a patient's primary insurance, Part D benefit stage,[53] and date of birth. (Actual Part D enrollment data is not available from CMS because it may contain sensitive personal information.)

However, the HHS OIG report found that the staged system for processing prescription drug claims can make it difficult for entities other than manufacturers to identify coupons as they move through the pharmacy transaction system. The report also noted that manufacturer discounts that are processed after the point of sale, such as mail-in rebates, may not be detected by electronic safeguard systems.

HHS issued a special advisory bulletin warning manufacturers that they faced potential penalties if they failed to take appropriate steps to ensure that such coupons do not induce the purchase of federal health care program items or services.[54]

In response to the 2014 HHS OIG guidance the NCPDP, which sets standards for electronic claims processing, in 2017 issued recommendations for better identifying coupons in Medicare Part D claims administration.[55]

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[51] Out-of-pocket spending amounts are adjusted annually. For more information, see CRS Report R40611, *Medicare Part D Prescription Drug Benefit*. In July 2014, the HHS OIG issued an advisory opinion regarding a direct-to-patient sales program sponsored by a specific pharmaceutical manufacturer under which an individual may buy a prescription drug at a fixed cash price through an online pharmacy. HHS OIG, "OIG Advisory Opinion 14-05," July 28, 2014, at https://oig.hhs.gov/compliance/advisory-opinions/14-05/. CMS has also issued separate guidance for Part D cash purchases at out-of-network pharmacies where coupon use is not involved. CMS, *Medicare Part D Prescription Drug Manual*, Chapter 14, Section 50.4.2, at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter14.pdf.

[52] HHS, OIG, *Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs*, September 2014, at http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf.

[53] For example, an individual enrolled in Part D might not have met the annual deductible.

[54] HHS OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons," September 2014, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.

[55] NCPDP, "Recommendations for Use of the NCPDP Telecommunication Standard to Prevent Use of Copayment Coupons by Medicare Part D Beneficiaries and Applicability to other Federal Programs," Version 1.1, May 1, 2017,

2020 HHS Rules on Co-payment Assistance

In 2020, HHS issued two final regulations affecting manufacturer coupon programs: one governing commercial plans sold on health insurance exchanges, and another affecting the calculation of prices for drugs sold through the state-federal Medicaid program. The rules were issued in response to increased use of accumulator programs, under which a health plan or issuer allows an enrollee to use a coupon or other manufacturer program to defray the out-of-pocket costs for filling a prescription but does not count the value of the manufacturer assistance against the enrollee's deductible and/or annual out-of-pocket maximum. (See "Insurance Market Response to Coupons/PAPs")

2020 HHS Coupon Accumulator Final Rule for Qualified Health Plans

In a final rule published in 2020,[56] HHS gave issuers of certain health plans authority to decide whether to count any form of direct pharmaceutical manufacturer support, such as coupons, as part of enrollee cost sharing for purposes of meeting annual OOP spending caps. The regulation applies to health plans sold on the health insurance exchanges, and non-grandfathered individual and group health plans sold off the exchanges.[57]

Under the rule, to "the extent consistent with state law, amounts of direct support offered by drug manufacturers to enrollees for specific prescription drugs towards reducing the cost sharing incurred by an enrollee using any form are not required to be counted toward the annual limitation on cost sharing."[58]

The 2020 final rule was a modification of a 2019 HHS final rule that held that issuers were not required to count enrollee manufacturer assistance toward annual OOP caps in cases where the manufacturer assistance was applied to brand-name drugs that had an "available and medically appropriate generic equivalent." HHS said it issued that rule due to concern about possible market distortions if consumers chose higher-cost brand-name drugs when less expensive generics were available.[59]

In response to comments from issuers and insurers, HHS subsequently announced it would not enforce the 2019 rule and would modify the requirement as part of rulemaking for the 2021 plan year. Insurers had been concerned that, among other things, the 2019 rule was in conflict with federal requirements for the operation of HSA-eligible HDHPs, which mandate that HDHP

available at https://www.ncpdp.org/White-Papers.aspx. It is up to individual entities to decide whether to adopt the NCPDP recommendations.

[56] CMS, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans," 85 *Federal Register* 29230, May 14, 2020, at https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021.

[57] Health insurance plans that were in existence (in the non-group, small-group, or large-group market) and in which at least one person was enrolled on the date of the ACA's enactment (March 23, 2010) are considered grandfathered and have a unique status under the ACA. As long as a plan maintains its grandfathered status, the plan has to comply with some but not all ACA provisions. CRS Report R44163, *The Patient Protection and Affordable Care Act's Essential Health Benefits (EHB)*.

[58] Ibid., p. 29253.

[59] CMS, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020," 84 *Federal Register* 17544, April 24, 2019, at https://www.federalregister.gov/d/2019-08017/p-885.

issuers disregard any provider discounts in determining whether enrollees meet plan deductible requirements.[60]

The final 2020 rule for the 2021 plan year states that issuers and group health plans have flexibility (subject to state law and other applicable requirements (if any)), to determine if and how to count manufacturer assistance, such as coupons, toward annual OOP limits. Plans that choose to impose limitations on manufacturer assistance must implement the limitations in a uniform, non-discriminatory manner. CMS encouraged issuers and health plans that limit manufacturer assistance to be transparent to enrollees by prominently providing information about their coupons/cost-sharing policies on websites and in brochures, plan summary documents, and other plan materials. According to CMS, "If we find that such transparency is not provided, HHS may consider future rulemaking to require that issuers provide this information in plan documents and collateral material."[61]

2020 Medicaid Best Price Final Rule

In a final rule issued in December 2020[62] (which was later struck down in court, see below) CMS said that, beginning in 2023, it would count the value of patient assistance when calculating a manufacturer's "best price" for the drug under the state-federal Medicaid program unless a manufacturer was able to demonstrate that the full value of a coupon or other assistance accrued to an individual, rather than to a payer, such as a private insurer.[63]

In general, pharmaceutical manufacturers that sell covered outpatient drugs through Medicaid are required to pay state Medicaid programs a basic rebate and, if they raise a drug's price faster than inflation, an additional rebate.[64] The basic rebate is determined by comparing each drug's per unit average manufacturer price (AMP)[65] to that drug's per unit best price. The best price is the drug manufacturer's lowest U.S. price any purchaser paid during a quarterly reporting period. The

[60] CMS, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans," 85 *Federal Register* 23921, May 14, 2020. According to CMS, Q&A–9 of IRS Notice 2004–50 states that the provision of drug discounts will not disqualify an individual from being an HSA-eligible individual if the individual is responsible for paying the costs of any drugs (taking into account the discount) until the deductible under the HDHP is satisfied. Thus, Q&A–9 of IRS Notice 2004–50 requires an HDHP to disregard drug discounts and other manufacturer and provider discounts when determining if the deductible for an HDHP has been satisfied, and only allows amounts actually paid by the individual to be taken into account for that purpose. CMS stated, therefore, that under this IRS policy, an issuer or sponsor of an HSA-qualified HDHP could be put in the position of complying with either the requirement under the 2019 final rule for limits on cost sharing in the case of direct support provided by drug manufacturers for a brand-name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously. According to CMS, the 2019 final rule implied that in situations where a medically appropriate generic equivalent is not available, "group health plans and issuers are required to count such coupon amounts toward the annual limitation on cost sharing."

[61] Ibid., p. 29233.

[62] CMS, "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements," 85 *Federal Register* 87048, December 31, 2020, at https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf.

[63] Ibid., p. 87000.

[64] Social Security Act Section 1927(k)(3), Covered Outpatient Drug.

[65] Social Security Act Section 1927(k)(1) defines the AMP as the average U.S. price manufacturers received for their product excluding specified price concessions when sold to retail community pharmacies.

basic rebate is either the greater of a specified percentage of AMP or the difference between the AMP and the best price.[66]

In its 2020 *Federal Register* notice outlining the final rule, CMS said that it had learned that some health plans, which are defined as providers for determining Medicaid best price, were using accumulator programs to apply patient assistance programs in a way that provided a financial benefit to the plan, rather than solely to the enrollee.[67] For example, by imposing accumulator programs that (1) allow an enrollee to use a coupon but (2) do not count the value of the coupon toward annual OOP requirements, health plans effectively delay the point at which they must provide certain benefits to enrollees, which allows them to realize cost savings. According to CMS, such savings amount to a reduction in the price of a drug, which should be included in determining the Medicaid best price.

CMS set a January 1, 2023, implementation date for the final rule so that manufacturers would have time to develop technical systems to track payment assistance offers to determine whether coupons and other benefits were delivered exclusively to consumers. PhRMA sued HHS and CMS, contending that the rule was inconsistent with the Medicaid statute. PhRMA asserted that manufacturers did not have control over the development or implementation of accumulator programs, and that there was not a reliable method for drug manufacturers to determine whether a cost-sharing offer was provided exclusively to a consumer.[68] In May 2022, the U.S. District Court for the District of Columbia struck down the final rule on the grounds that HHS had exceeded its authority.[69]

Pharmaceutical Assistance Programs

Pharmaceutical manufacturers, state governments, and independent charities operate PAPs to help uninsured or underinsured individuals pay for prescription drugs. Many nongovernmental PAPs are set up as 501(c)(3) nonprofit organizations to provide prescription drugs or financial subsidies to qualified patients.[70] 501(c)(3) entities are exempt from federal income taxes and qualify to

[66] Social Security Act Section 1927(c)(1)(C)(ii) defines *best price* to include cash discounts, free goods contingent on any purchase requirement, volume discounts, and rebates (other than the specified Medicaid rebates). Best price includes the lowest price available from the manufacturer to any U.S. purchaser, which includes with some exceptions a wholesaler, retailer, hospital, provider, HMO, nonprofit entity, or governmental entity.

[67] CMS, "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements," 85 *Federal Register* 87000, December 31, 2020, p. 87408, at https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and. Medicaid patients are not eligible for manufacturer-sponsored programs, but according to CMS the administration of these programs by commercial health plans and PBMs can affect the rebates that the Medicaid program receives from the manufacturer-sponsor of these programs. According to the *Federal Register* notice, when manufacturer-sponsored assistance does not accrue towards a patient's deductible or OOP limits, a health plan is able to delay the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan.

[68] Pharmaceutical Research and Manufacturers Of America (PhRMA) v. Xavier Becerra, Secretary of Health and Human Services, Civil Action No. 1:21-cv-1395, May 21, 2021, at https://www.courthousenews.com/wp-content/uploads/2021/05/pharma-HHS.pdf.

[69] Bloomberg Law, "Drugmakers Win Challenge to Medicaid Drug Price Rebate Rule," May 17, 2022, at https://news.bloomberglaw.com/health-law-and-business/drugmakers-win-challenge-to-medicaid-drug-price-rebate-rule. Pharmaceutical Research and Manufacturers Of America (PhRMA) v. Xavier Becerra, Secretary of Health and Human Services, Civil Action No. 1:21-cv-1395, May 17, 2022, at https://casetext.com/case/pharm-research-manufacturers-of-am-v-becerra-1.

[70] See "What Is a 501(c)(3) Organization?"

receive tax-deductible contributions.[71] As such, pharmaceutical companies and other donors can deduct donations of inventory or cash to PAPs.[72]

Different types of PAPs include the following:[73]

- **Pharmaceutical Manufacturer PAPs**. Many pharmaceutical makers distribute prescription drugs to individuals through their own 501(c)(3) organizations, which often are set up as private foundations. Manufacturer PAPs provide drugs to people enrolled in private insurance and public health programs, and the uninsured. Drug manufacturers may contract with outside companies in administering their PAPs.[74]
- **Independent Charity PAPs.** Independent charities operate PAPs that offer aid such as financial assistance to uninsured consumers or underinsured consumers who cannot meet their health plans' premiums or cost sharing, such as co-payments, coinsurance, and deductibles.
- **State PAPs (SPAPs).** As of 2021, CMS listed 20 state governments with 43 SPAPs that met certain criteria.[75] The SPAPs generally serve uninsured residents or fill in the gaps in Medicare, Medicaid, and private insurance coverage.[76] SPAPs are targeted at lower-income individuals and usually are the payer of last resort, meaning the SPAP will pay for drugs only after federal programs or any private insurance already has been billed. SPAP rules and coverage vary by state—some focus on seniors and some on specific disease groups, such as people with HIV/AIDs. This report concentrates on the other two types of PAPs, and refers to the state programs as SPAPs rather than PAPs for clarity.

What Is a 501(c)(3) Organization?

501(c)(3) organizations qualify for federal tax-exempt status.[77] To qualify, a 501(c)(3) organization must be "organized and operated exclusively" for at least one of the exempt purposes listed in statute, which include charitable and educational purposes. Although the statute uses the term "exclusively," this actually means the organization's activities must primarily be for

[71] 26 U.S.C. §§170, 501.

[72] See also "How are PAP Donations Valued?" In addition, see HHS OIG, "New Special Advisory Bulletin Provides Additional Guidance on Independent Charity Patient Assistance Programs for Federal Health Care Program Beneficiaries," May 21, 2014, at http://oig.hhs.gov/newsroom/news-releases/2014/charity.asp.

[73] Definitions come from HHS OIG publications.

[74] Outside administrators include Eversana, "Alleviate Patients' Financial Burdens and Increase Speed to Therapy," at https://www.eversana.com/solutions/integrated-commercial-services/affordability-programs/patient-assistance-programs/; and McKesson," Program Pharmacy Solutions for Biopharma From RxCrossroads," at http://www.mckesson.com/manufacturers/pharmaceuticals/oncology-and-specialty-pharmaceutical-services/patient-assistance-programs-paps/.

[75] CMS, "State Pharmaceutical Assistance Programs Excluded from Medicaid Best Price," May 2021, link to list at https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html. The Medicaid statute allows manufacturers participating in the Medicaid Drug Rebate Program to exclude prices to SPAPs from their Medicaid best price calculations.

[76] National Conference of State Legislatures, "State Pharmaceutical Assistance Programs," updated 2014 and material added January 2016, at http://www.ncsl.org/research/health/state-pharmaceutical-assistance-programs.aspx. See also Medicare.gov, "State Pharmaceutical Assistance Programs," at https://www.medicare.gov/pharmaceutical-assistance-program/state-programs.aspx.

[77] 26 U.S.C. §501(a).

an exempt purpose.[78] Furthermore, as part of the "organized and operated exclusively" requirement, the organization must serve a public, as opposed to private, interest.[79] When an organization engages in activities that benefit private industry, the question may arise as to whether it provides the public benefit necessary for 501(c)(3) status. If such activities are a substantial part of the organization's activities, then the organization would appear to no longer qualify for 501(c)(3) status.[80]

Another requirement for 501(c)(3) status is that the organization's earnings may not be used to benefit any private shareholder or individual.[81] Any level of private inurement may jeopardize the organization's tax-exempt status or, depending on the circumstances, may trigger a penalty tax.[82]

Charity vs. Foundation

A 501(c)(3) organization is either a public charity or a private foundation.[83] Public charities have broad public support and tend to provide charitable services directly to the intended beneficiaries. Private foundations often are tightly controlled, receive significant portions of their funds from a small number of donors, and make grants to other organizations rather than directly carry out charitable activities. Because these factors create the potential for self-dealing or abuse of position by the small group controlling the entity, private foundations are more closely regulated than public charities. As such, private foundations are subject to penalty taxes for doing things such as failing to distribute a certain amount of their income each year; having excess business holdings; and failing to maintain expenditure responsibility over certain grants. 501(c)(3) organizations are presumed to be private foundations and, if they want to be treated as a public charity, must tell the IRS how they qualify for public charity status based on the support and control tests found in Internal Revenue Code (IRC) Section 509.

How Are PAP Donations Valued?

Companies that donate cash or pharmaceuticals may be able to deduct the donation as a charitable contribution under IRC Section 170. Companies that donate cash or non-inventory property generally may deduct the amount of the cash donation or fair market value of the property, subject to various restrictions.[84]

If the company donates inventory, then a special valuation rule applies.[85] The general rule for donations of inventory is that the taxpayer may only claim a charitable deduction that equals its basis in the inventory (which is typically its cost). However, there is a special valuation rule that applies for C corporations.[86] Under it, C corporations donating inventory may deduct the lesser of

[78] 26 C.F.R. §1.501(c)(3)-1(c)(1). See also Better Business Bureau of Washington D.C., Inc. v. United States, 326 U.S. 279 (1945) (indicating that an organization will not qualify for Section 501(c)(3) status if it has a substantial purpose that is not an exempt purpose).

[79] See Treas. Reg. §1.501(c)(3)-1(d)(1)(ii).

[80] See Rev. Rul. 71-505, 1971-2 C.B. 232; Rev. Rul. 71-504, 1971-2 C.B. 231.

[81] 26 U.S.C. §501(c)(3) ("no part of the net earnings of which inures to the benefit of any private shareholder or individual").

[82] 26 U.S.C. §4958.

[83] 26 U.S.C. §509.

[84] For information on the general rules regarding the deduction of charitable contributions, see CRS Report RL34608, *Tax Issues Relating to Charitable Contributions and Organizations*, by Jane G. Gravelle and Molly F. Sherlock.

[85] 26 U.S.C. §170(e)(1).

[86] C corporations are large incorporated entities that are treated for federal tax purposes as a separate taxable entity

(1) the taxpayer's basis in the property plus 50% of the property's appreciated value or (2) two times the basis.[87] This is commonly referred to as an *enhanced deduction*.

To benefit from the enhanced deduction, the donation must be made to a qualified 501(c)(3) organization.[88] The donee's use of the donation must be related to its tax-exempt purpose and be "solely for the care of the ill, the needy, or infants."[89] Further, the donee may not exchange the donation for money, property, or services.[90] The taxpayer must obtain a written statement from the donee stating it will comply with these restrictions.[91] Finally, donated inventory such as food or drugs must comply with any applicable safety standards in the Federal Food, Drug, and Cosmetic Act on the date of the donation and for 180 days thereafter.[92]

Consumer Eligibility for PAP Assistance

Although specific criteria vary among PAPs, consumer eligibility for assistance generally appears to be based on (1) annual income, (2) insurance status, (3) physician endorsement, (4) prescription information, and (5) proof of U.S. citizenship or legal residence.

Income limits may vary for different drugs supported by a single PAP. A PAP could set a higher income for very expensive drugs, while imposing a lower limit for less expensive products. For example, the Lilly Cares Foundation patient assistance program has three drug assistance groupings with separate income cutoffs ranging from up to 300% of the federal poverty level (FPL) to up to 500% of FPL.[93] Separately, a 2019 study of the six largest charitable organizations offering pharmaceutical patient assistance, which included 274 patient assistance programs, found that 97% of the programs excluded uninsured patients, and the most common income eligibility limit was 500% of FPL.[94]

Most PAP support is provided for a limited time period, such as several months or a year. Individuals in many cases may reapply for assistance. PAPs may provide drugs or other aid directly to a patient or through a doctor, pharmacy, or other health care provider.

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apart from their owners. See 26 U.S.C. §§11, 1361. For more information, see CRS Report R43104, *A Brief Overview of Business Types and Their Tax Treatment*, by Mark P. Keightley.

[87] 26 U.S.C. §170(e)(3), (e)(3)(B); Treas. Reg. §1.170A-4A(c)(2).

[88] 26 U.S.C. §170(e)(3)(A).

[89] Ibid., §170(e)(3)(A)(i).

[90] Ibid., §170(e)(3)(A)(ii).

[91] Ibid., §170(e)(3)(A)(iii).

[92] Ibid., §170(e)(3)(A)(iv).

[93] Lilly Cares Foundation, "Check Your Eligibility," at https://www.lillycares.com/how-to-apply#check-eligibility.

[94] So-Yeon Kang et al., "Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs," *Journal of the American Medical Association*, JAMA. 2019 Aug 6; 322(5): 422–429, at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6686767/. There were 168 patient assistance programs (61%) that provided only co-payment assistance, 9 programs (3%) offered only assistance to subsidize the cost of health insurance premiums, and 90 programs (33%) allowed patients to choose between co-pay and insurance premium assistance. None of the patient assistance programs offered free drugs. The most common therapeutic areas covered were cancer or cancer treatment–related symptoms (113 programs; 41%) and genetic or rare diseases (93 programs; 34%). The study also found that the median 2016 Medicare Part D spending per beneficiary was $1,157 for medications covered by these programs compared with $367 for the medications not covered.

HHS Guidance Addressing PAP Giving

As is the case with manufacturer coupons, there are legal constraints on the use of PAP funding in conjunction with federal health care programs.

2005 HHS OIG Bulletin

In November 2005, just before Medicare Part D took effect, the HHS OIG issued a special advisory bulletin on PAPs.[95] The OIG said that although manufacturer-based PAPs that offered subsidized Part D cost sharing presented heightened risks under the anti-kickback statute,[96] cost-sharing assistance offered by truly independent charities should not raise anti-kickback concerns, even if the charities received cash donations from drugmakers.[97] The bulletin affirmed that manufacturer-based PAPs could operate "outside" the Part D benefit, meaning that they could provide drugs to Part D enrollees but that no manufacturer donation could be filed with a Part D plan and the assistance would not count against Part D out-of-pocket spending requirements.[98] Manufacturers that were operating PAPs before enactment of Part D had concerns about the legal implications of providing aid to Part D enrollees, and some companies took steps to limit programs. After release of the HHS OIG guidance and entreaties from members of Congress, manufacturers generally continued assistance through manufacturer PAPs.[99] A number of independent charity PAPs also were created in the early 2000s to aid Medicare enrollees and other consumers.[100]

The HHS OIG guidance also limits the dissemination of data from PAPs. Specifically, PAPs may not provide detailed data that would enable pharmaceutical firms to determine how much of any donated funds were being used to support prescriptions for the specific drugs they manufacture.[101] The pharmaceutical manufacturer cannot solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

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[95] HHS OIG, "Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," 70 *Federal Register* 70623, November 22, 2005, p. 70626, at https://oig.hhs.gov/documents/special-advisory-bulletins/880/2005PAPSpecialAdvisoryBulletin.pdf.

[96] Ibid. The HHS OIG noted that subsidies by manufacturer PAPs had the practical effect of "locking beneficiaries into the manufacturer's product, even if there were other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives)."

[97] Ibid. The HHS OIG said that in-kind donations of drugs to independent charity PAPs posed additional risks not yet directly addressed in prior OIG guidance, and that the HHS OIG had insufficient experience to offer detailed guidance. "While in-kind donations have the potential benefit of increasing the value of donations (because marginal costs of drugs are generally low), they also have the effect of creating a direct correlation between the donation and use of a particular donor's product, thereby weakening important safeguards of an independent charity PAP arrangement." HHS also noted potential accounting and valuation issues regarding in-kind donations. See footnote 14 of the HHS Bulletin.

[98] The HHS OIG also issues separate advisory opinions to specific manufacturer and charitable PAPs that seek clarification as to whether their programs are in compliance.

[99] Senate Finance Committee, "Senators Invite Drug Company Execs to Discuss Prescription Drug Assistance Programs," May 8, 2006, at http://www.finance.senate.gov/newsroom/chairman/release/?id=8e7de26d-bcd6-4e87-aa02-f53fe7797aa0. See also http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2006/TauzinPAP.pdf.

[100] Alex Berenson, "In Drug-Aid Foundations a Web of Corporate Interests," *New York Times*, April 8, 2006, at http://www.nytimes.com/2006/04/08/business/08foundation.html.

[101] HHS OIG, "Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," 70 *Federal Register* 70623, November 22, 2005, p. 70626, at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf.

2014 Update to HHS OIG Bulletin

In May 2014, the HHS OIG updated its 2005 bulletin. In its update,[102] the HHS OIG said it would increase scrutiny of independent charity PAPs that established or operated funds that narrowly defined specific diseases or limited assistance to a subset of available products, such as covering co-payments only for expensive or specialty drugs. In an accompanying press release, the HHS OIG said it had seen a general tendency away from broad disease funds and toward narrower funds, such as a fund for a specific stage or complication of a disease. It also said charities had sought advisory opinions that would allow them to narrow the scope of the drugs that they covered to specialty or expensive pharmaceuticals. The HHS OIG said such restrictions could be harmful to patients, taxpayers, and federal programs. "If assistance is available only for the highest-cost drugs, patients may be steered to those pharmaceuticals rather than to equally effective, lower-cost alternatives. If, instead, assistance is available for a broader range of equally effective treatments, patients, and their prescribers, have greater freedom of choice."[103]

According to the update, the cost of a drug was not an appropriate stand-alone factor for determining need. Generous financial support, particularly for a PAP with a limited number of drugs or limited to the drugs of a major donor manufacturer, could be evidence of intent to induce use of particular drugs rather than to support financially needy patients.[104] A number of charitable PAPs agreed to make operational changes in response to the HHS OIG's 2014 guidance. More recently, the HHS OIG has issued supplemental advisory opinions regarding new operations of individual charitable PAPs.[105]

Another recent development appears to be an increased willingness by manufacturers to offer direct assistance to enrollees in federal programs such as Medicare Part D through their own manufacturer PAPs (as opposed to or in addition to donating to an independent charity PAP). For example, Novo Nordisk, a main insulin producer, offers Medicare Part D enrollees up to a 120-day supply of a medication or device through its PAP through the end of a calendar year.[106] Eli Lilly, another major insulin producer, offers aid to Part D enrollees through its Lilly Cares Foundation.[107]

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[102] HHS OIG, "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," 79 *Federal Register* 31120, May 30, 2014, p. 31120-31123, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf.

[103] HHS OIG, "New Special Advisory Bulletin Provides Additional Guidance on Independent Charity Patient Assistance Programs for Federal Health Care Program Beneficiaries," May 21, 2014, at http://oig.hhs.gov/newsroom/news-releases/2014/charity.asp.

[104] Andrew Pollack, "Drug Maker's Donations to Co-Pay Charity Face Scrutiny," *New York Times*, December 19, 2013, at http://www.nytimes.com/2013/12/19/business/shake-up-at-big-co-pay-fund-raises-scrutiny-on-similar-charities.html; and Bill Alpert, "Too Close for Comfort," *Barron's*, October 19, 2013, at http://www.barrons.com/articles/SB50001424053111904462504579137163650125276.

[105] See HHS OIG at http://oig.hhs.gov/compliance/advisory-opinions/#advisory.

[106] Novo Nordisk, "Novo Nordisk Patient Assistance Program Application," PAP-Application-EN.pdf (novocare.com).

[107] Lilly Cares, at https://www.lillycares.com/. As part of the application for aid, Part D enrollees must agree not to submit any claim for reimbursement to any third party or government insurer for any product provided to them through the Lilly Cares Program; if enrolled in Part D, not to seek to have the cost/value associated with the medication they receive through the Program counted as out-of-pocket costs for prescription drugs and to inform the covering Part D plan about their enrollment in Lilly Cares.

Data Sources for Annual PAP Revenue and Giving

As previously noted, manufacturer and independent charity PAPs are now among the larger U.S. nonprofit organizations. However, it is difficult to assess the total dollar value of PAP giving or the total number of consumers aided each year. There is no central PAP database and no uniform national patient eligibility criteria.

A primary source of PAP data is the annual information return (Form 990 series) that 501(c)(3) organizations generally are required to file with the IRS.[108] On the form, the organizations must disclose information related to income, expenses, assets, and officers and employees, among other things.[109] The form has several schedules that ask for information in such areas as the organization's substantial donors (Schedule B) and related organizations (Schedule R). Furthermore, an organization that conducts business activities unrelated to its exempt purpose must file a tax return (Form 990-T) and pay tax on the earnings.[110]

The organization and the IRS must make the organization's Form 990, accompanying schedules, and Form 990-T publicly available.[111] Identifying information about the donors reported on the Schedule B is not subject to public disclosure unless the 501(c)(3) entity is a private foundation.[112]

There is variation in the type and amount of information that the PAPs include in their Form 990s. Some Form 990s examined by CRS provided aggregate information about the value of donated drugs or cash, whereas others provided detailed data about the specific drugs or the type of patients supported.

PAPs Appear to Have Increased in Size and Scope

Based on rankings of nonprofit organizations, IRS annual reports filed by manufacturer and independent charity PAPs, and outside studies, PAP contributions and revenues for some of the largest organizations appear to have increased in recent years.

A 2016 study of IRS information found that charitable expenditures by 10 leading manufacturers increased from $3.1 billion in 2008 to $6.1 billion in 2014, and contributions by five independent charity PAPs increased from $50 million in 2005 to $868 million in 2014.[113] A study of charitable PAPs found that, in 2017, the six largest independent charity PAPs had total revenue ranging from $24 million to $532 million, and spending on patient assistance ranging from $24 million to $353 million, representing on average, 86% of their revenue.[114]

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[108] 26 U.S.C. §6033.

[109] Ibid., §6033(a).

[110] Ibid., §§511, 6011.

[111] Ibid., §6104(b), (d).

[112] Ibid.

[113] Austin Frerick, "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity," *Tax Notes*, November 28, 2016. The study of pharmaceutical giving includes data on the manufacturer and charitable PAPs going back to 2005. However, not all organizations were included in the data in the earlier years. The figures in the text represent the change in giving over the time periods for which there is information from all the PAPs.

[114] So-Yeon Kang et al., "Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs," *Journal of the American Medical Association*, JAMA, vol. 322, no. 5, (August 6, 2019), pp. 422–429, at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6686767/.

Based on recent, available Form 990 filings, some of the largest manufacturer PAPs include

- the Johnson & Johnson Patient Assistance Foundation, with about $1.8 billion in contributions and grants in 2019;
- the Bristol-Myers Squibb Patient Assistance Foundation with $1.3 billion in contributions and grants in 2019;
- the Lilly Cares Foundation with $1.7 billion in contributions and grants in 2020;
- the Merck Patient Assistance Program, with $1.4 billion in contributions and grants in 2019;
- the Pfizer Patient Assistance Foundation with $1.1 billion in contributions and grants in 2018; and
- the Sanofi Cares North America (formerly Sanofi-Aventis Patient Assistance Foundation) with $779 million in contributions and grants in 2019.[115]

Five charitable PAPs were included in a 2021 list of top 100 U.S. nonprofits (ranked by revenue), including

- the Heathwell Foundation, ranked 37st with $559 million in revenue;
- the Patient Access Network Foundation (PAN Foundation), ranked 44th with $451 million in revenue;
- the Assistance Fund, ranked 53rd with $383 million in revenue;
- Good Days, ranked 66th with $323 million in revenues; and
- the Patient Advocate Foundation, ranked 74th with $301 million in revenue.[116]

According to the PAN Foundation's annual report, in 2020 the Foundation provided $454 million in financial assistance to more than 170,000 patients. The average grant was about $6,000, and 98% of assisted patients had Medicare coverage.[117]

Insurance Market Response to Coupons/PAPs

In response to the growth in manufacturer coupons and PAPs, health care issuers and payers have made changes to their prescription drug benefits to directly address these programs. The changes have made it more difficult to assess the financial impact of manufacturer offers on health payers and enrollees.

For example, a number of health payers, often working with PBMs, have redesigned their prescription drug benefits to maximize the amount of pharmaceutical coupon and PAP payments that the health plans can receive directly from manufacturers, sometimes while limiting the

[115] Form 990s for the PAPs are available at ProPublica Nonprofit Explorer, at https://projects.propublica.org/nonprofits/organizations/562591004.

[116] *The NonProfit Times*, "The 2021 NPT 100: Donors Stood Tall, Led With BIG Gifts," November 3, 2021, at https://www.thenonprofittimes.com/report/the-2021-npt-100-donors-stood-tall-led-with-big-gifts/. The NPT 100 is a report on the largest nonprofits in the United States that derive at least 10% of revenue from public support. The organizations were ranked by total revenue.

[117] PAN Foundation, *Annual Report 2020*, available at https://www.panfoundation.org/about-pan/annual-reports/. According to the PAN Foundation 2021 Form 990, the organization provided $380 million in grants and other assistance during the year, aiding 160,554 patients. The Form 990 is also available at https://www.panfoundation.org/about-pan/annual-reports/.

overall financial benefit of the assistance to enrollees. Among the new systems are accumulator and maximizer programs (see below).

Due to market consolidation, many health insurers now own PBMs and specialty pharmacies that earn large fees for dispensing expensive specialty drugs to plan enrollees, and thus have an interest in ensuring patients sign up for manufacturer assistance.[118] In another example of the increasingly complex relationships between payers and manufacturers, managed health care insurer Centene owns a subsidiary that helps health payers maximize collection of manufacturer assistance program dollars, while limiting the payers' own costs for the drugs.[119]

Following is a description of emerging health plan approaches.

Cost-Sharing Accumulators

Under an accumulator program, a health plan allows an enrollee to use a coupon or other manufacturer assistance such as a co-payment card or voucher to reduce the enrollee's out-of-pocket (OOP) cost-sharing for filling a prescription, for example, while in the deductible or when a co-payment or coinsurance is owed. However, the plan does not count the value of the assistance toward meeting the enrollee's deductible or annual OOP limit. (See example in "Accumulator Programs" below.) By not counting the value of the manufacturer assistance, the plan delays the point at which the enrollee would otherwise meet the annual deductible and/or OOP cap by using the coupon, thereby limiting the plan's additional financial exposure. (For example, delaying the point at which a plan might have to pay 100% of the cost of the drug because the enrollee met the annual OOP cap.)

Accumulator Programs

For an example of an accumulator program, assume a consumer is enrolled in a health insurance plan with a $1,000 annual deductible and has a manufacturer co-payment coupon worth $250.

In a plan without a co-pay accumulator policy, the $250 manufacturer coupon would reduce the enrollee's OOP cost for the drug and also would be applied toward the plan deductible, reducing the beneficiary's deductible obligation to $750.

In a plan with a co-pay accumulator, the $250 coupon would be used to reduce the enrollee's OOP cost for the prescription drug, but would not count toward the deductible, leaving the enrollee to meet the full $1,000 deductible from the enrollee's own OOP spending before plan benefits commenced. The coupon value would also not apply to meeting enrollee annual caps on OOP spending.

Patient advocates say that the programs can reduce the financial value of the assistance for patients which, in turn, may affect their ability to afford a particular medication and undo some of the medical benefits related to medication adherence. For example, an enrollee could reach the maximum value of a coupon offer prior to the end of a plan year, without having satisfied out of pocket spending requirements. In such a case, the enrollee may not be able to afford the cost-sharing necessary to continue a course of treatment. That could be a problem for individuals with

[118] Insurers that own specialty pharmacies reap large fees for administering and dispensing specialty products, and thus may have a financial incentive to ensure patients can access the products. See for example, Humana, Patient Assistance, at https://www.humana.com/pharmacy/specialty-rx/patient-assistance. According to the website: "Humana Specialty Pharmacy® offers patient assistance programs to help with the financial costs of specialty medications. In 2019, Humana Specialty Pharmacy® helped patients find over $108.9 million in patient assistance funds and has relationships with over 175 funding sources."

[119] Centene in 2019 acquired Health Smart Rx Solutions, which designs patient assistance accumulator and maximizer programs. See Health Smart, at https://www.healthsmart.com/SmartRxAssist.

chronic diseases such as AIDS, who are highly dependent on manufacturer assistance.[120] In addition, advocates say insurance plan documents may not be clear as to whether an accumulator program is in effect, leaving consumers who have been relying on coupons to discover only after annual enrollment that expected coverage is less extensive than expected.

Accumulator programs appear to be growing in use, although there is no single source measuring national prevalence.[121] According to one pharmaceutical industry analysis, 80% of people in commercially insured managed care plans in 2021 appear to have been enrolled in plans with co-pay accumulator or maximizer features (discussed in the next section) as part of the plan design.[122] Among employers with 500 or more employees that offered prescription drug benefits in 2021, 18% had programs that excluded subsidies from prescription drug manufacturers, such as coupons, from counting towards an enrollee's deductible or out-of-pocket limit.[123]

The 2020 CMS rules allow accumulator programs (when not prohibited by state law) in health plans sold on the exchanges and in non-grandfathered individual and group health plans sold off the exchanges. (See "2020 HHS Coupon Accumulator Final Rule for Qualified Health Plans") As of fall 2021, a dozen states and Puerto Rico had policies to limit the use of the accumulator programs in the health plans they regulated.[124]

Coupon Maximizers

Under a coupon maximizer program, a health plan enrolls eligible beneficiaries in manufacturer cost-sharing programs for certain prescribed drugs. Once a beneficiary is enrolled in a manufacturer assistance program, the payer increases the health plan's required cost-sharing amount for the drug to the maximum dollar amount of the manufacturer coupon or PAP offer.[125] Most or all of the cost sharing would be covered by the manufacturer program; the enrollee's

[120] The AIDS Institute, "Copay Accumulators and Insurance Issues," February 1, 2022, available at https://aidsinstitute.net/protecting-patients-and-removing-barriers-to-care/copay-accumulators-and-insurance-issues.

[121] Ibid. The study looked at 2022 health insurance exchange plans in states that did not restrict the practice, and found that in 35 states, there was at least one plan with a co-pay accumulator adjustment policy. In eight states, every plan included a co-pay accumulator policy: Alabama, Alaska, Delaware, Idaho, Indiana, Iowa, Montana and South Carolina. According to the study, 12 states had restrictions on accumulator policies in such plans.

[122] Drug Channels, "Copay Accumulator and Maximizer Update: Adoption Accelerating as Pushback Grows," November 17, 2020, at https://www.drugchannels.net/2020/11/copay-accumulator-and-maximizer-update.html. Figures are based on data from U.S. commercial managed care plans that cover nearly 130 million people. The accumulator programs were part of the plan designs, but might not be applied by all plans.

[123] Kaiser Family Foundation, "2021 Employer Health Benefits Survey," Section 13, p. 19, at https://www.kff.org/health-costs/report/2021-employer-health-benefits-survey/. Larger firms were more likely to institute such programs – 24% of companies with 5,000 or more workers had such programs. In addition, 14% of firms with more than 500 workers said they did not know if their plan included accumulator and similar programs.

[124] National Conference of State Legislatures, "Copayment Adjustment Programs," October 7, 2021, at https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx.

[125] According to *Drug Channels*, "The value of the manufacturer's copayment program is applied evenly throughout the benefit year. The patient's out-of-pocket obligations aren't based on the list or net price of the drug—but are instead set to equal the maximum value of a manufacturer's copayment program. To avoid these extraordinary costs, the beneficiaries must enroll in a separate copay maximizer program." See "Copay Accumulator and Maximizer Update: Adoption Accelerating as Pushback Grows," November 17, 2020, at https://www.drugchannels.net/2020/11/copay-accumulator-and-maximizer-update.html. According to a recent IQVIA analysis, the proliferation of accumulator/maximizer programs in tandem with changes in federal Medicaid policy (separate from the accumulator rule that was struck down), could have a big financial effect on manufacturers. IQVIA, "Trends to Watch through 2023: Copay Accumulator Adjuster Programs," March 21, 2022, at https://www.iqvia.com/locations/united-states/blogs/2022/03/trends-copay-accumulator-adjuster-programs.

actual OOP obligation for that specific drug could be reduced or eliminated.[126] (See example in "Co-pay Maximizer Program" box.)

Co-pay Maximizer Program

For an example of a maximizer program, assume a consumer is in a plan with 25% coinsurance and is prescribed a drug with an estimated monthly cost of $2,000. The enrollee is eligible for a manufacturer coupon that provides up to $1,500 a month in coverage and requires an enrollee contribution of $20.

Without the coupon, the enrollee would pay $500 a month in cost sharing, and the plan would cover $1,500.

Under a manufacturer's regular coupon offer, the coupon would cover $480 of the cost sharing and the enrollee would pay $20.

Under a health plan maximizer program, the monthly cost sharing for the drug would be increased to $1,520, of which the coupon would cover $1,500, the enrollee would pay $20, and the plan would cover $480. Depending how the program is set up, the value of the coupon may not count toward the enrollee's deductible or annual OOP cap.

The programs provide the issuer/payer the maximum manufacturer assistance for the drug, in addition to other rebates/discounts that the plan may have negotiated separately with the manufacturer for placing the drug on the plan formulary. A health plan may directly administer a coupon maximizer program or contract with a third party firm to administer such a program. The program administrator tracks all pharmaceutical assistance offers, and manages the paperwork to enroll a plan beneficiary in a manufacturer program including addressing income and/or any prior authorization requirements.

In a related move, some payers have designed programs that remove certain drugs from their formularies and help enrollees sign up for manufacturer assistance programs for the drugs, which would become the enrollees' de facto coverage.[127]

Justice Department Action on Prescription Drug Aid Programs

As patient assistance programs have grown in importance, the Justice Department and HHS have stepped up scrutiny. During the past several years, the Justice Department has announced financial settlements with manufacturers, PAP operators, and pharmacies regarding alleged violation of the anti-kickback and other federal statutes. Below is a list of selected settlements.

Manufacturers

Following are selected settlements with manufacturers announced by the Justice Department:

- Incyte Corporation in 2021 agreed to pay $12.6 million to resolve allegations that it used an independent foundation as a conduit to pay the co-pays of certain

[126] According to Truveris, a drug benefit analytics and consulting firm, "Maximizers, sometimes called variable copay programs, reclassify a subset of specialty medications as 'non-essential,' removing the ACA requirements related to maximum out-of-pocket spending. These medications are assigned a percentage of coinsurance within the benefit, but patients are always charged $0 for these drugs. PBMs identify the available copay assistance and spread that across a patient's benefit year to maximize the use of those available funds." See https://truveris.com/pharma-accumulators-maximizers/.

[127] Smart RxAssist, HealthSmart, at https://healthsmart.com/Copay-Maximizer. Site contains a link to a webinar on accumulator/maximizer programs.

federal beneficiaries taking Incyte's drug Jakafi. According to the Department of Justice, Incyte was the sole donor to a fund that assisted only myleofibrosis patients.[128]

- Biogen in 2020 agreed to pay $22 million to resolve claims that it illegally used foundations to pay the co-pays of Medicare patients taking Biogen's multiple sclerosis drugs, Avonex and Tysabri.[129]
- Gilead Sciences, Inc. in 2020 agreed to pay $97 million to resolve claims that it illegally used a foundation to pay the Medicare co-pays for its drug Letairis.[130]
- Novartis in 2020 agreed to pay $51.25 million to resolve allegations that it illegally paid the co-pay obligations for Medicare patients taking its drugs. The payment was part of an overall $642 million settlement with Novartis that included allegations of improper payments to physicians.[131]
- Sanofi-Aventis U.S., LLC in 2020 agreed to pay $11.85 million to resolve allegations that it paid kickbacks to Medicare patients through a purportedly independent charitable foundation, The Assistance Fund ("TAF").[132]
- US WorldMeds LLC in 2019 agreed to pay $17.5 million to resolve allegations that it paid kickbacks to patients and physicians to improperly induce prescriptions of its drugs, Apokyn® and Myobloc®.[133]
- Astellas Pharma US Inc. and Amgen Inc. in 2019 agreed to pay a total of $124.75 million to resolve allegations that they each illegally paid the Medicare co-pays for their own products, through purportedly independent foundations.[134]
- Jazz Pharmaceuticals plc, Lundbeck LLC and Alexion Pharmaceuticals Inc. in 2018 agreed to pay a total of $122.6 million to resolve allegations that they

[128] Department of Justice, "Incyte Corporation to Pay $12.6 Million to Resolve False Claims Act Allegations for Paying Kickbacks," May 4, 2021, at https://www.justice.gov/opa/pr/incyte-corporation-pay-126-million-resolve-false-claims-act-allegations-paying-kickbacks.

[129] Department of Justice, "Biogen Agrees To Pay $22 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks," December 17, 2020, at https://www.justice.gov/opa/pr/biogen-agrees-pay-22-million-resolve-alleged-false-claims-act-liability-paying-kickbacks.

[130] Department of Justice, "Gilead Agrees to Pay $97 Million to Resolve Allegations that it Paid Kickbacks through a Co-Pay Foundation," September 23, 2020, at https://www.justice.gov/usao-ma/pr/gilead-agrees-pay-97-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[131] Department of Justice, "Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians," July 1, 2020, at https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians. See also: "Novartis Agrees to Pay Over $51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations," at https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[132] Department of Justice, "Sanofi Agrees to Pay $11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation," February 28, 2020, at https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[133] Department of Justice, "Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians," April 30, 2019, at https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients.

[134] Department of Justice, "Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations," April 25, 2019, at https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid#:~:text=The%20Department%20of%20Justice%20announced%20today%20that%20two,foundations%20that%20the%20companies%20used%20as%20mere%20conduits.

illegally paid the Medicare or Civilian Health and Medical Program (ChampVA) co-pays for their own products, through purportedly independent foundations.[135]

- Pfizer Inc. in 2018 agreed to pay $23.85 million to resolve allegations that it paid kickbacks to Medicare patients through a purportedly independent charitable foundation.[136]
- United Therapeutics in 2017 agreed to pay $210 million to resolve claims that it used a patient assistance foundation as a conduit to pay the co-pays of Medicare patients taking the firm's pulmonary arterial hypertension drugs.[137]

Patient Assistance Programs

Following are selected Justice Department settlements with PAPs:

- Patient Services, Inc. agreed to pay $3 million in 2020 to resolve allegations that it enabled certain pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.[138]
- The Assistance Fund ("TAF"), in 2019 agreed to pay $4 million to resolve allegations that it enabled certain pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.[139]
- The Chronic Disease Fund, Inc. d/b/a Good Days from CDF ("CDF"), and Patient Access Network Foundation in 2019 agreed to pay $2 million and $4 million, respectively, to resolve allegations that they enabled pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.[140]

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[135] Department of Justice, "Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations," April 4, 2019, at https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid.

[136] Department of Justice, "Pfizer Agrees to Pay $23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation," May 24, 2018, at https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[137] Department of Justice, "Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 20, 2017, at https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

[138] U.S. Department of Justice, "Patient Services Inc. Agrees to Pay $3 Million for Allegedly Serving as a Conduit for Pharmaceutical Companies to Illegally Pay Patient Copayments," January 21, 2020, at https://www.justice.gov/opa/pr/patient-services-inc-agrees-pay-3-million-allegedly-serving-conduit-pharmaceutical-companies. The Justice Department "alleged that PSI coordinated with three pharmaceutical manufacturers – Insys, Aegerion, and Alexion – to enable them to pay kickbacks to Medicare patients taking their drugs. PSI allegedly worked with these companies to design and operate certain funds that funneled money from the companies to patients taking the specific drugs the companies sold. These schemes allegedly minimized the possibility that the companies' contributions to the funds would go to patients taking competing drugs made by other companies and undermined the nature of these contributions as bona fide donations. The United States previously entered into settlement agreements with Insys, Aegerion, and Alexion covering their use of PSI as a conduit to pay their patients' copays."

[139] Department of Justice, "Third Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients," November 20, 2019, at https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks.

[140] Department of Justice, "Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients," October 25, 2019, at https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare.

Pharmacy Settlements

The Justice Department has also announced this settlement with a pharmacy: Specialty pharmacy Advanced Care Scripts Inc. in 2020 agreed to pay $3.5 million to resolve allegations that it conspired with pharmaceutical manufacturer Teva Neuroscience, Inc. (Teva), to enable Teva to pay kickbacks to Medicare patients taking Copaxone for multiple sclerosis.[141] According to the announcement, ACS acknowledged, among other things, that it relayed data from two foundations, Chronic Disease Fund and The Assistance Fund, to Teva to correlate its payments to the foundations with the amounts of money the foundations spent on Copaxone patients.

Financial Impact of Coupons and PAPs

Analyses by marketing firms and academics indicate that coupons and patient assistance programs can benefit manufacturers by helping to create demand for newly introduced drugs, maintaining market share in therapeutic areas with competing drugs available, supporting higher list prices, and increasing consumer adherence to existing prescriptions.[142]

Manufacturers build the cost of the programs into their budget and pricing strategies and use analytics to target the offers.[143] There is no comprehensive information on how much PAPs and coupons may contribute to higher drug list prices, or stimulate sales of more expensive drugs when cheaper generics or other therapeutic substitutes are available, although there have been some targeted academic studies on the impact of manufacturer assistance, some of which are summarized in the remainder of this section.

A 2022 study of brand-name drugs without generic equivalents found that coupons increased the quantity of the drugs sold in the commercial market by 21-23% relative to Medicare Advantage in the year after introduction. The study also suggested that co-payment coupons increased spending on multiple sclerosis drugs by up to 8% and nearly $1 billion in annual spending.[144] "Combined, the results suggest co-payment coupons increase spending on couponed drugs without bioequivalent generics by up to 30 percent," according to the study.

A 2016 study of coupons for brand-name drugs for which generics were available found the coupons reduced the rate of generic substitution. The brand-name drugs with coupon offers had

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[141] Department of Justice, "Specialty Pharmacy Advanced Care Scripts Agrees to Pay $3.5 Million to Resolve Allegations that it Served as a Kickback Conduit," August 13, 2020, at https://www.justice.gov/usao-ma/pr/specialty-pharmacy-advanced-care-scripts-agrees-pay-35-million-resolve-allegations-it.

[142] Marketing firm analyses include Mason Tenaglia, "Copay Cards and Coupons: Letting Facts Get in the Way," *Pharmaceutical Executive,* January 1, 2012, at https://www.pharmexec.com/view/copay-cards-and-coupons-letting-facts-get-way; Merkle, "Beyond Price Wars: Using Copay Programs to Drive Adoption," May 29, 2018, at https://www.merkleinc.com/blog/beyond-price-wars-using-copay-programs-drive-adoption; McKesson, "Optimizing Co-Pay Assistance Programs to Improve Medication Adherence," September 3, 2019, at https://www.mckesson.com/Blog/Copay-Assistance-Medication-Adherence/; Truveris, "Is Your Copay Program Costing You More Than It's Earning? Keep These Top 5 Metrics in Mind," January 11, 2021, Truveris, at https://truveris.com/is-your-copay-program-costing-you-more-than-its-earning-keep-these-top-5-metrics-in-mind/.

[143] Trialcard, "Leveraging Data and Analytics to Enhance Copay Program Performance," *Pharmaceutical Executive,* Special Advertising Section.

[144] Leemore Dafny, Kate Ho, and Edward Kong, "How Do Copayment Coupons Affect Branded Drug Prices and Quantities Purchased," NBER Working Paper No. 29735, February 2022, at http://www.nber.org/papers/w29735. The paper used data from a PBM and from Medicare to evaluate the impact of co-pay coupons on prices and quantities of branded drugs without generics. The authors: (1) created a model that compared pre vs. post-coupon prices and quantities for the commercially insured vs. the Medicare Advantage population, which is ineligible to use coupons and (2) built a second model of medications for multiple sclerosis to predict the effect of coupons on list prices.

12%-13% annual price growth, compared to 7%-8% annual price growth for those without coupons.[145] According to the study, the co-payment coupons increased retail spending from 1.2% to 4.6% in the five years following the introduction of a generic, which corresponded to increased spending of $30-$120 million for the average drug studied. In addition, an earlier, targeted study of consumers using statins to control cholesterol levels found that the use of manufacturer coupons increased enrollee prescription adherence, but at the cost of higher out-of-pocket spending for consumers and higher costs to their insurance plans than for those using generic drugs or brand-name drugs that did not offer coupons.[146]

Other studies have examined whether manufacturers target coupons at drugs for which lower-cost substitutes are available, thus inducing beneficiaries to use higher-priced drugs. A 2013 study examined whether widely advertised coupons were being offered for drugs with available generic substitutes or therapeutically equivalent products.[147] According to that study, based on 374 coupons for brand-name prescription drugs advertised on the website http://www.internetdrugcoupons.com, about 60% of the offers were for products with generic alternatives in the same drug class.[148]

A 2018 study of the top 200 top-selling drugs in 2014, found no coupons offered for the 68 generics in the group. Of the remaining 132 brand drugs, 90 had coupons of which: 21% had a generic equivalent, 28% had a generic drug among close therapeutic substitutes, 12% had no substitute and 39% had only single-source branded competitors. According to the study:

> While we cannot determine whether coupons raise drug costs directly, our classification suggests which coupons may be more or less likely to raise costs, and if they raise costs, whether they are providing a clear benefit in exchange. The 21% of coupons on drugs with generic equivalents seem very likely to raise costs without any obvious benefit. At the other end of the spectrum, the 12% of coupons on drugs with no therapeutic substitute of any kind may or may not raise costs, but improve access for more price.[149]

A 2020 study found that drugs that were later entrants to the market, were more expensive than in-class competitors, or faced competitors offering coupons were more likely to have greater

[145] Leemore Daffny, Christopher Ody, and Matt Schmitt, "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," NBER Working Paper No. 22745, October 2016, at http://www.nber.org/papers/w22745. The study found that coupons supported prices of brand-name drugs by reducing sales of generic substitutes. The study did not find an association between coupons and quantity levels or growth rates for the drugs.

[146] Jonas Daugherty, Matthew Maciejewski, and Joel Farley, "The Impact of Manufacturer Coupon Use in the Statin Market," *Journal of Managed Care Pharmacy*, vol. 19, no. 9 (October 2013). The study used commercially available claims data spanning three years and representing 340,350 patients to compare demographics, statin use, and expenditures of patients initiating generic statins, brand-name statins without manufacturer coupons, and brand-name statins with manufacturer coupons.

[147] According to the FDA, drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drugs must meet specific guidelines to be deemed therapeutically equivalent. See http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#T.

[148] Joseph Ross and Aaron Kesselheim, "Prescription-Drug Coupons—No Such Thing as a Free Lunch," *New England Journal of Medicine,* vol. 369, no. 13 (September 26, 2013), at http://www.nejm.org/doi/full/10.1056/NEJMp1301993. The authors used the FDA website and the Tarascon Pharmacopoeia to determine that a lower-cost FDA-approved therapeutic equivalent was available for 8% of the drugs in their sample. For more than half the remaining products there was a lower-cost generic alternative within the same drug class.

[149] Karen Van Nuys et al., "Prescription Drug Copayment Coupon Landscape," USC Schaffer, February 7, 2018, at https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/. The study was based on data from PBM Optum's Clinformatics® and looked at the top 200 drugs by spending in 2014 that had been in the market since at least 2012.

coupon use. Drugs with higher mean patient co-pay were no more likely to be offered coupons than those with lower co-pay.[150]

A 2014 study using data from Prime Therapeutics, a PBM owned by a group of Blue Cross and Blue Shield plans, found that coupons helped consumers save $6 of every $10 in out-of-pocket costs for specialty drugs.[151]

There is less information available on the impact of PAPs. While in the past, some charitable PAPs and marketers made forecasts regarding return on investment from their programs, PAP operating procedures have changed in response to the more stringent oversight from HHS OIG and the Department of Justice.

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[150] So-Yeon Kang et al., "Factors Associated With Manufacturer Drug Coupon Use at US Pharmacies," JAMA Health Forum, August 13, 2021, at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2783127. The study used a nationally representative database sample of 2,501 unique brand-name prescription drugs accounting for 8,995,141 claims. "From a 5% nationally random sample of 26 774 102 unique individuals using any copay offset between October 2017 and September 2019, we excluded claims for which a federal health plan was the payer and identified brand-name prescription drugs with at least one transaction where a manufacturer's product-specific coupon was used. We examined the method of payment and payer names to identify claims using manufacturer drug coupons as either the primary or secondary payer for the transaction."

[151] Catherine Starner et al., "Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums," *Health Affairs*, vol. 33, no. 10 (October 2014), pp. 1761-1769. The study examined 264,801 specialty drug prescriptions in 2013 covered by the insurance plans the PBM, Prime Therapeutics, served. Spending for the specialty claims totaled $911.8 million, of which $35.3 million (3.9%) was paid OOP by enrollees. Beneficiaries used coupons for 44.3% of the prescriptions, which offset $21.2 million (60.2%) of the $35.3 million in charges. In most cases, the coupons reduced monthly out-of-pocket costs to less than $250, a price at which Prime Therapeutics said separate data indicated that patients using high-cost drugs were less likely to abandon therapy.