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# Prescription Drug Discount Coupons: Implications for Public and Commercial Health Care Plans

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## Summary

U.S. pharmaceutical manufacturers offer co-payment coupons to consumers with health insurance to help defray the cost of prescription drugs. Drugmakers offer the coupons on corporate websites, in physician offices, and through television and other media to create a market for a newly introduced drug, to increase the likelihood that a patient will continue an existing prescription, or to bolster the market for brand-name drugs that have lost patent exclusivity and face competition from lower-priced generic substitutes. Coupons can be especially important to individuals who have been prescribed expensive specialty drugs to treat cancer, hepatitis C, and other serious conditions.

The number of pharmaceutical coupon offers has increased in recent years, with manufacturers tendering coupons for more than 500 prescription drugs in 2014, compared with fewer than 100 in 2011. According to one study, coupons were used for about 8% of brand-name prescriptions in 2014, up from 3% in 2011. While manufacturer coupons may reduce or eliminate a consumer's out-of-pocket spending requirement, generally they do not reduce the price an insurer or government program is charged for a drug. Health care payers, such as commercial insurers, unions and employers, and government programs, say that coupons can actually increase their costs if enrollees use them to buy more expensive brand-name drugs when cheaper generics or other substitute drugs are available.

In addition to offering coupons, manufacturers and charitable organizations run pharmaceutical assistance programs that provide free drugs and other aid to consumers who may not have insurance or are unable to afford a prescribed drug. Retail drugstores and other businesses also offer their own discount cards and customer-incentive programs to increase demand.

Coupon use is prohibited in conjunction with federal health programs such as the Medicare Part D prescription drug benefit. Federal statutes, including antikickback law (Section 1128B (b) of the Social Security Act), prohibit 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. Manufacturers may be liable under the antikickback statute if they offer coupons to induce consumers to purchase drugs under federal programs. In a September 2014 audit, the Department of Health and Human Services' Office of Inspector General found that manufacturers did not have consistent controls in place to prevent Medicare enrollees from using prescription drug coupons in conjunction with their Part D benefits.

In the private sector, some payers have begun to bar enrollees from redeeming coupons for certain prescription products or have chosen not to cover certain drugs that qualify for coupon discounts. Others allow or encourage enrollees to redeem coupons for expensive specialty drugs to improve the odds that the enrollees will complete a prescribed treatment. Studies have shown that enrollees are less likely to adhere to a full course of medication when out-of-pocket payments increase.

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## Introduction

Many U.S. pharmaceutical manufacturers offer co-payment coupons, or cards, to defray the consumer cost of prescription drugs. Coupons are designed to reduce or eliminate out-of-pocket payments for insured consumers, such as mandatory prescription co-payments or coinsurance.<sup>1</sup> Many co-payment coupons are targeted at people with chronic conditions and can be particularly important in helping consumers afford new, expensive specialty drugs<sup>2</sup> that are used to treat conditions such as cancer, hepatitis C, and other serious ailments.

A recent study of retail pharmacy data found that enrollees in commercial insurance plans used co-payment coupons for about 8% of brand-name<sup>3</sup> drug prescriptions in 2014, up from 3% in 2011.<sup>4</sup> Some high-cost drugs, including those for multiple sclerosis and rheumatoid arthritis, had 70% coupon usage. Manufacturers also commonly use coupons to support sales of drugs that are not included on insurance plan formularies, or lists of covered drugs.

Pharmaceutical manufacturers, which spend billions of dollars annually on coupons,<sup>5</sup> see co-payment assistance as a necessary response to cost-control strategies by health care payers<sup>6</sup> that can impose large enrollee out-of-pocket payments for some pharmaceuticals, thereby affecting volume and drug pricing.<sup>7</sup> (See “Tiered Pricing.”) In addition, studies have found that consumers are less likely to initiate or complete a prescribed course of medication as cost-sharing increases, which can affect overall health outcomes.<sup>8</sup>

Health care payers say that co-payment coupons can provide an incentive for consumers to select more expensive drugs even when cheaper substitutes are available. Although the coupons reduce consumer payments, they do not reduce the price of the drug to health payers. For that reason, coupon redemptions can increase spending by commercial and government payers.<sup>9</sup> More

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<sup>1</sup> See text box entitled “Common Insurance Terms,” below.

<sup>2</sup> There is no set definition of *specialty drugs*, although insurers and other health care payers often characterize them as expensive prescription products requiring extra handling or administration that are used to treat complex diseases. Biologics, or drugs derived from living cells, are often specialty drugs. See CRS Report R44132, *Specialty Drugs: Background and Policy Concerns*, by (name redacted).

<sup>3</sup> The Food and Drug Administration defines a *brand-name drug* as a drug marketed under a proprietary, trademark-protected name. See “Brand Name Drug,” *Drugs@FDA Glossary of Terms*, at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#B>.

<sup>4</sup> IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, April 2015, p. 25, at <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=3f140a4331e8c410VgnVCM1000000e2e2ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default>.

<sup>5</sup> Mason Tenaglia, “Copay Cards and Coupons: Letting Facts Get in the Way,” *Pharmaceutical Executive*, January 1, 2012, at <http://www.pharmexec.com/pharmexec/Commentary/Copay-Cards-and-Coupons-Letting-the-Facts-Get-in-t/ArticleStandard/Article/detail/755091>. For example, North Carolina-based firm Trialcard manages more than \$1 billion in patient reimbursement annually through co-payment programs for more than 140 brands and 60 manufacturers. See Trialcard, “Patient Affordability Services,” at <http://corp.trialcard.com/Pages/PatientAffordability.aspx>.

<sup>6</sup> Health care payers include commercial insurers, unions and employers, and government programs.

<sup>7</sup> PhRMA, “Copay Coupons, Get the Full Story,” June 22, 2012, at <http://www.phrma.org/copay-coupons-get-the-full-story/>.

<sup>8</sup> Stacie Dusetzina, Aaron Winn, Gregory Abel, Haiden Huskamp, and Nancy Keating, “Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients With Chronic Myeloid Leukemia,” *Journal of Clinical Oncology*, December 23, 2013, at <http://jco.ascopubs.org/content/early/2013/12/23/JCO.2013.52.9123>.

<sup>9</sup> David Grande, “The Cost of Drug Coupons,” *The Journal of the American Medical Association* (vol. 307, no. 22), June 13, 2012, at <http://jama.jamanetwork.com/article.aspx?articleid=1182868>; and Department of Health and Human (continued...)

broadly, when consumers are relieved of co-payment obligations, there may be less market constraint on overall drug prices.<sup>10</sup>

There are restrictions on coupon use. The federal antikickback law<sup>11</sup> (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. Pharmaceutical manufacturers may be in violation of the antikickback statute if they offer coupons to induce consumers to purchase drugs under federal programs, such as the voluntary Medicare Part D prescription drug program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA; P.L. 108-173).<sup>12</sup> (See “Restrictions on Coupon Use.”)

In the private sector, some payers and pharmacy benefit managers (PBMs)<sup>13</sup> have barred enrollees from redeeming coupons for certain drugs. Others have decided not to include specific drugs that are eligible for coupon discounts on their formularies.<sup>14</sup>

This report will provide an overview of prescription drug use and payment; explain the difference between coupons and other pharmaceutical assistance and incentive programs offered by manufacturers, pharmacies, states, and nonprofit organizations; and outline federal laws and regulations and private-sector policies relating to coupons and other financial incentives for consumers/patients to purchase prescription drugs.

### Common Insurance Terms

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

**Coinsurance:** The percentage share that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer may charge 10% coinsurance for a \$100 prescription drug, meaning the consumer’s out-of-pocket cost is \$10.

**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

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Services (HHS), Office of Inspector General (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>. In addition, payers often negotiate additional rebates or other price concessions from drug companies based on the volume of specific drugs used by their enrollees. If enrollees switch to other drugs, based on coupon offers, the payers might not realize the expected financial benefits of the volume-based agreements.

<sup>10</sup> HHS, OIG, “Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons,” September 2014, at [http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB\\_Copayment\\_Coupons.pdf](http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf); Lara Maggs and Aaron Kesselheim, “The Short-Term and Long-Term Outlook Of Drug Coupons,” *Health Affairs Blog*, November 12, 2014, at <http://healthaffairs.org/blog/2014/11/12/the-short-term-and-long-term-outlook-of-drug-coupons/>.

<sup>11</sup> See, generally, CRS Report RS22743, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, by (name redacted).

<sup>12</sup> CRS Report R40611, *Medicare Part D Prescription Drug Benefit*, by (name redacted) and (name redacted).

<sup>13</sup> See text box entitled “Common Insurance Terms,” below.

<sup>14</sup> Express Scripts, “Smart Formulary Management,” January 2, 2014, at <http://lab.express-scripts.com/insights/drug-options/smart-formulary-management>. The preferred formulary is selected by about 30% of health care payer clients Express Scripts serves. Suzanne Shelley, “Copay Programs’ Increased Value to Manufacturers is Matched by Rising Criticism,” *Pharmaceutical Commerce*, January 15, 2014, at [http://www.pharmaceuticalcommerce.com/latest\\_news?articleid=27073&keyword=copay%20programs-insurance-coupons-pharmacy](http://www.pharmaceuticalcommerce.com/latest_news?articleid=27073&keyword=copay%20programs-insurance-coupons-pharmacy).

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 what are known as *tight formularies*, which include a more limited number of drugs than traditional formularies. Insurers also are using *tiered formularies*, under which patients are charged lower co-payments or coinsurance for less expensive generic drugs and certain brand-name drugs that are designated by the plan as preferred drugs because they are lower cost or deemed by an insurer to be safer or more effective. Under these tiered formularies, patients are charged higher co-payments or coinsurance for more expensive drugs or drugs that the plan deems to be less effective.

**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 are not counted toward an out-of-pocket maximum, or cap.

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

**Pharmacy Benefit Managers (PBMs):** Intermediaries between insurers and manufacturers that carry out functions such as designing drug formularies; negotiating prices; creating price tiers and other utilization controls; and administering prescription drug payment systems for health plans, pharmacies, and manufacturers.

**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.

## U.S. Spending for Prescription Drugs

U.S. prescription drug use has grown substantially during the past several decades as researchers have developed groundbreaking therapies, the number of consumers with prescription drug coverage has expanded, and pharmaceutical companies have increased advertising and other marketing efforts.<sup>15</sup> Reflecting these changes, prescription drugs accounted for about 10% of U.S. health care spending in 2014, up from about 5.5% in 1990.<sup>16</sup>

As recently as 1990, consumers accounted for the bulk of prescription drug spending. Consumer out-of-pocket spending—which includes insurance deductibles and coinsurance or co-payments for filled prescriptions<sup>17</sup>—was 57% of U.S. prescription spending in 1990, whereas commercial payers and taxpayer-financed health programs accounted for about 43%.<sup>18</sup> (See **Figure 1**.)

<sup>15</sup> Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS), *2013 NCHS Chartbook: Special Feature on Prescription Drugs*, at [http://www.cdc.gov/nchs/hus/chartbook.htm#chartbook\\_special\\_feature](http://www.cdc.gov/nchs/hus/chartbook.htm#chartbook_special_feature); and Centers for Medicare & Medicaid Services (CMS), “Projections of National Health Expenditures: Methodology and Model Specifications,” September 3, 2014, p. 27, at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>.

<sup>16</sup> CMS, “National Health Expenditure Data,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>. The National Health Expenditure drug estimates are based on U.S. Census Bureau and IMS Health drug data. The figures include retail sales of prescription drugs, subtract manufacturer rebates, and add government spending for drugs provided by government-owned mail-order facilities. They do not include drugs dispensed in institutional settings such as hospitals or clinics. See CMS, “National Health Expenditure Accounts Methodology Paper 2010: Definitions, Sources and Methods,” at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-10.pdf>. For example, less than 2% of the U.S. population used prescription drugs to control high blood pressure from 1988 to 1994, compared with 12.5% from 2007 to 2010. For those aged 65 and older, the percentage rose from 5.9% to 46.7% during that period.

<sup>17</sup> See CMS, *National Health Expenditure Accounts Methodology Paper*, 2013, p. 15, at <https://www.cms.gov/> (continued...)

In the ensuing decades, government health care programs, such as Medicare and Medicaid, expanded prescription drug coverage to tens of millions of consumers.<sup>19</sup> Congress was spurred by rising drug prices, as prescription drug inflation rose faster than inflation for other medical services in the 1990s and early 2000s. The higher prices posed a financial burden for groups such as the uninsured elderly and lower-income consumers.<sup>20</sup> In addition, a larger share of insurance now comes through commercial managed-care plans, which generally impose lower out-of-pocket costs for drugs than other insurance products.<sup>21</sup>

Reflecting these changes in payer mix and policies, consumer out-of-pocket spending is forecast to make up only 16% of prescription drug expenditures in 2014, with private and public health programs covering 84%.<sup>22</sup>

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Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-13.pdf. The CMS data define out-of-pocket spending as direct consumer spending for services not covered by insurance and the amount of coinsurance or deductibles required by private health insurance and public programs such as Medicare and Medicaid (not paid by some other third party), as well as payments covered by health savings accounts linked to high-deductible health plans. Premium payments are not included in out-of-pocket costs.

<sup>18</sup> CMS, “National Health Expenditure Data,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>

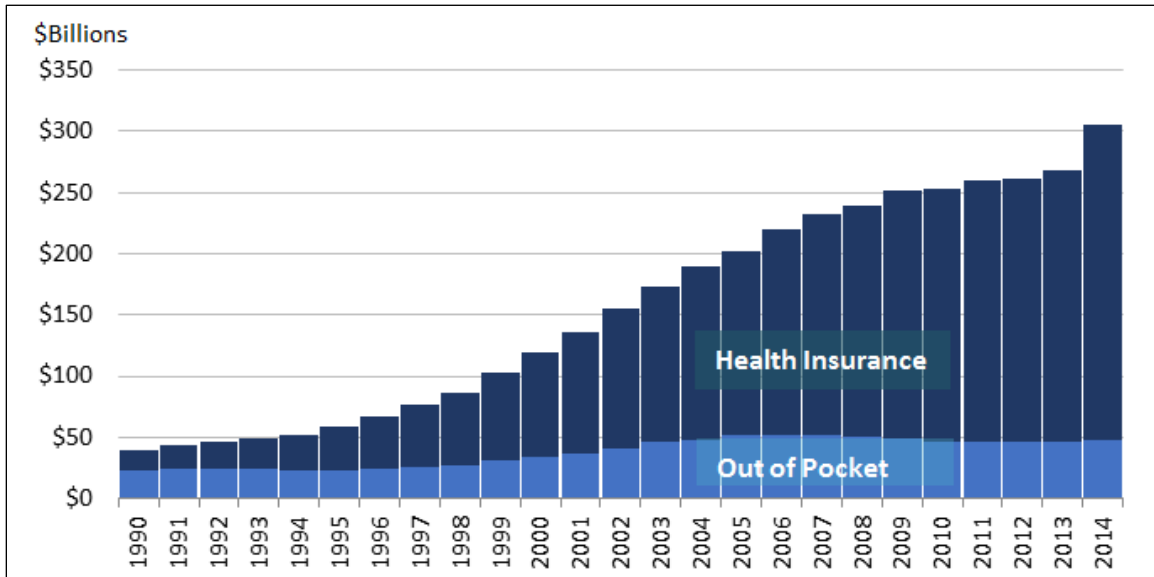
<sup>19</sup> Among notable prescription drug legislation, Congress has enacted the voluntary Medicare Part D prescription drug program (Medicare Modernization Act of 2003, P.L. 108-173), and the 2010 Patient Protection and Affordable Care Act (ACA; P.L. 111-148), which also expanded Medicaid coverage. See CRS Report R41125, *Medicaid and CHIP: Changes Made by the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152) to the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148)*, coordinated by (name redacted) and (name redacted)

<sup>20</sup> Thomas Oliver, Philip Lee, and Helene Lipton, “A Political History of Medicare and Prescription Drug Coverage,” *The Milbank Quarterly*, (vol. 82, no. 2, June 2004, pp 283–354, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690175/>).

<sup>21</sup> Cynthia Smith, “Retail Spending in the National Health Accounts,” *Health Affairs*, vol. 23, no. 1 (January/February 2004), pp. 160-167.

<sup>22</sup> CMS, “National Health Expenditure Data,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>. More than 99% of covered workers in employer-sponsored plans in 2014 were in a plan that had a prescription drug benefit. Kaiser Family Foundation, *2014 Employer Health Benefits Survey: Section Nine: Prescription Drug Benefits*, September 10, 2014, at <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

**Figure I. Consumer Out-of-Pocket Spending for Prescription Drugs**



**Source:** Centers for Medicaid & Medicare Services, National Health Expenditures Data.

**Note:** Health Insurance includes commercial plans and government programs such as Medicare and Medicaid.

Although out-of-pocket spending has declined as a share of overall drug spending, consumer out-of-pocket spending rose from \$23 billion in 1990 to \$48 billion in 2014 and is expected to grow to \$70 billion by 2024, according to government estimates.<sup>23</sup>

There is also a great deal of variability in out-of-pocket spending among insured individuals depending on the specific drugs they are prescribed and the structure of their health plans. For example, in 2014, only about 20% of brand-name prescriptions filled by consumers across different types of commercial plans had co-payments of \$50 or more, according to a study of retail data. However, consumers enrolled in high-deductible health plans (HDHP)<sup>24</sup> were more likely to face co-payments of \$50 or more, including about 25% of HDHP claims for brand-name drugs with co-payments of \$100 or above.<sup>25</sup>

## Insurer Prescription Drug Cost Controls

Health care payers use a number of strategies to manage and monitor enrollee pharmaceutical use. Some programs are designed to assist patients with chronic or complex conditions who may be using a number of drugs and are at risk for adverse drug interactions or other health issues.

<sup>23</sup> CMS, National Health Expenditure Projections, 2014-2024, Forecast Summary, at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2014.pdf>. Even with the increase, out-of-pocket spending will decline as a share of overall prescription drug spending as Medicare spending grows.

<sup>24</sup> A high-deductible health plan (HDHP) has a higher deductible than traditional insurance products. For example, in 2015, Internal Revenue Service (IRS) regulations allow contributions to tax-advantaged savings accounts for enrollees in HDHPs, which are defined as plans with a minimum annual deductible of \$1,300 for individual coverage and \$2,600 for family coverage. The IRS also imposes limits on out-of-pocket spending under the plans. See IRS, Rev. Proc. 2014-30, at <https://www.irs.gov/pub/irs-drop/rp-14-30.pdf>.

<sup>25</sup> IMS Health, *Medicine and the Shifting Costs of Healthcare*, April 2014, p. 26.



Other strategies are more focused on containing costs by steering patients toward less expensive pharmaceuticals, when available.

Cost-control efforts have intensified in recent years as more high-priced specialty drugs have come to the market. Specialty medications now account for about a third of U.S. prescription drug spending, and some analysts predict that specialty drugs could make up as much as one-half of total drug spending by 2018.<sup>26</sup> In 2014, U.S. prescription drug spending rose by 12.6% from the previous year—the fastest rate since 2001—led by a 26.5% increase in spending on specialty drugs, according to industry and government data.<sup>27</sup>

Following are some prescription drug cost-management techniques employed by health payers. Even though consumers may face high cost sharing for certain prescriptions, many are enrolled in health care plans that have an overall limit on the amount that enrolled consumers must pay out of pocket for prescription drugs and other health care services during the course of a year. (See text box entitled “Out-of-Pocket Spending Limits,” below.)

## Deductible

A *deductible* is the amount an insured consumer must pay for covered services before his or her health plan begins to provide reimbursement. If a plan has a \$500 deductible, for example, an enrollee would be required to cover expenses up to \$500, at which point the plan would begin to pay its share.

An increasing share of the insured population is enrolled in HDHPs, which have higher deductibles than traditional health care plans. HDHPs often are paired with tax-exempt health savings accounts (HSAs) that enrollees can use to pay for qualified medical expenses, such as prescription drugs.<sup>28</sup> Some HDHPs may cover certain prescription drugs as a preventive service without cost sharing, while others may require enrollees to cover prescription costs through an HSA or another spending source until the costs reach a set limit. Some studies have found that

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<sup>26</sup> See Express Scripts, “U.S. Rx Spending Increased 13.1% in 2014,” March 10, 2015, at <http://lab.express-scripts.com/insights/industry-updates/us-rx-spending-increased-13-percent-in-2014>. Express Scripts said specialty drugs made up 31.8% of total U.S. drug spending in 2014.

<sup>27</sup> IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013*, April 2014, p. 40, at <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=2684d47626745410VgnVCM10000076192ca2RCRD>. IMS Institute, *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, April 2015, p. 8, at <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=3f140a4331e8c410VgnVCM1000000e2e2ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>. UnitedHealthcare Center for Health Reform & Modernization, *The Growth of Specialty Pharmacy: Current Trends and Future Opportunities*, April 2014, p.1, at <http://www.unitedhealthgroup.com/Modernization/KeyIssues/SpecialtyPharmacy.aspx>. U.S. health care spending grew by a projected 5.5% in 2014, while prescription drug spending rose by 12.6%, driven by specialty drugs and increased prescription drug use. CMS, “National Health Expenditure Projections 2014-2024,” p. 2, at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2014.pdf>.

<sup>28</sup> According to a survey by America’s Health Insurance Plans (AHIP), there were nearly 17.4 million enrollees in HDHPs with health savings accounts (HSAs) in January 2014, up from 11.4 million in January 2011. HDHPs have grown 15% annually on average since 2011. AHIP, “New Census Survey Shows Increased Growth in HSA Enrollment,” July 9, 2014, at <https://www.ahip.org/Press-Room/2014/HSA-Census-Survey/>. HDHP enrollees may pay for drugs and other services with HSAs or may have access to other, employer-provided health reimbursement. See CRS Report RS21573, *Tax-Advantaged Accounts for Health Care Expenses: Side-by-Side Comparison, 2013*, by (name redacted).

enrollees in HDHPs may reduce drug utilization, even in plans where pharmaceuticals are exempt from the deductible.<sup>29</sup>

Many insurance plans sold on state health exchanges established by the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) impose prescription drug deductibles. An analysis of select ACA plans with prescription drug deductibles found that average annual drug deductibles ranged from \$465 for the least generous plans offered to \$134 for the most comprehensive products.<sup>30</sup> In general, enrollees in plans with drug deductibles appear to be less likely to adhere to prescriptions than those in plans without such coverage restrictions, and the differences are greater when out-of-pocket costs exceed \$50.<sup>31</sup>

After a deductible has been met, health insurance plans may impose co-payments or coinsurance for filled prescriptions. (See “Tiered Pricing.”)

## Tiered Pricing

Payers commonly use a strategy known as *tiered pricing* to control drug costs and access. In a tiered system, payers impose different co-payments or coinsurance for prescription drugs based on the drug’s price, the insurer’s assessment of the drug’s effectiveness, and the availability of substitute therapies.<sup>32</sup> Payers generally impose lower co-payments for generic<sup>33</sup> or preferred brand-name drugs (i.e., they place the drugs on a lower cost tier), whereas they place drugs that are more expensive or deemed less effective on tiers with higher co-payments or coinsurance.<sup>34</sup> (See **Figure 2**.) For example, a generic drug may carry a minimal or zero co-payment, while an enrollee may face 30% coinsurance or more for an expensive specialty drug.

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<sup>29</sup> Peter J. Huckfeldt et al., “Patient Responses to Incentives in Consumer-Directed Health Plans: Evidence from Pharmaceuticals,” National Bureau of Economic Research Working Paper 20927, February 2015, at <http://www.nber.org/papers/w20927.pdf>.

<sup>30</sup> Kaiser Family Foundation, “Medical and Prescription Drug Deductibles for Plans Offered in Federally Facilitated and Partnership Marketplaces for 2015,” November 18, 2014, at <http://kff.org/health-reform/fact-sheet/medical-and-prescription-drug-deductibles-for-plans-offered-in-federally-facilitated-and-partnership-marketplaces-for-2015/>. The study looked at insurance plans that imposed separate medical and drug deductibles.

<sup>31</sup> IMS Institute for Healthcare Informatics, *Emergence and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans*, September 2015, p. 17.

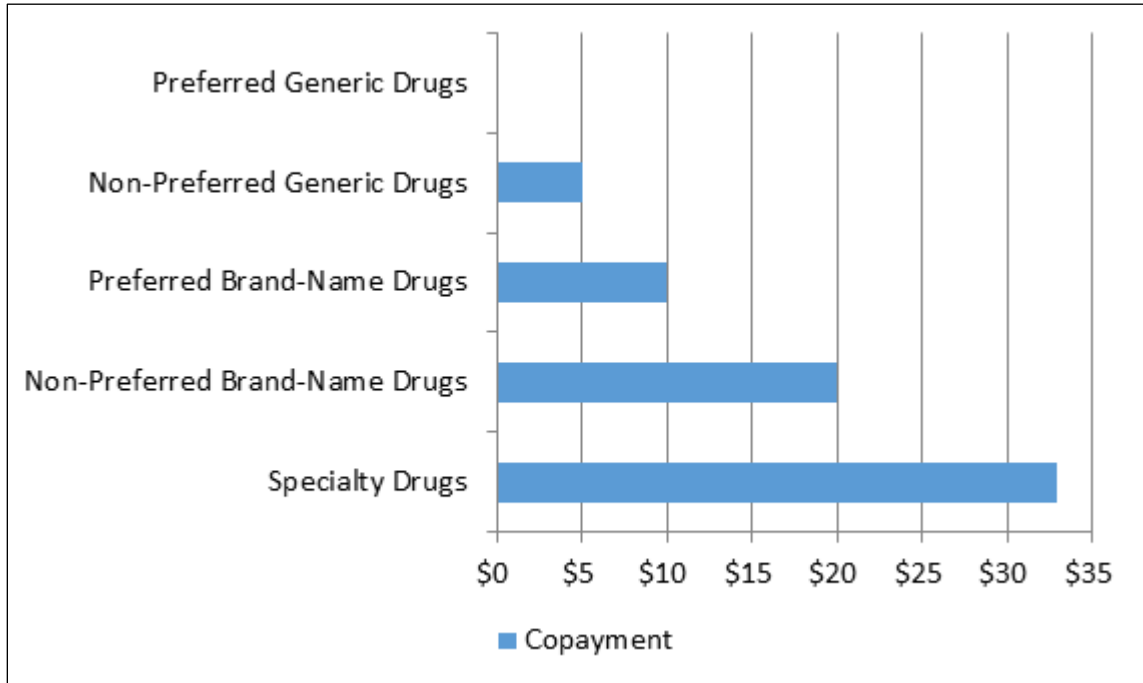
<sup>32</sup> Insurers also use other prescription drug cost controls, often in conjunction with tiered pricing, including 1) requiring physicians and enrollees to obtain preauthorization for certain prescriptions; 2) imposing step therapy, where enrollees must first try a less expensive drug before moving to a higher-cost product; 3) creating preferred pharmacy networks where enrollees pay less for drugs if they agree to patronize a small number of designated drugstores; 4) requiring enrollees to use mail-order pharmacies; 5) creating tight formularies (lists of covered drugs); or 6) limiting the amount of drugs that may dispensed in an initial prescription. See CRS Report R44132, *Specialty Drugs: Background and Policy Concerns*, by (name redacted).

<sup>33</sup> 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. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 billion to \$10 billion a year at retail pharmacies. Even more billions of dollars are saved when hospitals use generics. For more information, see CRS Report RL33605, *Authorized Generic Pharmaceuticals: Effects on Innovation*, by (name redacted).

<sup>34</sup> The tiering system can be fluid. For example, with prices for some generic drugs increasing, insurers are instituting preferred and non-preferred generic tiers or placing higher-cost generics on what had been a brand-name tier and moving some lower-priced brand-name drugs down to what had been a generic tier.

**Figure 2. Tiered Formulary**

(illustrative example of pricing under a tiered formulary for a drug with a \$100 price tag)



**Source:** Congressional Research Service.

**Notes:** For purposes of this graphic, the preferred generic tier has a \$0 co-payment, non-preferred generics have a \$5 co-payment, preferred brand names have a \$10 co-payment, non-preferred brand names have a \$20 co-payment, and specialty drugs have 33% coinsurance.

In 2014, 80% of consumers with employer-sponsored insurance were enrolled in plans that had three or more prescription drug tiers and 20% of consumers were in plans with four or more tiers.<sup>35</sup> Price tiers are used in government health care programs as well. Private insurers that offer Medicare Part D are allowed to place drugs with a negotiated price of more than \$600 per month on a specialty tier, with up to 33% coinsurance.<sup>36</sup> Specialty tier drugs made up 0.25% of prescriptions filled by Part D enrollees in 2013 but more than 11% of total Part D drug spending.

There has been a gradual increase in the use of tiered pricing and in the practice of imposing coinsurance, as opposed to flat co-payments, for more expensive drugs. The differential between price tiers has widened over time, imposing a greater financial burden on consumers who use higher-priced drugs.<sup>37</sup> In 2000, a two- or three-tier design was most common in commercial insurance plans, with an average \$8 co-payment for a tier-one drug and an average \$29 co-payment for a tier-three product. By 2014, more insurers had moved to plans with a higher-priced

<sup>35</sup> Kaiser Family Foundation, *2014 Employer Health Benefits Survey: Section Nine: Prescription Drug Benefits*, September 10, 2014, at <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

<sup>36</sup> CMS, “Medicare Part D Specialty Tier,” April 7, 2014, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/SpecialtyTierMethodology.pdf>.

<sup>37</sup> Shelly Carrey, Pharmacy Benefit Management Institute, “8 Ways Pharmacy Benefit Design May Evolve in 2013,” Institute for Health Care Consumerism, at [http://www.theihcc.com/en/communities/pharmacy\\_benefit\\_management/8-ways-pharmacy-benefit-design-may-evolve-in-2013\\_hfpq9mpi.html](http://www.theihcc.com/en/communities/pharmacy_benefit_management/8-ways-pharmacy-benefit-design-may-evolve-in-2013_hfpq9mpi.html).

fourth tier for specialty drugs. In 2014, the average first-tier co-payment was \$11 and the average fourth-tier co-payment was \$83.<sup>38</sup>

Not all specialty drugs placed on high cost-sharing tiers have lower-cost equivalents.<sup>39</sup> Further, in some instances, insurers have clustered most or all drugs for treating specific conditions, such as HIV/AIDS, on specialty price tiers.<sup>40</sup> The Centers for Medicare & Medicaid Services (CMS) in February 2015 warned insurers offering health insurance through ACA exchanges that placing most or all drugs to treat a specific condition on the highest cost tiers would “effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions.”<sup>41</sup>

### Out-of-Pocket Spending Limits

Most private health insurance plans place an annual cap, or maximum, on enrollee out-of-pocket spending, after which the payer covers all or most of the cost of health care services.<sup>42</sup> For 2015, the ACA limits out-of-pocket spending for non-grandfathered non-group and small-group health insurance sold on and off state health exchanges to \$6,600 for non-group and \$13,200 for small-group plans. The spending limit includes out-of-pocket payments for prescription drugs. For 2015, Medicare Part D enrollees who incur \$4,700 in annual out-of-pocket spending enter the catastrophic portion of the benefit, in which they pay a maximum of 5% coinsurance or a nominal co-payment, whichever is greater.

## Manufacturer Co-payment Coupons

Pharmaceutical firms offer co-payment coupons or cards to consumers to help reduce the out-of-pocket costs of prescription drugs. These coupons may benefit pharmaceutical firms by helping to create demand for newly introduced drugs, increase consumer adherence to existing prescriptions, and bolster the market for brand-name drugs that have lost patent exclusivity and face competition from lower-priced generics or other substitutes.<sup>43</sup>

<sup>38</sup> Kaiser Family Foundation, *2014 Employer Health Benefits Survey*, Section Nine, Exhibit 9.4, at <http://kff.org/report-section/ehbs-2014-section-nine-prescription-drug-benefits/>. There were also wider differentials in coinsurance percentages between tiers for insurers requiring coinsurance.

<sup>39</sup> Charles River Associates, “The Economics of Co-Pay Coupons, CRA Insights: Life Sciences,” November 2014, at [http://www.crai.com/sites/default/files/publications/LS-Insights-Litigation-The-economics-of-copay-coupons-1114\\_0.pdf](http://www.crai.com/sites/default/files/publications/LS-Insights-Litigation-The-economics-of-copay-coupons-1114_0.pdf).

<sup>40</sup> Avalere, “Exchange Plans Increase Costs of Specialty Drugs for Patients in 2015,” December 2, 2014, at <http://avalere.com/news/exchange-plans-increase-costs-of-specialty-drugs-for-patients-in-2015>.

<sup>41</sup> Ibid and CMS, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016,” 79 *Federal Register* 70673, November 21, 2014, at <https://www.federalregister.gov/articles/2014/11/26/2014-27858/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2016>.

<sup>42</sup> Kaiser Family Foundation, *2014 Employer Health Benefits Survey: Section Seven: Employee Cost Sharing*, September 10, 2014, at <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

<sup>43</sup> Generic drugs can cost 70%-80% less than their brand-name alternatives. See CRS Report RL33605, *Authorized Generic Pharmaceuticals: Effects on Innovation*, by (name redacted). Aggressive discounting may reduce a manufacturer’s profit margin on a drug but result in a greater volume of sales. A 2012 study by the Amundsen Group, a health care consulting firm, estimated that co-payment offset programs produced manufacturer returns on investment of about 4 to 1 and as much as 6 to 1. According to the firm, a well-designed coupon program could add 30 days to 60 days of patient drug use during a year. Mason Tenaglia, “Coplay Cards and Coupons: Letting Facts Get in the Way,” *Pharmaceutical Executive*, January 1, 2012, at <http://www.pharmexec.com/pharmexec/Commentary/Coplay-Cards-and-Coupons-Letting-the-Facts-Get-in-t/ArticleStandard/Article/detail/755091>.

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.<sup>44</sup> The payer places the drug on a specialty price tier that imposes 25% enrollee coinsurance up to the plan's annual out-of-pocket maximum. To bolster 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, up to a maximum subsidy of \$2,000. 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). With a coupon, the consumer would pay \$100 per fill and the manufacturer would cover the remaining \$150 of the required coinsurance.

Most co-payment coupons include disclaimers stating that they cannot be used by individuals enrolled in federal health programs, including Medicare, Medicaid, and the Veterans Health Administration. (See "Restrictions on Coupon Use.") Manufacturers build the cost of co-payment coupons into their budget and pricing strategies.<sup>45</sup>

## Coupon Processing

Coupons come in many forms. They can be printed in a magazine or circular, offered electronically—such as a discount number sent as a text to a smart device—or presented as a debit-type card.<sup>46</sup> Coupons loaded on smartphones can provide automatic reminders to a consumer to refill a prescription. 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.<sup>47</sup>

When an insured consumer presents a prescription at a pharmacy, the pharmacist uses an electronic routing system<sup>48</sup> to submit a claim to the pharmacy benefit manager (PBM) that manages the consumer's specific pharmacy benefit. The PBM processes the initial drug claim and determines the patient's cost-sharing obligation for the drug. The PBM's electronic processing system then submits secondary claims to other payers. Secondary payments can include a second insurance policy held by the individual or a manufacturer coupon. If a coupon is presented, the PBM system, using special codes, will route a coupon to a manufacturer for payment.<sup>49</sup> After all payments are processed, the consumer covers the remaining co-payment, if any.

In some cases, manufacturer discounts are not processed through the electronic system. Some coupon offers 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

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<sup>44</sup> Insurers and pharmacy benefit managers 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 been kept out to simplify the transaction.

<sup>45</sup> Trialcard, "Leveraging Data and Analytics to Enhance Copay Program Performance," *Pharmaceutical Executive*, special advertising section.

<sup>46</sup> HHS, OIG, "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs," September 2014, p. 5, at <http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf>.

<sup>47</sup> Lash Group, Amerisource Bergen, "Co-Pay Mechanisms: Which Card is Right for Your Product?" Available with registration at <http://www.lashgroup.com/resource-center/copay-assistance>.

<sup>48</sup> National Council for Prescription Drug Programs, "Transformation and the Use of HIT in Pharmacy," [https://www.ncdpd.org/NCPDP/media/pdf/wp/RxforImprovingHealthcare\\_TransformationHIT.pdf](https://www.ncdpd.org/NCPDP/media/pdf/wp/RxforImprovingHealthcare_TransformationHIT.pdf).

<sup>49</sup> 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>.

prescription, then send the pharmacy receipt and rebate offer to the manufacturer to secure the promised discount.<sup>50</sup> Consumers also may use a coupon and pay cash for a drug that is not covered by an insurance plan.

## Coupon Distribution and Market Impact

Manufacturers advertise coupons through the media and via direct-mail offers. Consumers can download coupons from manufacturer websites or browse available coupons on special websites that aggregate offers from a variety of drugmakers.<sup>51</sup>

Industry data on co-payment coupon distribution and use are available from manufacturers, consulting firms, PBMs, and various websites that serve as online clearinghouses for coupon offers. According to consulting firm Zitter Health Insights, there were 423 co-payment offset programs in winter 2014, covering 544 brands from 131 manufacturers.<sup>52</sup> The company reported that discount offers for hepatitis C drugs such as Sovaldi under these programs had a maximum yearly benefit of \$33,563, reflecting the high price of the specialty products. Cancer drug discount offers under these programs had an average annual benefit of \$21,103. Drugs for treating rheumatoid arthritis had the highest number of specialty drug co-payment programs.

A separate analysis of retail pharmacy data found that co-payment coupons or vouchers were used by more than 14 million patients in the 12-month period ending in October 2012, of whom 90% used one program and 10% used multiple programs.<sup>53</sup> Most of the coupons were used by patients with chronic conditions. The range of savings was wide, with coupons reducing costs by \$40 on average.

One industry analyst has estimated that manufacturer coupon offers are equal to about 1%-2% of annual retail drug spending.<sup>54</sup> While coupon offers may be for a limited time period, such as six months or one year, they are often renewed by manufacturers, who use them as a means to build loyalty to a brand.<sup>55</sup> Manufacturers may use coupons as part of a marketing strategy to keep prices for brand-name drugs higher than they otherwise would be after a lower-cost generic substitute comes to market. Such a strategy was used when Pfizer blockbuster drug Lipitor was exposed to generic competition, for example.<sup>56</sup> Vendors that work with pharmaceutical companies

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<sup>50</sup> Ibid.

<sup>51</sup> MedImpact/ScriptSave power point, October 28, 2014, at <http://medimpactpbm.com/v/kbuua8wbmyne3rsl6pe>. Some health care consultants have designed integrated programs in which insurance plan enrollees can use a pre-programmed card to pay for drugs covered by their insurance benefit and to access coupon offers for products that are not included on a plan formulary.

<sup>52</sup> Zitter Health Insights, "Co-Pay Offset Monitor Environmental Report," PhRMA, March 2015. Made available to CRS by Zitter Health Insights.

<sup>53</sup> IMS Health, "Patient Savings Program Use Analysis," February 2014, at <http://www.imshealth.com/portal/site/imshealth/menuitem.0be132395225d98ee566e5661ad8c22a/?vgnnextoid=a64de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>. The study was funded by drug manufacturer Pfizer. It is based on IMS Health anonymized patient longitudinal prescription data as reported by retail pharmacies and did not include mail-order or other non-retail pharmacies. The patient savings programs were limited to those with 100 or more unique patients assisted during the 12-month period ending October 31, 2012.

<sup>54</sup> Mason Tenaglia, "Copay Cards and Coupons: Letting Facts Get in the Way," *Pharmaceutical Executive*, January 1, 2012, at <http://www.pharmexec.com/pharmexec/Commentary/Copay-Cards-and-Coupons-Letting-the-Facts-Get-in-t/ArticleStandard/Article/detail/755091>.

<sup>55</sup> IMS Institute for Healthcare Informatics, "Patient Savings Program Use Analysis," February 2014; Chris Dowd, "Broadening Your Co-Pay Approach," *PM 360*, April 30, 2015, at <http://www.pm360online.com/broadening-your-co-pay-approach/>.

<sup>56</sup> Jonathan Rockoff, "Goodbye, Lipitor. Pfizer Bids a Farewell," *Wall Street Journal*, May 9, 2012, at (continued...)

to distribute pharmaceutical coupons say their internal data show that the programs increase prescription drug adherence and increase the duration of therapy.<sup>57</sup>

In addition, coupon programs can generate data regarding patient income, age, and insurance status that can be used by a company to develop pricing, marketing, and other strategies.<sup>58</sup> For example, companies can use data on differences in patient adherence to drugs in various U.S. geographic regions to target coupon offers and other marketing efforts. Electronic coupons can generate data regarding what drugs physicians prescribe and which patients use them. Companies can correlate the information with other electronic data on consumer shopping patterns.

## Physicians

Physicians, who prescribe most of the drugs used in the United States, are a focal point for manufacturers. A number of physicians have questioned the cost-effectiveness of some high-priced medications.<sup>59</sup> At the same time, physicians often search out coupons, samples, or other assistance to help their patients afford needed treatments. (See “Patient Assistance Programs.”)

The widespread adoption of electronic health records by physician practices is offering a faster, more efficient way for manufacturers and marketers to reach physicians and their patients. Physicians may now enter a prescription into an electronic system that has been programmed to automatically call up information on co-payment coupon offers<sup>60</sup> and can send the offer to a pharmacy along with the prescription. When the consumer fills the claim, the pharmacy processes the coupon as it fills the prescription.

Web-based platforms and software applications have been developed to help health care professionals locate coupons, distribute samples, or procure other discounts for their patients. In one example, Physicians Interactive and McKesson Patient Relationship Solutions announced Coupons on Demand, a web-based platform that physicians can search to find coupons and other discounts.<sup>61</sup>

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<http://www.wsj.com/articles/SB10001424052702304543904577394263634380548>.

<sup>57</sup> Trialcard, “How the Affordable Care Act Made Co-pay Programs a Requirement for Patient Access,” 2014. Available for download with registration at <http://corp.trialcard.com/Pages/WhitePaper.aspx>; and Lash Group, AmeriSource Bergen, “How Simplified Co-Pay Processes Increased Regimen Adherence by 30%.” Available for download with registration at <http://www.lashgroup.com/resource-center/copay-assistance>.

<sup>58</sup> IMS Health/Amundsen, “Co-Pay Offset Program Case Study,” April 2014, at <http://www.amundsendgroup.com/capabilitiescase-studiesco-pay-offset-program-case-study/>. Manufacturers may ask consumers to provide certain information as a condition for receiving a coupon.

<sup>59</sup> Andrew Pollack, “Cancer Doctors Offer Way to Compare Medicines, Including by Cost,” *New York Times*, June 22, 2015, at <http://www.nytimes.com/2015/06/23/business/cancer-doctors-offer-way-to-compare-medicines-including-by-cost.html>.

<sup>60</sup> Physicians Interactive, “eCoupons,” 2015. Available with registration at <http://www.physiciansinteractive.com/resources/ecouponing-delivering-greater-value-in-the-clinicians-prescribing-workflow/>. OptimizeRx, “About OptimizeRx Corporation,” at <http://www.optimizerx.com/about/index.php> and “OptimizeRx Corp. and Allscripts Expand Partnership to Automate Savings Within EHR to Improve Patient Adherence,” *Marketwired*, August 3, 2015, at <http://www.marketwired.com/press-release/optimize-rx-corp-allscripts-expand-partnership-automate-savings-within-ehr-improve-patient-otcqb-oprx-2044400.htm>.

<sup>61</sup> Physicians Interactive, “Physicians Interactive and McKesson Announce Partnership to Provide Coupons on Demand™,” March 4, 2014, at <http://www.physiciansinteractive.com/news/physicians-interactive-and-mckesson-announce-partnership-to-provide-coupons-on-demand/>.

## Other Drug Discount Coupons

Pharmacies, insurers, and other nonprofit groups may offer their own prescription drug cards or programs. These cards generally cannot be used with government benefits or private insurance. Consumer organizations say that drugstore discount cards can provide valuable benefits but that it can be hard to determine whether consumers are receiving the best price with the coupons given that retail drug prices can vary widely among pharmacies in the same geographic area.<sup>62</sup> Although a card may show the price for a specific drug at participating pharmacies, it may not show the full range of prices at all area pharmacies. Websites such as Good Rx<sup>63</sup> have been created to help consumers comparison shop for prescription drugs.

## Restrictions on Coupon Use

### Federal Programs

Co-payment coupons cannot be used in conjunction with federal health benefits, including Medicare, Medicaid, TRICARE military insurance, and Veterans Health Administration programs. The prohibition is based on the federal antikickback statute,<sup>64</sup> which covers various types of remuneration—including kickbacks, bribes, and rebates—whether made directly or indirectly, overtly or covertly, in cash or in kind.<sup>65</sup> Pharmaceutical companies may be liable under the antikickback statute, for example, 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 the antikickback statute may also face civil monetary penalties and damages under the False Claims Act.<sup>66</sup> For example, the Kmart corporation paid \$1.4 million to resolve allegations that it violated the False Claims Act by using manufacturer drug coupons and gasoline discounts to induce Medicare Part D beneficiaries to use its pharmacies.<sup>67</sup>

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<sup>62</sup> *Consumer Reports*, “A Drugstore Tool We’re Not Crazy About,” December 2012, at <http://www.consumerreports.org/cro/2012/12/a-drugstore-tool-we-re-not-crazy-about/index.htm>.

<sup>63</sup> Good Rx, <http://www.goodrx.com/>.

<sup>64</sup> §1128B(b) of the Social Security Act.

<sup>65</sup> The HHS OIG in October 2014 issued proposed regulations that would create safe harbors from the antikickback statute for certain Part D program activities. For example, the proposed rules would 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. 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>.

<sup>66</sup> 31 U.S.C. §§3729-3733. See also 42 U.S.C. §1320a-7b(g).

<sup>67</sup> U.S. Department of Justice, “KMART Corporation Pays \$1.4 Million to Resolve False Claims Act Allegations in Connection with Drug Manufacturer Coupons and Gas Discounts,” September 1, 2015, at <http://www.justice.gov/opa/pr/kmart-corporation-pays-14-million-resolve-false-claims-act-allegations-connection-drug>.



## Federal Employees Health Benefit Program and ACA Qualified Health Plans

Private health plans sold to federal workers through the Federal Employees Health Benefit (FEHB) Program are not considered government programs. Enrollees in these plans may use drug discount coupons or pharmacy incentive programs in concert with their insurance benefits.<sup>68</sup>

The situation is somewhat less clear regarding individuals who enroll in qualified health plans<sup>69</sup> sold through ACA state exchanges. Former HHS Secretary Kathleen Sebelius in an October 2013 letter to Representative James McDermott<sup>70</sup> and a February 2014 letter to Senator Charles Grassley<sup>71</sup> said the HHS did not consider qualified health plans, as well as tax subsidies and other assistance to ACA consumers, to be federal programs. Some manufacturers and health care analysts were concerned that the letter does not constitute formal policy and asked HHS for clarification. Other manufacturers offer coupons to individuals who sign up for ACA-qualified health plans.

### Exceptions to the Federal Coupon Prohibition

In 2013, in response to a request from retailers, the HHS OIG issued an advisory opinion stating that supermarkets that operated in-store or stand-alone pharmacies could provide gasoline discounts to customers who signed up for free store cards. The store cards offered financial rewards based on the amount the customers spent in the store, including spending on items covered by federal health care programs. The OIG found that the arrangements would not be subject to enforcement under the false claims or the antikickback statutes.<sup>72</sup> The HHS OIG in October 2014 proposed rules that would include a safe harbor from the antikickback statute and civil monetary penalty rules for certain retailer reward programs.<sup>73</sup>

## Purchases by Enrollees “Outside” a Government Benefit

There may be cases in which an individual covered by a federal health plan goes “outside” his or her federal benefit to purchase prescription drugs. A Medicare Part D beneficiary may decide 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

<sup>68</sup> See 42 U.S.C. §1320a-7b(f)(1). See also Office of Personnel Management, “Frequently Asked Questions: Insurance,” at <http://www.opm.gov/faqs/QA.aspx?fid=fd635746-de0a-4dd7-997d-b5706a0fd8d2&pid=c8263db8-cf0e-4144-9e8a-13a1ef38c084>.

<sup>69</sup> An *ACA-qualified health plan* is an insurance plan that is certified by a state 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/>.

<sup>70</sup> Letter from Kathleen Sebelius, HHS Secretary, to Rep. McDermott, October 2014, at [http://gallery.mailchimp.com/31e15e5fee7b5a6208b646806/files/The\\_Honorable\\_Jim\\_McDermott.pdf?utm\\_source=Arent+Fox+List&utm\\_campaign=19e4815037-20131104\\_Legal\\_Alert\\_DHHS&utm\\_medium=email&utm\\_term=0\\_3a013c8d3d-19e4815037-](http://gallery.mailchimp.com/31e15e5fee7b5a6208b646806/files/The_Honorable_Jim_McDermott.pdf?utm_source=Arent+Fox+List&utm_campaign=19e4815037-20131104_Legal_Alert_DHHS&utm_medium=email&utm_term=0_3a013c8d3d-19e4815037-).

<sup>71</sup> Letter from Kathleen Sebelius to Sen. Charles Grassley, February 12, 2014, at <http://online.wsj.com/public/resources/documents/GrassleyLetter0219.pdf>.

<sup>72</sup> CRS Legal Sidebar WSLG246, *Earning Rewards when Buying Drugs Covered by Medicare and Medicaid: HHS Gives the Green Light*, by (name redacted).

<sup>73</sup> HHS, OIG, “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>.

spending limits.<sup>74</sup> Some manufacturers have aimed coupons at Medicare recipients who go outside the benefit. Pfizer has made coupons for Lipitor, a cholesterol-battling drug, available to Part D beneficiaries who agree not to use them in tandem with their Part D benefit.<sup>75</sup>

Pharmacists may be unwilling to redeem coupons for enrollees in federal programs, even if the enrollees pay outside of their benefits, due to concerns about possible violations of federal law.

## HHS Office of Inspector General Report

A recent report from the Department of Health and Human Services' Office of Inspector General (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.<sup>76</sup>

According to the report, not all manufacturer offers carry 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,<sup>77</sup> and date of birth. (Actual Part D enrollment data is not available from CMS.)

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 coupons redeemed 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.<sup>78</sup>

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<sup>74</sup> 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. The offer is open to patients who have a valid prescription and are uninsured, have commercial prescription drug insurance, or are enrolled in Medicare Part D or other federal programs. The product is sold outside of all federal drug benefits. The manufacturer does not enter into rebate agreements with third-party payers and requires patients to provide full information regarding insurance status. HHS ruled that in this limited case, even though the arrangement could potentially generate prohibited remuneration under the antikickback statute, it would not impose administrative sanctions against the company. HHS, OIG, "OIG Advisory Opinion 14-05," July 28, 2014, at <https://oig.hhs.gov/compliance/advisory-opinions/>. CMS has also issued separate guidance for Part D cash purchases at out-of-network pharmacies where coupon use is not involved. See CMS, "Understanding True Out-of-Pocket (TrOOP) Costs," at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11223-P.pdf>; and 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>.

<sup>75</sup> Tracy Staton, "Pfizer launches next new Lipitor copay program, Medicare and ACA included," *FiercePharma*, June 2, 2014, at [www.fiercepharmamarketing.com/story/pfizer-launches-next-new-lipitor-copay-program-medicard-and-aca-included/2014-06-02](http://www.fiercepharmamarketing.com/story/pfizer-launches-next-new-lipitor-copay-program-medicard-and-aca-included/2014-06-02). Also see "About the Lipitor Choice Card" at <https://www.lipitor.com/choice-card>.

<sup>76</sup> 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>.

<sup>77</sup> For example, an individual could be enrolled in Part D but not yet have met the annual deductible. The individual's coverage would not begin until he or she meets the deductible.

<sup>78</sup> HHS, OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons," September 2014, at (continued...)

## Private Insurance

Commercial payers have varying policies regarding coupon use. A 2014 Pharmacy Benefits Management Institute survey found that some large employers (or the plans they contracted with) limited the ability of employees covered under health plans they offer to redeem coupons on the grounds that the coupons interfered with price tiers and other cost-control strategies. Some large employers increased required coinsurance for drugs if a coupon was available.<sup>79</sup>

In 2012, UnitedHealthcare began to bar enrollees from using co-payment coupons for certain specialty drugs.<sup>80</sup> Express Scripts, the nation's largest PBM, dropped 48 drugs from its preferred formulary in 2014, basing its decision partly on the availability of manufacturer co-payment coupons for the drugs.<sup>81</sup> (Insurers that contract with PBMs are not bound to use the PBMs' drug benefit formularies, though many do.) In announcing its decision, Express Scripts noted that prices for the most commonly used generic medications had decreased by more than 40% during the previous five years, whereas prices for commonly used brand-name drugs had risen by more than 65%—meaning that choosing brand-name drugs over generics was imposing a growing cost on insurance plans.

Some patients and manufacturers get around plan prohibitions by using debit cards and rebate offers after the point of sale. For example, one company uses a case study to market its prescription-drug debit card. The case study notes that a manufacturer risked losing thousands of patients after a payer decided to bar co-payment cards for a rheumatoid arthritis drug and instead recommended that its enrollees use a less expensive generic drug. In response, the manufacturer adopted a debit card system, where patients paid the required co-payment at the pharmacy and were reimbursed after the point of the sale—usually within a few days. The debit card vendor reported that this approach resulted in a high patient retention rate.<sup>82</sup>

## Insurer Lawsuits

In 2012, a group of union-based health plans brought lawsuits against eight drug manufacturers, charging that their coupon programs violated federal racketeering and commercial bribery laws. Federal district courts have dismissed several of the lawsuits, which were coordinated by the Prescription Action Litigation Coalition of the nonprofit group Community Catalyst.<sup>83</sup>

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[http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB\\_Copayment\\_Coupons.pdf](http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf).

<sup>79</sup> Pharmacy Benefits Management Institute, *Prescription Drug Benefit Cost and Plan Design Report 2014-2015 Edition*, p. 27. Report is sponsored by Takeda Pharmaceuticals. Data are based on a survey of 353 employers representing more than 29 million members. Larger employers are those that cover more than 5,000 lives, and smaller employers are those that cover fewer than 5,000 lives. The survey was conducted in April 2014.

<sup>80</sup> *The Pink Sheet Daily*, "UnitedHealthcare Program Will Bar Copay Coupons For Six Specialty Drugs," October 26, 2012. In March 2014, UnitedHealthcare said it would partner with retail pharmacies to discontinue the use of co-payment coupons. However, in April 2014 the insurer said it would delay the initiative. UnitedHealthcare, "July 1, 2014, Retail Coupons Policy," at <http://broker.uhc.com/assets/Coupon%20Policy.pdf>; and UnitedHealthcare, "Pharmacy Retail Coupon Update," April 11, 2014, at <http://broker.uhc.com/articleView-13383>.

<sup>81</sup> Express Scripts, "Smart Formulary Management," January 2, 2014, at <http://lab.express-scripts.com/insights/drug-options/smart-formulary-management>. The preferred formulary is selected by about 30% of Express Scripts clients.

<sup>82</sup> IMS Health, "Maintaining Patient Access to Affordable Medication through OPUS Health's DebitRx™ Solution," at [http://www.rm.imshealth.com/Docs\\_CaseStudies/Marketing/DebitRx\\_CaseStudy\\_Rheumatoid-Arthritis.pdf](http://www.rm.imshealth.com/Docs_CaseStudies/Marketing/DebitRx_CaseStudy_Rheumatoid-Arthritis.pdf). Opus Health is owned by IMS.

<sup>83</sup> Community Catalyst, "Current Lawsuits," at <http://www.communitycatalyst.org/initiatives-and-issues/initiatives/prescription-access-litigation/current-lawsuits>; David McAfee, "Merck Escapes Suits Over Prescription Copay (continued...)"

## Financial Impact of Coupons

Health care payers and government officials have complained that drug coupons mask the actual price of drugs and may prompt beneficiaries to choose more expensive drugs, even if cheaper, equally effective drugs are available, which can drive up health care spending.<sup>84</sup> Manufacturers have countered that coupons are targeted primarily at higher-priced drugs for which there are few generic substitutes.<sup>85</sup> By improving adherence, they say, the coupons can help to hold down other associated health care costs, such as hospitalizations.

Studies have sought to quantify the impacts of coupon use on consumer behavior and payer spending. For example, a targeted study of consumers using statins to control cholesterol levels found 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.<sup>86</sup>

A 2014 *Health Affairs* 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, making the high-cost products affordable for more patients and potentially improving adherence. However, the increased use of coupons could increase costs for other beneficiaries in a health care plan if a payer decides to raise plan premiums or deductibles to offset some of the expenses of higher drug utilization.<sup>87</sup>

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Coupons,” *law360*, April 29, 2013, at <http://www.law360.com/articles/437025/merck-escapes-suits-over-prescription-copay-coupons>; and Paul Milford and Dawn McCarty, “Pfizer, Abbott, Glaxo Sued Over Brand-Drug Co-Pay Discounts,” *Bloomberg*, March 7, 2012, at <http://www.bloomberg.com/news/2012-03-07/pfizer-abbott-face-allegations-over-co-pay-coupon-promotions.html>.

<sup>83</sup> *New England Carpenters Health and Welfare Fund vs. Abbott Laboratories and Abbie*, U.S. District Court for the Northern District of Illinois, Eastern Division, Case No. 12 CV 1662, at <http://www.policymed.com/2014/10/federal-court-dismisses-rico-allegations-pharmaceutical-manufacturers-and-pharmacies-not-in-racketee.html>.

<sup>84</sup> Catherine Stamer, G. Caleb Alexander, Kevin Bowen, Yang Qiu, Peter Wickersham, and Patrick Gleason, “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.

<sup>85</sup> Mason Tenaglia, “Copay Cards and Coupons: Letting Facts Get in the Way,” *Pharmaceutical Executive*, January 1, 2012, at <http://www.pharmexec.com/pharmexec/Commentary/Copay-Cards-and-Coupons-Letting-the-Facts-Get-in-t/ArticleStandard/Article/detail/755091>.

<sup>86</sup> 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. The number of statin fills in the 12 months following initiation was highest for coupon users, slightly lower for patients initiating generic statins, and lowest for non-coupon users. Coupon users had higher total statin prescription costs than generic initiators and non-coupon users (\$798 vs. \$92 vs. \$678) and higher pre-coupon out-of-pocket costs (\$339 vs. \$53 vs. \$169;  $P < 0.001$ ). Health plan costs for statins excluding rebates were lower for coupon users than non-coupon users (\$460 vs. \$508;  $P < 0.001$ ) but much higher compared with generic statin initiators (\$460 vs. \$39).

<sup>87</sup> Catherine Stamer 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 it served. Spending for the specialty claims totaled \$911.8 million, of which \$35.3 million (3.9%) was paid out of pocket 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.

Other studies have examined whether coupons are targeted at drugs for which lower-cost substitutes are available, thus inducing beneficiaries to use higher-priced drugs. A 2013 study looked at whether coupons were being offered for drugs for which either a generic substitute or a therapeutically equivalent product<sup>88</sup> was available. According to that study, about 60% of the coupons examined were for drugs with lower-cost alternatives in the same drug class.<sup>89</sup>

## Patient Assistance Programs

Pharmaceutical manufacturers, state governments, and nonprofit groups offer additional assistance programs for both insured and uninsured consumers.

### Pharmaceutical Patient Assistance Programs

A number of manufacturers and nonprofit groups offer patient assistance programs (PAPs) to help uninsured or underinsured individuals obtain access to drugs.<sup>90</sup> PAPs may provide financial assistance or free or reduced-price drugs. Some PAPs provide aid directly to patients, whereas others work through health care providers, such as clinics or hospitals.<sup>91</sup>

To participate in a PAP, an individual generally fills out an application listing information including income,<sup>92</sup> insurance status, medical background, and proof of U.S. citizenship or legal residence. Applications often must be signed by a patient and a physician. Some PAPs provide drugs free of charge to patients who qualify, whereas others subsidize most of the cost of the products. The pharmaceutical industry operates the Partnership for Prescription Assistance,<sup>93</sup> a clearinghouse for information about more than 475 PAPs. According to the partnership, the pharmaceutical industry has aided 8.5 million U.S. consumers through such programs. Other websites with information about such PAPs include NeedyMeds and RxAssist.

CMS has special data exchanges that coordinate government programs with PAPs, State Pharmaceutical Assistance Programs (SPAPs) (see “State Pharmaceutical Assistance Programs”) and AIDS drug assistance programs.<sup>94</sup> CMS operates a webpage where consumers can check to

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<sup>88</sup> 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>.

<sup>89</sup> 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>.

<sup>90</sup> For illustrative descriptions see CMS, “Pharmaceutical Manufacturer Patient Assistance Program,” at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html> and National Alliance of Mental Illness, at [http://www.nami.org/Content/ContentGroups/Helpline1/Prescription\\_Drug\\_Patient\\_Assistance\\_Programs.htm](http://www.nami.org/Content/ContentGroups/Helpline1/Prescription_Drug_Patient_Assistance_Programs.htm).

<sup>91</sup> Suzanne Shelley, “Pharma Struggles to Manage the Complexity of its Patient Assistance Programs,” *Pharmaceutical Commerce*, February 26, 2013, at [http://pharmaceuticalcommerce.com/brand\\_communications?articleid=26770](http://pharmaceuticalcommerce.com/brand_communications?articleid=26770).

<sup>92</sup> To qualify, individuals often must have annual incomes below 200% of the federal poverty level.

<sup>93</sup> See Partnership for Prescription Assistance at [https://www.pparx.org/about\\_us/patient\\_advocates](https://www.pparx.org/about_us/patient_advocates).

<sup>94</sup> CMS, “Prescription Drug Assistance Programs,” at <http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Prescription-Drug-Assistance-Programs/Overview.html>.

see whether there is a PAP for a particular drug.<sup>95</sup> Some PAPs do not accept applications from individuals who are enrolled in Medicare.<sup>96</sup>

## HHS OIG Advisory Opinions

In November 2005, HHS OIG issued a special advisory bulletin regarding the application of federal antikickback and other laws to PAPs that aid Medicare Part D beneficiaries.<sup>97</sup> The OIG recognized that manufacturer-based PAPs that subsidize Part D cost sharing presented heightened risks under the antikickback statute. However, it said that cost-sharing assistance provided by truly independent charities should not raise antikickback concerns, even if the charities received manufacturer donations. The OIG also said manufacturer-based PAPs could operate outside the Part D benefit, meaning that no PAP payment for a covered drug could be filed with a Part D plan and manufacturer assistance would not count toward a beneficiary's Part D out-of-pocket spending totals.<sup>98</sup>

In a follow-up bulletin in May 2014,<sup>99</sup> the HHS OIG expanded on its original guidance and said it would apply increased scrutiny to charitable PAPs that establish or operate disease funds that limit assistance to a subset of available products, such as covering co-payments only for expensive or specialty drugs. The bulletin said the cost of a drug was not an appropriate stand-alone factor for determining individual financial need and that generous financial support, particularly for a PAP with a limited number of drugs or the drugs of a major donor manufacturer, could be evidence of intent to induce use of that drug rather than to support financially needy patients.

## State Pharmaceutical Assistance Programs

SPAPs are financed by states to serve uninsured residents or to fill in the gaps in Medicare, Medicaid, and private insurance coverage. SPAPs are aimed at lower-income individuals and usually are the payer of last resort, meaning the SPAP will pay only after federal government programs or any private insurance has already been billed. SPAP rules and coverage vary by state—some are targeted at seniors; some at specific disease groups such as people with HIV/AIDs. Medicare provides a link to SPAPs by state at <http://www.medicare.gov/pharmaceutical-assistance-program/state-programs.aspx>.<sup>100</sup>

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<sup>95</sup> Medicare.gov, “Pharmaceutical Assistance Programs,” at <http://www.medicare.gov/pharmaceutical-assistance-program/>. See also [https://www.pparx.org/prescription\\_assistance\\_programs/list\\_of\\_participating\\_programs](https://www.pparx.org/prescription_assistance_programs/list_of_participating_programs).

<sup>96</sup> See RxAssist at <http://www.rxassist.org/faqs>.

<sup>97</sup> CMS, “Pharmaceutical Manufacturer Patient Assistance Program Information,” at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html>.

<sup>98</sup> In December 2014, the HHS OIG issued another advisory opinion regarding a specific PAP targeted at people suffering from Crohn's Disease and ulcerative colitis. Under the proposed program, a nonprofit group would provide co-payment and other assistance to financially needy patients on a first-come, first-served basis. Before receiving the aid, patients would choose their own doctor and their specific medication. The program would be funded from a variety of sources, including drug manufacturers, but the funders would not have influence over the program, according to information submitted to HHS. The OIG determined that because of the way the PAP was structured—with no donor exerting direct control, patients choosing their own course of treatment, and limited exchange of patient information—it posed a very low risk for potential fraud and abuse. HHS OIG, “Re: OIG Advisory Opinion No. 14-11,” December 29, 2014, at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2014/AdvOpn14-11.pdf>.

<sup>99</sup> HHS, OIG, “Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs,” 79 *Federal Register* 31120-31123, at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>.

<sup>100</sup> Medicare.gov, “State Pharmaceutical Association Programs,” at <http://www.medicare.gov/pharmaceutical-> (continued...)

## Appendix A. National Expenditure Data

For purposes of the National Health Expenditures prescription drug data:

- *Private insurance* includes employer-sponsored insurance and other private insurance, including plans sold through Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) state marketplaces. Private insurance accounted for about 42.8% of prescription drug spending in 2014.
- *Government health care* includes Medicare and Medicaid, which made up 27.9% and 8.9% of prescription drug spending, respectively, in 2014.
- *Other health insurance programs* include the Children's Health Insurance Program and Department of Defense and Department of Veterans Affairs coverage. These programs made up 3.4% of spending in 2014.
- *Other third-party payers* include worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, other federal programs, Substance Abuse and Mental Health Services Administration, other state and local programs, and school health. They made up less than 1% of spending in 2014.

The National Health Expenditures data measure retail prescription drug spending and do not capture some pharmacy spending by institutions, such as hospitals and physicians' offices.

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[assistance-program/state-programs.aspx](#).

## Appendix B. Federal Health Programs

### Federal Role in Prescription Drug Coverage

**Medicare Part D:** The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) established a voluntary outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug plans (MA-PDs) that offer coverage as part of broader, managed-care plans. Private drug plans participating in Part D bear some financial risk, though federal subsidies cover most program costs in an effort to encourage participation and keep benefits affordable.<sup>101</sup>

**Medicare Part B:** Certain specified outpatient prescription drugs are covered under Medicare Part B, including drugs furnished incident to physicians' services, immunosuppressive drugs following a Medicare-covered organ transplant, oral anticancer drugs (provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if furnished incident to physicians' services), and drugs used for durable medical equipment. Generally, Medicare reimburses physicians and other providers, such as hospital outpatient clinics, for covered Part B drugs and biologics at 106% of a drug manufacturer's average sales price.<sup>102</sup>

**Medicaid:** Medicaid is a federal-state entitlement program that pays for health care and related services on behalf of certain low-income individuals. Prescription drugs are an optional Medicaid benefit, and all states cover outpatient drugs. States can create formularies, but federal rules tend to result in comprehensive coverage, even for beneficiaries enrolled in Medicaid managed-care plans. Pharmaceutical manufacturers that voluntarily participate in Medicaid are required to pay rebates to states on covered outpatient drugs, which help Medicaid receive manufacturers' lowest or best price.<sup>103</sup>

**Children's Health Insurance Program:** The state Children's Health Insurance Program (CHIP) is a federal-state program that provides health coverage to certain uninsured, low-income children and pregnant women in families that have annual income above Medicaid eligibility levels but that have no health insurance. CHIP is jointly financed by the federal government and states. Most CHIP plans cover major medical benefits, such as inpatient and outpatient care, physician services, and prescription drugs.<sup>104</sup>

**The Veterans Health Administration (VA):** The VA offers all enrolled veterans a standard medical benefits package that includes (among other things) inpatient care, outpatient care, and prescription drugs. Prescription drug benefits include over-the-counter drugs and medical and surgical supplies available under the VA national formulary system. The Department of Defense and the VA use certain federal pricing arrangements for these direct purchases, including Federal Supply Schedule prices and prices available to the four largest federal purchasers.<sup>105</sup>

**ACA Exchange Plans:** The ACA requires that U.S. health care plans offered in the non-group and small-group markets cover at least 10 essential health benefits (EHB), including prescription drugs. Although the ACA imposed minimum standards for the drug benefit, recent studies have found significant differences in the cost and scope of drug coverage among health plans. The Centers for Medicare & Medicaid Services in February 2015 announced more stringent rules for the EHB drug benefit and warned insurers that imposing high cost sharing for most or all medications used to treat a specific disease could constitute discrimination.<sup>106</sup>

<sup>101</sup> CRS Report R40611, *Medicare Part D Prescription Drug Benefit*, by (name redacted) and (name redacted)

<sup>102</sup> CRS Report R40425, *Medicare Primer*, coordinated by (name redacted) and (name redacted).

<sup>103</sup> CRS Report R43778, *Medicaid Prescription Drug Pricing and Policy*, by (name redacted)

<sup>104</sup> CRS Report R43627, *State Children's Health Insurance Program: An Overview*, by (name redacted) and (name redacted).

<sup>105</sup> CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*, by (name redacted)

<sup>106</sup> CMS, "Final HHS Notice of Benefit and Payment Parameters for 2016," February 20, 2015, at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-02-20.html>.



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