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MANUFACTURER SAFEGUARDS MAY NOT PREVENT COPAYMENT COUPON USE FOR PART D DRUGS

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EXECUTIVE SUMMARY: MANUFACTURER SAFEGUARDS MAY NOT PREVENT COPAYMENT COUPON USE FOR PART D DRUGS
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WHY WE DID THIS STUDY

Pharmaceutical manufacturers offer copayment coupons to reduce or eliminate the cost of patients' out-of-pocket copayments for specific brand-name drugs. The anti-kickback statute prohibits the knowing and willful offer or payment of remuneration to a person to induce the purchase of any item or service for which payment may be made by a Federal health care program. Manufacturers 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, including Medicare Part D. The anti-kickback statute applies to all Federal health care programs, but this study focused on Part D. The use of coupons by Medicare beneficiaries could impose significant costs on the Part D program because many coupons encourage beneficiaries to choose more expensive brand-name drugs over less expensive alternative drugs. In two surveys by outside groups, approximately 6 percent to 7 percent of seniors surveyed reported using coupons to purchase prescription drugs.

HOW WE DID THIS STUDY

To identify the safeguards pharmaceutical manufacturers employ to prevent their copayment coupons from being used for drugs paid for by Part D and to identify vulnerabilities in those safeguards, we surveyed 30 manufacturers of the top 100 Part D brand-name drugs with coupons and with the highest Medicare expenditures. We also reviewed selected safeguards offered for a purposive sample of those drugs. In addition, we interviewed staff at various organizations involved in pharmacy claims transactions to understand other vulnerabilities associated with coupon use in Part D.

WHAT WE FOUND

Pharmaceutical manufacturers' current safeguards may not prevent all copayment coupons from being used for drugs paid for by Part D. All surveyed manufacturers provide notices directed to beneficiaries and pharmacists that coupons may not be used in Federal health care programs. Most surveyed manufacturers use pharmacy claims edits to prevent coupons from being processed for drugs covered by Part D. Most of these edits may not prevent all coupons from being processed for Part D-covered drugs. Finally, Part D plans and other entities cannot identify coupons within pharmacy claims.

WHAT WE RECOMMEND

The Office of Inspector General's concurrent Special Advisory Bulletin affirms that pharmaceutical manufacturers are at risk of sanctions if they fail to take appropriate steps to ensure that their copayment coupons do not induce the purchase of Federal health care programs items or services, including but not limited to, drugs paid for by Medicare Part D. For this reason, manufacturers may engage industry stakeholders and the Centers for Medicare & Medicaid Services (CMS) in an effort to identify a solution to ensure that coupons are not used for drugs paid for by Part D. CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claims edits and make coupons transparent. CMS concurred with our recommendation.

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OBJECTIVES

1. To describe safeguards pharmaceutical manufacturers employ to prevent copayment coupon use for drugs paid for by Medicare Part D.
2. To identify vulnerabilities in these safeguards.
3. To identify any other vulnerabilities associated with copayment coupon use for drugs paid for by Medicare Part D.

BACKGROUND

Pharmaceutical manufacturers offer copayment coupons to reduce or eliminate the cost of patients' out-of-pocket copayments for specific brand-name drugs and thereby induce the purchase of those drugs. Although coupons reduce individual patients' immediate costs, coupons may increase the cost of prescription drugs for health insurers, including those offering Medicare prescription drug coverage through Part D plans.[1]

The anti-kickback statute prohibits knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a Federal health care program.[2] Pharmaceutical manufacturers may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by Medicare Part D or any other Federal health care program.[3]

Recent surveys by outside organizations found that approximately 6 percent to 7 percent of surveyed seniors reported using manufacturer coupons toward their copayment for prescription drugs purchased through

[1] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013. David Grande, "The Cost of Drug Coupons," *JAMA*, June 13, 2012, http://jama.jamanetwork.com/article.aspx?articleid=1182868. Accessed on June 14, 2012. These articles describe how the use of coupons to encourage brand-name drug utilization could increase insurers' costs. This description applies to Medicare Part D, which uses an insurance model to provide prescription drug benefits.

[2] 42 U.S.C. § 1320a-7b(b).

[3] "Federal health care program" is defined in the anti-kickback statute as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5; or (2) any State health care program, as defined in section 1320a-7(h) of this title." 42 U.S.C. § 1320a-7b(f).

their Medicare prescription plans.[4, 5] Applying these results to the population of 36 million Part D beneficiaries, the utilization of copayment coupons to obtain prescription drugs paid for by Part D could exceed 2 million beneficiaries.

Pharmaceutical manufacturers' use of coupons to reduce the cost-sharing obligations for Medicare Part D drugs could impose significant costs on Federal health care programs and taxpayers. A 2013 study from *The New England Journal of Medicine* found that 58 percent of coupons were for brand-name drugs for which a lower cost generic alternative was available.[6] If manufacturer coupons encourage Medicare beneficiaries to obtain more expensive brand-name drugs when lower cost alternatives are available, the coupon may reduce individual beneficiaries' immediate out-of-pocket costs but Part D plans' and the Part D program's costs may increase, ultimately increasing costs to taxpayers.[7]

Medicare Part D Cost Controls

CMS contracts with private insurance companies, called sponsors, to provide Part D prescription drug benefits for approximately 36 million beneficiaries.[8, 9] Sponsors use a variety of methods to control prescription drug coverage costs through the Part D program.

Part D Formularies. Sponsors can establish formularies, or lists of covered drugs, to give preference to more effective drugs over less effective drugs or less expensive drugs over more expensive drugs that treat the same condition. To drive utilization toward equally effective but less expensive drugs, formularies are generally organized into tiers, which have different beneficiary copayments for a prescription drug. Drugs in lower tiers are typically the least expensive and have the lowest beneficiary copayments. Drugs in the subsequent and ascending tiers are,

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[4] National Coalition on Health Care (NCHC), "Seniors' Awareness And Use of Prescription Co-pay Coupons in Medicare," Survey. March 26-30, 2012.

[5] Pharmaceutical Care Management Association (PCMA), "Survey of Seniors Enrolled in the Medicare Prescription Drug Plan," Survey. February 15-17, 2011.

[6] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013.

[7] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013. David Grande, "The Cost of Drug Coupons," *JAMA*, June 13, 2012, http://jama.jamanetwork.com/article.aspx?articleid=1182868. Accessed on June 14, 2012.

[8] The Part D program was established as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 101; Social Security Act, § 1860D-1 and it was codified at 42 U.S.C. § 1395w-101 et seq.

[9] 42 U.S.C. § 1395w-101 et seq.

in general, relatively more expensive and have increasing beneficiary copayments. For example, a lower tier drug is typically a low-cost generic drug for which a beneficiary might have a $5 or $10 copayment, while a higher tier drug is likely to be a more expensive brand-name drug for which a beneficiary might have a $45 copayment.

Generic Substitution. Sponsors can control prescription drug costs by requiring less expensive, chemically equivalent generic drugs to be substituted for costlier brand-name drugs. Generic substitution may reduce the amounts that both Part D plans and beneficiaries pay for covered drugs. For instance, the average brand-name drug prescription costs $89, while the average generic drug prescription costs $23, a difference of $66.[10]

Beneficiary Copayments in Part D

Beneficiaries, Part D plans, and CMS share Part D prescription drug coverage costs. Beneficiary cost sharing begins in the initial benefit stage, which beneficiaries reach after paying their deductible. Beneficiaries' cost-sharing responsibilities for covered drugs then change as they move through different stages of the Part D benefit.[11]

During the initial benefit stage, beneficiaries pay copayments for prescription drugs on the basis of factors such as whether the drug is a generic or a brand, which formulary tier the drug is on, and whether the pharmacy is preferred or nonpreferred by the Part D plan.[12, 13, 14]

After reaching an initial coverage limit set in statute, beneficiaries typically enter the coverage gap stage where their cost-sharing increases.[15, 16] In this stage, in 2013, pharmaceutical manufacturers provided beneficiaries a 50-percent discount on applicable drugs (generally, covered brand-name drugs) at the point of sale.[17] For most generic drugs, in 2013, beneficiaries were responsible for 79 percent of the cost as their copayment.[18]

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[10] Congressional Budget Office, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*, September 2010, p. 8.

[11] 42 CFR § 423.104.

[12] *See*, e.g., CMS, Copayment/coinsurance in drug plans, http://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html. Accessed on April 24, 2014.

[13] 42 CFR § 423.104(d)(2)(ii).

[14] 42 CFR § 423.120(a)(9).

[15] 42 U.S.C. § 1395w-102(b)(2)(A).

[16] *See*, e.g., CMS, Costs in the coverage gap, http://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html. Accessed on April 30, 2014.

[17] 42 U.S.C. § 1395w-114a.

[18] 42 U.S.C. § 1395w-102(b)(2)(C).

The coverage gap continues until beneficiaries' true out-of-pocket (TrOOP) spending reaches the annual TrOOP threshold.[19] Generally, for brand-name drugs, the full amount of drug costs, including the out-of-pocket amount beneficiaries paid, counts toward their TrOOP.[20] For generic drugs, only the out-of-pocket amount counts toward beneficiaries' TrOOP thresholds.

After reaching the TrOOP threshold, beneficiaries enter the catastrophic benefit stage.[21] During catastrophic coverage, the Part D program pays the majority of beneficiaries' drug costs and beneficiaries are generally responsible for limited cost sharing through copayments.

Copayment Coupons

Pharmaceutical manufacturers typically offer copayment coupons to insured patients to reduce or eliminate patients' out-of-pocket costs for specific brand-name drugs. Manufacturers may contract with coupon vendors to create and administer coupon programs on their behalf. ("Manufacturers" includes all manufacturers or vendors acting on their behalf.) A manufacturer may offer a coupon for a brand-name drug that reduces the copayment for that drug and makes it cheaper than the copayment for a competitor drug. For example, a coupon may reduce a patient's copayment for Brand Drug A from $20 to $4, making the copayment for the brand drug cheaper than the copayment for a generic equivalent, which may be $10. In some cases, the coupon eliminates the copayment altogether.

Pharmaceutical manufacturers may offer copayment coupons for several reasons. It has been reported that manufacturers may use coupons to try to retain market share when generic and other brand-name drugs that treat the same condition become available to patients. It also has been reported that manufacturers may use coupons to attract new patients who may be using an alternative therapy. Additionally, manufacturers indicate that they offer coupons to encourage patients to adhere to their prescription drug regimen. Finally, it has been reported that manufacturers may offer

[19] For 2013, the TROOP threshold was $4,750. Generally, TrOOP spending includes all beneficiary payments (excluding monthly premiums) and any payments made by other approved payers, such as health savings accounts and certain charities. 42 CFR § 423.104(d)(5)(B)(iii); CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 5, § 30.

[20] *See*, e.g., CMS, Costs in the coverage gap, http://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html. Accessed on April 30, 2014.

[21] *See*, e.g., CMS, Catastrophic coverage, http://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html. Accessed on May 9, 2014.

coupons to offset the high cost of specialty and biologic drugs, which may not have generic alternatives.[22]

Copayment coupons have become increasingly prevalent. In recent years, the number of coupons has increased from 86 in July 2009[23] to 525 in December 2012.[24] This increase may be related to competition from generic drugs. From 2009 to 2012, numerous "blockbuster" drugs—drugs that have generated $1 billion in sales—lost their patent protection. For many of those drugs, generic versions became available. The number of generic drugs the Food and Drug Administration (FDA) approved increased 27 percent between 2009 and 2012.[25]

Copayment Coupon Formats. Copayment coupons typically are available in four formats: (1) print coupons, (2) electronic coupons, (3) debit cards, and (4) direct reimbursements. Print coupons are printed cards or documents that the patient physically takes or sends to the pharmacy to purchase a prescription drug. Electronic coupons are cardless programs that evaluate prescription drug claims as they are submitted through the pharmacy claims transaction system, which applies copayment reductions. Debit cards include any prepaid and/or bank-authorized card that is processed at the point of sale to pay for some predetermined portion of the copayment. Direct reimbursements are any payments by a manufacturer offered directly to a patient for all or part of the patient's out-of-pocket cost for a purchased prescription drug. Direct reimbursements occur after a prescription drug is purchased and generally do not involve pharmacies.

Most coupons offered by manufacturers are typically in the format of print coupons. Manufacturers offer electronic coupons to a lesser extent. A small number of coupons are offered in the format of debit cards and direct reimbursements. See Table 1, on the next page, for a breakdown of the prevalence of coupon formats among 30 manufacturers surveyed by the Office of Inspector General (OIG).

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[22] Biologics are among the most expensive drugs available. The average cost of a biologic drug is about 22 times that of nonbiologic drugs. "Health Policy Brief: Biosimilars," *Health Affairs*, October 10, 2013, http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_100.pdf. Accessed on December 6, 2013.

[23] Cleveland Research Company, "Co-Pay Cards: The Past, Present, and Future," March 2012.

[24] OIG analysis of drugs available on http://www.internetdrugcoupons.com.

[25] OIG analysis of 2009 to 2012 FDA Abbreviated New Drug Approvals (ANDAs) by month available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu.

Table 1: Coupon Formats for Manufacturers Surveyed by OIG

Coupon Format	Number of Manufacturers Offering	Percentage of All Coupons Offered by Manufacturers
Print	27	71%
Electronic	22	26%
Debit Card	9	2%
Direct Reimbursement	16	1%

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

Accessing Copayment Coupons. Patients commonly access copayment coupons in four ways. Patients may access or receive coupons from their prescribing physicians. Patients also may access coupons through Web sites and toll-free telephone numbers managed by manufacturers or companies hired to manage their coupon programs. Finally, patients may be given coupons by pharmacists filling their prescriptions.

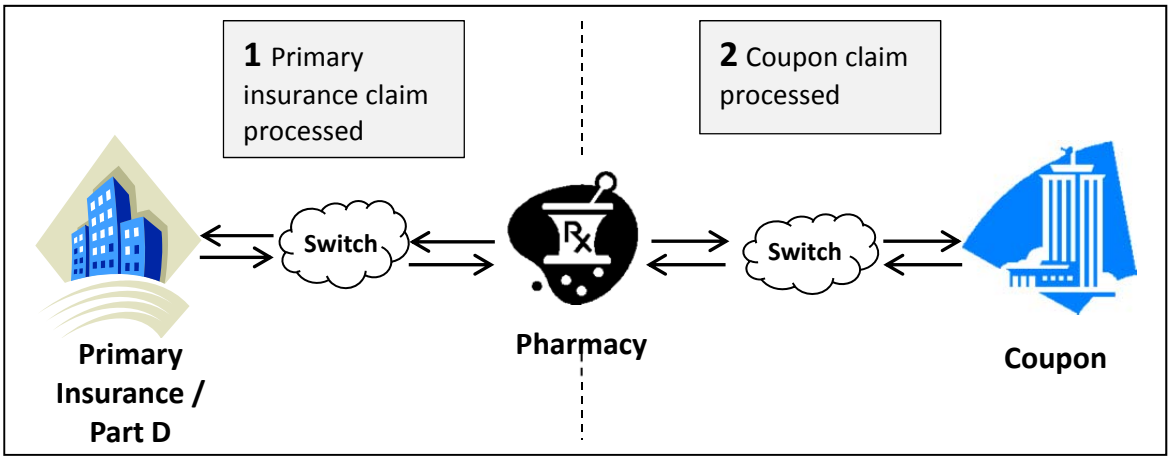
Redeeming Copayment Coupons. Patients typically redeem copayment coupons at pharmacies when they purchase prescription drugs. However, patients do not always redeem coupons at pharmacies and may request reimbursements directly from the manufacturer after purchasing prescription drugs.

Copayment Coupons and Pharmacy Claims Processing

Copayment coupon claims are typically processed in the same way as payments received from a secondary insurance source using the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard D.0 for pharmacy claims. Using this standard format, all pharmacy claims, including coupon claims, are electronically routed from the pharmacy to various payers by companies known as "switches." Once a claim is routed to a payer, the payer sends coverage and payment information back to the pharmacy through the switch.

The processing of primary insurance and coupon claims occurs in real time and involves several steps to coordinate payment for a single claim. First, a patient's primary insurance claim is processed, and the patient's copayment amount is determined. Second, the coupon claim is processed, and how much of the copayment the manufacturer will pay is determined. Finally, the patient pays the remaining copayment balance, if any. See Figure 1, on the next page, for an illustration of how primary insurance and coupon claims are processed.

Figure 1: Processing of Primary Insurance and Coupon Claims



Source: OIG analysis of interview responses, 2013.

The coordination of primary insurance and coupon or secondary payers is facilitated by unique identifiers that route the claim to the entity responsible for paying the claim. One identifier is the Bank Identification Number (BIN), which identifies the responsible payer. Primary insurers, including Part D plans, have BINs that route primary insurance claims to them for payment. Manufacturers also have BINs that route their coupon claims to them for payment. The Processor Control Number (PCN) is a secondary identifier that is internal to an insurance company or manufacturer and further routes the claim within that company.

To attempt to determine a patient's Part D enrollment status before submitting a coupon claim, a pharmacist may submit an optional enrollment verification request, called an E1 transaction, to the Part D Transaction Facilitator. CMS contracts with the Transaction Facilitator to track Part D beneficiaries' benefit stages and to conduct E1 transactions, which provide pharmacists with information about a patient's Part D enrollment status.[26] The pharmacist submits the patient's identification information to the Transaction Facilitator, which compares it to patient information in CMS's Medicare enrollment database to determine whether the patient is enrolled in Part D. Pharmacies pay less than 1 cent per transaction to submit this verification request.[27]

[26] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 14, § 30.4.

[27] CMS, *Changes Involving Medicare Eligibility Queries (E1) and Other TrOOP Facilitator-related Transactions*, December 9, 2010, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoE1ChangesTipSheet_120910.pdf. Accessed on November 30, 2012.

METHODOLOGY

Scope

The anti-kickback statute applies to all Federal health care programs, but this study focused on Medicare Part D. This study analyzed the copayment coupon safeguards of pharmaceutical manufacturers for the most costly brand-name Part D prescription drugs with coupons covered in 2012. These prescription drugs were covered under stand-alone prescription drug plans and Medicare Advantage prescription drug plans. The study did not include coupons for generic drugs because copayment coupons are not commonly offered for generic drugs. This study did not estimate the use of coupons by Part D beneficiaries. It also did not estimate the overall cost of coupons to Part D plans and the Part D program.

Data Collection and Analysis

We collected information on safeguards pharmaceutical manufacturers employ to prevent copayment coupon use for drugs paid for by Medicare Part D through a survey of manufacturers and a review of copayment coupons and coupon Web sites. We collected information on other vulnerabilities through interviews with a variety of industry stakeholders.

We sent an online survey to 34 pharmaceutical manufacturers of drugs with coupons, and 30 responded. We selected these manufacturers by identifying the manufacturers offering the top 100 Part D-covered brand-name drugs with coupons by cost to Part D. The 30 complete surveys we received represented an 88-percent response rate. We analyzed survey responses to determine the extent to which manufacturers surveyed had safeguards in place to prevent the use of coupons for drugs paid for by Part D.

We also reviewed safeguards in place for a subset of the top 100 Part D-covered brand-name drugs with coupons. We attempted to obtain 50 coupons to determine the extent to which manufacturers had safeguards directed to beneficiaries and pharmacists in place. We reviewed these safeguards for the 40 coupons that we obtained.

In addition, we conducted structured interviews with staff at organizations involved in the pharmacy claims transaction process, including pharmacists, coupon vendors, a switching company, and NCPDP, to understand other vulnerabilities associated with coupon use in Part D.

For a discussion of our data collection and analysis, see Appendix A.

Data Limitations

Although we did not verify manufacturers' survey responses, we selected a sample of coupons offered by surveyed manufacturers to review

safeguards on or associated with coupons. We used this information to confirm the accuracy of manufacturers' responses. We could not review safeguards that were not on coupons or on coupon Web sites. For these safeguards, this report relies on self-reported data.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

All surveyed manufacturers provide notices to beneficiaries and pharmacists that copayment coupons may not be used in Federal health care programs

All manufacturers surveyed report providing notices directed to Federal health care program beneficiaries or pharmacists for at least one of the coupon formats they offer. These notices state that copayment coupons may not be used to purchase drugs paid for by Federal health care programs, including Medicare Part D. Notices to beneficiaries and pharmacists are more prevalent for print coupons, which is the most commonly offered coupon format according to manufacturers surveyed. Notices are still widely used for other formats, but to a lesser extent. See Table 2 for the percentages of surveyed manufacturers that report using notices for the coupon formats they offer.

Table 2: Notices by Coupon Format

Notice	Print n = 27	Electronic n = 22	Debit Card n = 9	Direct Reimbursement n = 16	Any Format n = 30
Beneficiary Notices	27 (100%)	16 (73%)	8 (89%)	13 (81%)	30 (100%)
Pharmacist Notices	18 (67%)	7 (32%)	2 (22%)	N/A[28]	20 (67%)

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

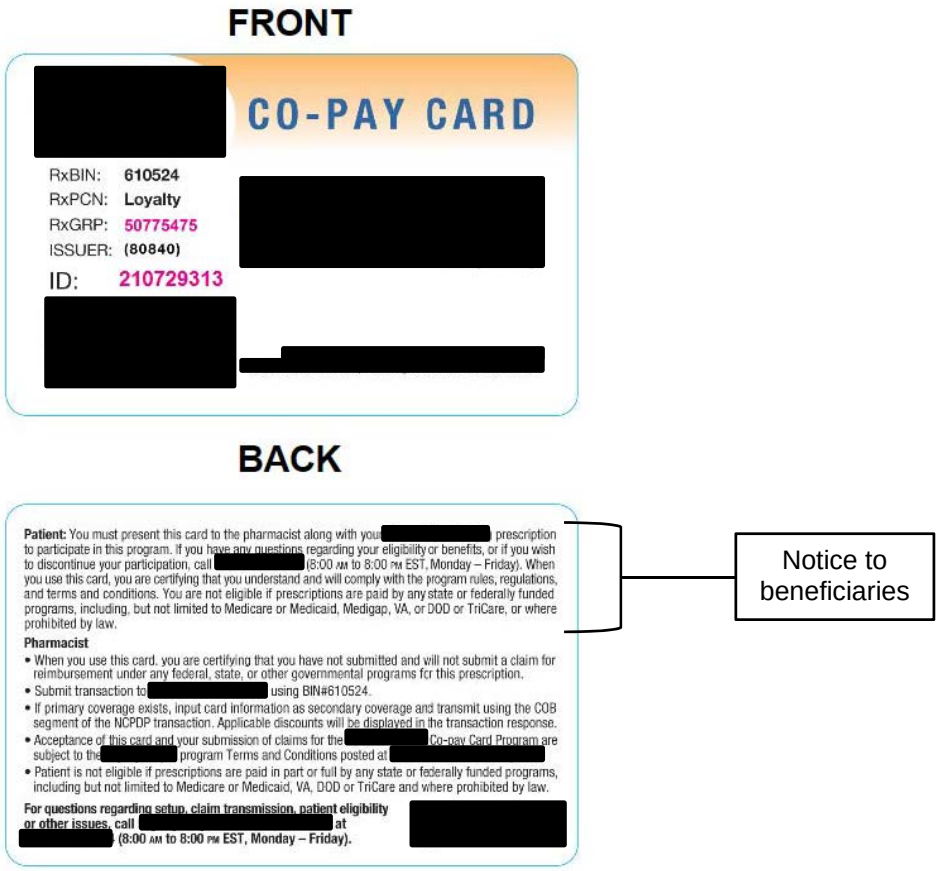
Notices Directed to Beneficiaries. Manufacturers' notices directed to beneficiaries are typically printed on coupons or on materials associated with coupons, such as coupon brochures, Web sites, or advertisements. Notices also can be triggered by eligibility questions asked online or over the telephone. Eligibility questions may ask patients: "Do you purchase your prescription medication through Medicare, Medicaid, or a similar Federal or State prescription drug program?" If patients indicate that they are enrolled in Federal health care programs, these manufacturers notify them that they are not eligible to access the coupon.

OIG's review of 40 coupons offered by surveyed manufacturers found results similar to the survey responses. Nearly all of the coupons OIG obtained had a notice printed on them, and 80 percent had a notice printed on the coupon Web site. Further, 75 percent had an eligibility question online or over the phone. However, only 3 percent had a tracking mechanism on their Web sites to prevent a patient from changing his or her answer to the eligibility question to obtain the coupon.

[28] Notices to pharmacists do not pertain to direct reimbursements because direct reimbursements are not adjudicated by the pharmacy.

Manufacturers' notices to beneficiaries are typically printed in small font. In some instances, notices are printed on the back of a coupon. See Figure 2 for an example of a coupon with a notice printed in small font on the back. This coupon is approximately the size of a credit card.

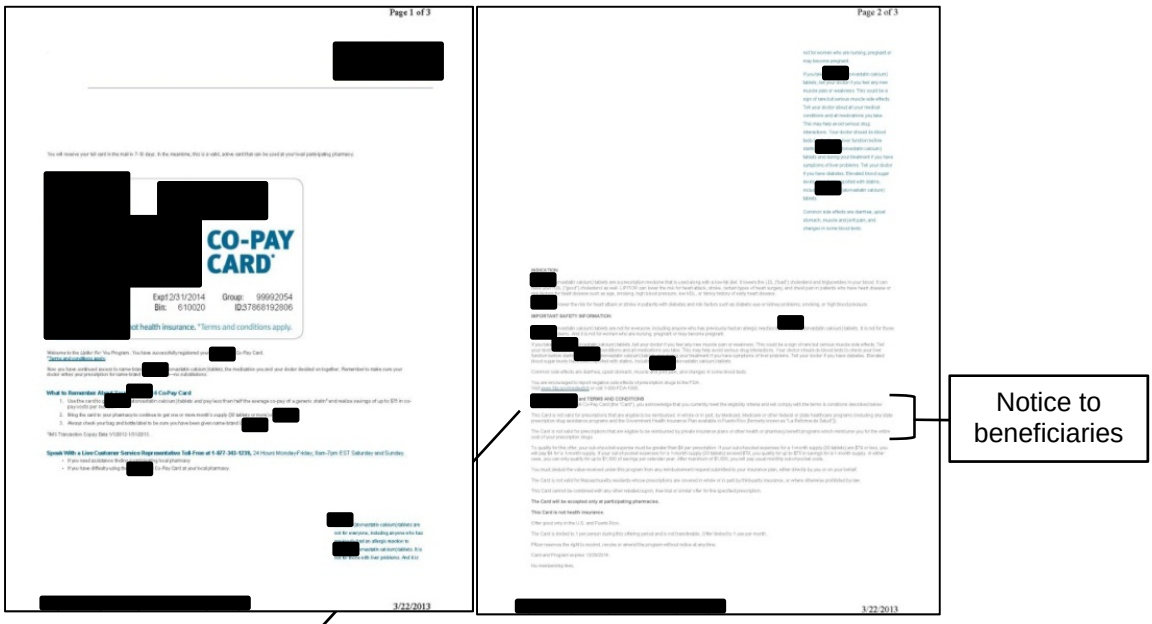
Figure 2: Example of a Coupon With a Notice Printed in Small Font on Back of Coupon



Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

In some instances, notices to beneficiaries, particularly those downloaded and printed from the Internet, are on pages following the coupons and not on the coupons themselves. See Figure 3 for an example of a coupon and a notice on the following page. The actual size of each page below is 8½ by 11 inches.

Figure 3: Example of a Coupon With a Notice Printed on Following Page



[redacted] Co-Pay Card TERMS AND CONDITIONS

By using the [redacted] Co-Pay Card (the "Card"), you acknowledge that you currently meet the eligibility criteria and will comply with the terms & conditions described below:

This Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]).

The Card is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs which reimburse you for the entire cost of your prescription drugs.

Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

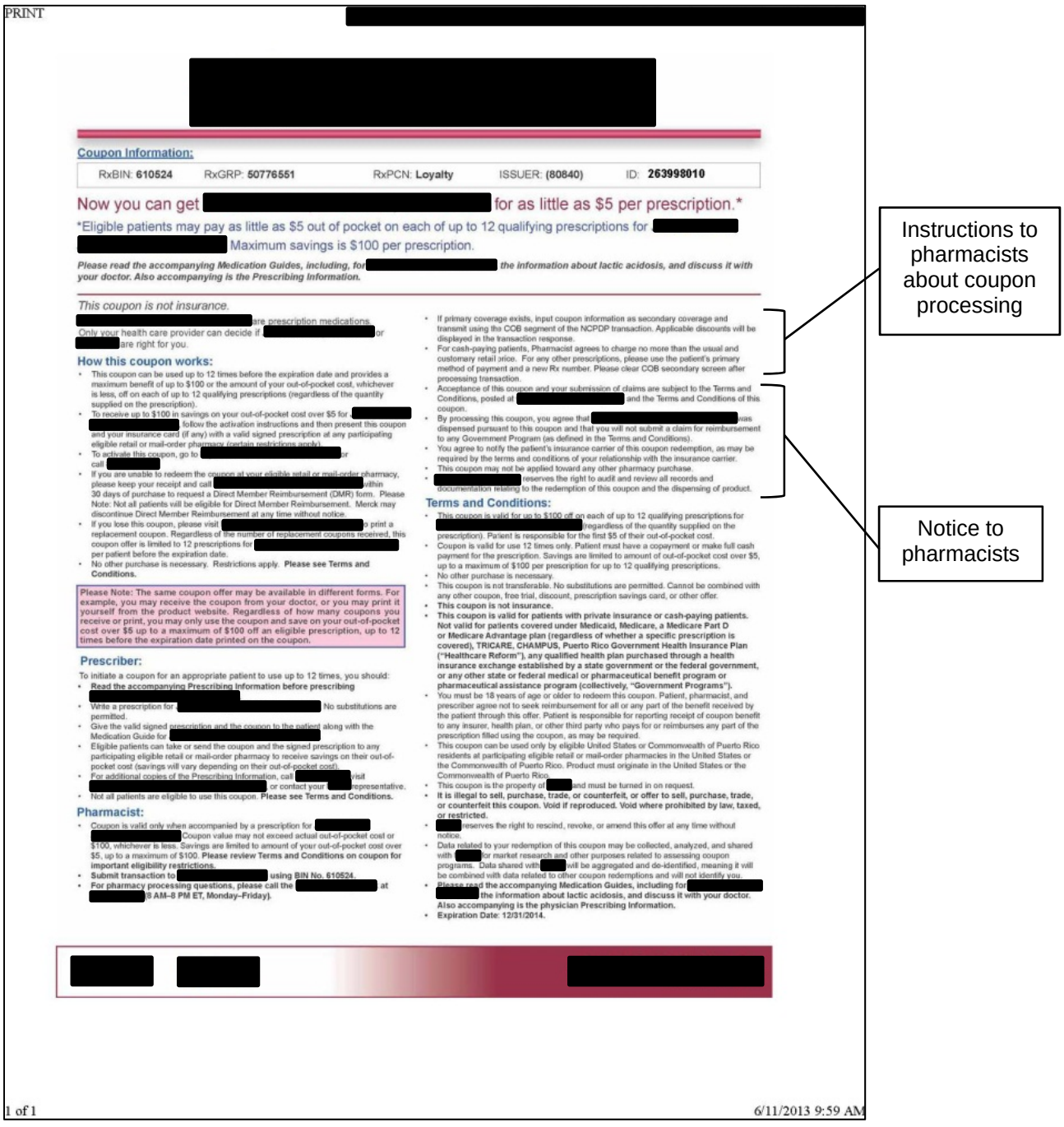
Notices Directed to Pharmacists. Two-thirds of manufacturers surveyed report providing notices to pharmacists for at least one of the coupon formats they offer. See Table 2, on page 9, for the percentage of survey manufacturers that report using notices to pharmacists broken out by coupon format.

Manufacturers' notices to pharmacists typically include reminders to pharmacists not to accept coupons for drugs paid for by Federal health care programs. These notices may include statements such as "Do not process coupon if Government beneficiary." Or, they may include more specific language, such as "Pharmacist: When you use this card, you are certifying that you have not submitted and will not submit a claim for reimbursement under any Federal, State, or other Governmental programs for this prescription." Notices to pharmacists can be printed on coupons or on associated materials. They also may appear as alerts to pharmacists through the pharmacy claims transaction system.

OIG's review of the 40 coupons obtained found that slightly more than half, or 58 percent, of coupons we reviewed had notices with specific language directed to pharmacists.

Manufacturers' notices to pharmacists, in some instances, are printed in small font among other types of information, such as instructions on how to process the coupon. See Figure 4 for an example of a coupon with a notice printed among instructions to pharmacists. The actual size of the coupon below is 8½ by 11 inches.

Figure 4: Example of a Coupon With a Notice Printed Among Instructions to Pharmacists



Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

Additionally, manufacturers' notices may be sent through alert messages within the pharmacy claims transaction system. Studies show that pharmacists may experience "alert fatigue" because of the high volume of drug alert notices that appear through the pharmacy claims transaction system.[29] A notice to check enrollment status in Federal health care programs may be one of the many notices that pharmacists receive.

Manufacturers' notices to beneficiaries and pharmacists only communicate information stipulating the terms and conditions of copayment coupons. These notices cannot necessarily stop coupons from being processed to purchase drugs paid for by Federal health care programs.

Most surveyed manufacturers use pharmacy claims edits to prevent copayment coupons from being processed for drugs paid for by Part D

Most surveyed manufacturers report having edits in the pharmacy claims transaction system to prevent the use of copayment coupons for drugs paid for by Part D. Twenty-eight of thirty manufacturers surveyed use claims processing edits for at least one of the coupon formats they offer. Of these manufacturers, 13 offered specific information about their edits. More of these manufacturers report using edits for print coupons than for other coupon formats. See Table 3 for information about a breakdown of these edits by coupon formats offered.

Table 3: Claims Processing Edits by Coupon Format

Edit	Print n = 27	Electronic n = 22	Debit Card n = 9	Direct Reimbursement n = 16	Any Format n = 30
Primary Insurance Information	7 (26%)	3 (14%)	1 (11%)	2 (13%)	9 (30%)
Benefit Stage Information	5 (19%)	3 (14%)	0 (0%)	1 (6%)	6 (20%)
Patient Date of Birth	4 (15%)	1 (5%)	0 (0%)	0 (0%)	5 (17%)

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

All of the manufacturers that offered specific information about their claims processing edits use proxies to approximate Part D coverage. The data these manufacturers' edits use as proxies are routinely transmitted on pharmacy claims and include information about a patient's primary insurance, Part D benefit stage, and date of birth. Manufacturers rely on proxies to approximate Part D coverage because they lack access to Part D enrollment status. CMS indicated that Part D enrollment data are not

[29] John R. Horn and Philip D. Hantse, "Making Computerized Screening Work for You," *Pharmacy Times*, February 2006, p. 26.

available to manufacturers because they contain sensitive health care information.[30]

Thirty Percent of Manufacturers Use Edits Relying on Primary Insurer's BIN. These manufacturers report having a claims processing edit that uses the primary insurer's BIN for at least one of the coupon formats they offer. The primary insurer's BIN is the only information identifying a patient's primary insurance that is transmitted to manufacturers on the coupon claim. Manufacturers attempt to determine which BINs are used by insurance companies that offer Part D plans by assembling lists of BINs from previously adjudicated primary insurer pharmacy claims and other sources, such as payer sheets.[31] The edit compares the primary insurer's BIN on the coupon claim to the list of collected BINs. If the edit identifies that the primary insurer's BIN represents an insurance company that offers a Part D plan, the claims processing system may automatically stop the coupon from being processed and/or send a message to the pharmacist that the patient is not eligible to use the coupon.

Four surveyed manufacturers report using an edit that relies on the primary insurer's BIN and PCN, the secondary identifier specifying unique insurance plans offered by the same insurance company. The PCN must be obtained from the primary insurance claim because it is not transmitted on the coupon claim. These edits use the BIN and PCN in combination to determine whether the primary insurance claim is being submitted to a Part D plan or a commercial plan within the same insurance company.

Twenty Percent of Manufacturers Use Edits Relying on the Part D Benefit Stage. These manufacturers report having a claims processing edit that uses Part D benefit stage information for at least one of the coupon formats they offer. Benefit stage fields contain data only if the claim is for a Part D beneficiary. If the edit identifies data in these fields, the edit either automatically stops the coupon from being processed or sends a message to the pharmacist to reverse the claim.

Seventeen Percent of Manufacturers Use Edits Relying on Patient Date of Birth. These manufacturers report having an edit that uses the patient's date of birth for at least one of the coupon formats they offer. Manufacturers use edits relying on patient's date of birth to calculate a

[30] Because Part D enrollment status is unavailable to manufacturers, those manufacturers that did not offer specific information about their edits likely use proxies and face the same challenges outlined in this report.

[31] Payer sheets are templates created to help claims processors communicate necessary claims processing information to pharmacies, vendors, and other entities. Information on payer sheets can vary by insurance plan but generally contains the BIN.

patient's age. Manufacturers may require pharmacists to submit the patient date of birth as part of the coupon claim. If a pharmacy claim indicates that the patient is at or older than a certain threshold—typically age 62 or 65—these edits will either stop the coupon from being processed or send a message to the pharmacist to verify Part D enrollment.

Surveyed manufacturers' pharmacy claims edits may not prevent copayment coupons from being processed for drugs paid for by Part D

Pharmaceutical manufacturers' claims processing edits currently in use may not stop all coupons from being processed for drugs paid for by Part D because manufacturers cannot accurately identify a beneficiary's Part D enrollment status. Manufacturers' claims processing edits use proxies that are substitutes for but do not replicate actual enrollment information. These proxies use data that may be unreliable or cannot be obtained by all manufacturers.

Claims Processing Edits Using Primary Insurance BINs Cannot Always Accurately Identify Part D Coverage. Manufacturers' claims processing edits that use primary insurers' BINs cannot always identify Part D coverage because they may be unreliable proxies. These edits may not be reliable because they use BIN lists that are collected at a point in time and may not be accurate or current. Further, BINs may not provide the specificity needed to determine whether a patient is enrolled in a Part D plan. Coupon vendors report that the BIN indicates the insurance company but does not, in most cases, distinguish a company's Part D plan from other commercial plans the company offers. To avoid stopping coupon claims associated with commercial plans, manufacturers' BINs lists may contain only BINs known to be exclusively for insurance companies' Part D plans. For instance, one manufacturer reported that its BIN edit relies on a list of BINs dedicated to Part D plans. Thus, this manufacturer's claims processing edit would allow coupons to be processed for claims containing BINs for insurance companies that offer both Part D and commercial plans.

Claims Processing Edits Using Patient Date of Birth Cannot Identify All Part D Beneficiaries. Manufacturer claims processing edits that rely on patient date of birth cannot always approximate Part D coverage. These edits may not identify all Part D beneficiaries because not all Medicare beneficiaries fit a specific age demographic. In fact, 17 percent of Medicare beneficiaries are disabled and under age 65.[32] Additionally,

[32] Henry J. Kaiser Family Foundation, "Medicare at a Glance," November 14, 2012, http://kff.org/medicare/fact-sheet/medicare-at-a-glance-fact-sheet/. Accessed on November 27, 2013.

some individuals who are eligible for Medicare may be enrolled in commercial plans and not in Part D.

Some Claims Processing Edits Use More Accurate Proxies To Identify Part D Coverage, but Cannot Be Used by All Manufacturers. Claims processing edits that more accurately determine Part D enrollment are imperfect because these edits use information that cannot be obtained by all manufacturers. These edits rely on the more accurate proxies of BIN/PCN and benefit stage information.

While edits that rely on the primary insurer's BIN/PCN are more accurate proxies, access to this combination of information is limited. To access the BIN/PCN, a manufacturer's coupon vendor needs to have access to primary insurance claims because the PCN is not transmitted as part of the coupon claim. OIG identified one entity with such access to the BIN/PCN. This entity plays a dual role as a coupon vendor and a switching company that electronically routes claims, giving it access to the primary insurance claim containing the BIN/PCN that indicates Part D insurance.

For other manufacturers' coupon vendors to access the PCN, NCPDP would need to revise its pharmacy claims transaction standards to enable the PCN to be transmitted as part of the coupon claim. Revising the NCPDP standards is an industrywide process that typically takes years to complete and requires all involved entities to update their claims transaction systems to comply with the new standards. The current NCPDP standards were updated and released in 2009.

Edits that rely on benefit stage information also are more accurate proxies, but access to this information also is limited. Although some manufacturers report having this edit, it is unclear how they obtain benefit stage information. As cited by NCPDP guidance, only entities that report Part D beneficiaries' financial TrOOP amounts are allowed to request or receive this information, such as insurance companies that offer Part D plans.[33, 34]

Other Vulnerabilities in Claims Processing Edits Exist. In addition to the vulnerabilities associated with the proxies manufacturers use for edits, there may be implementation errors in claims processing edits. Most surveyed manufacturers have no way to verify that edits are being applied

[33] NCPDP, "NCPDP WG9 Medicare Part D Questions and Answers," Version 3.0, August 2013, p. 12. Accessed at http://www.ncpdp.org/members/wg09/NCPDP_WG9_Medicare_Part_D_FAQ_Document_v3.0.pdf on January 30, 2014.

[34] Entities that can obtain benefit stage information may include State pharmaceutical assistance programs.

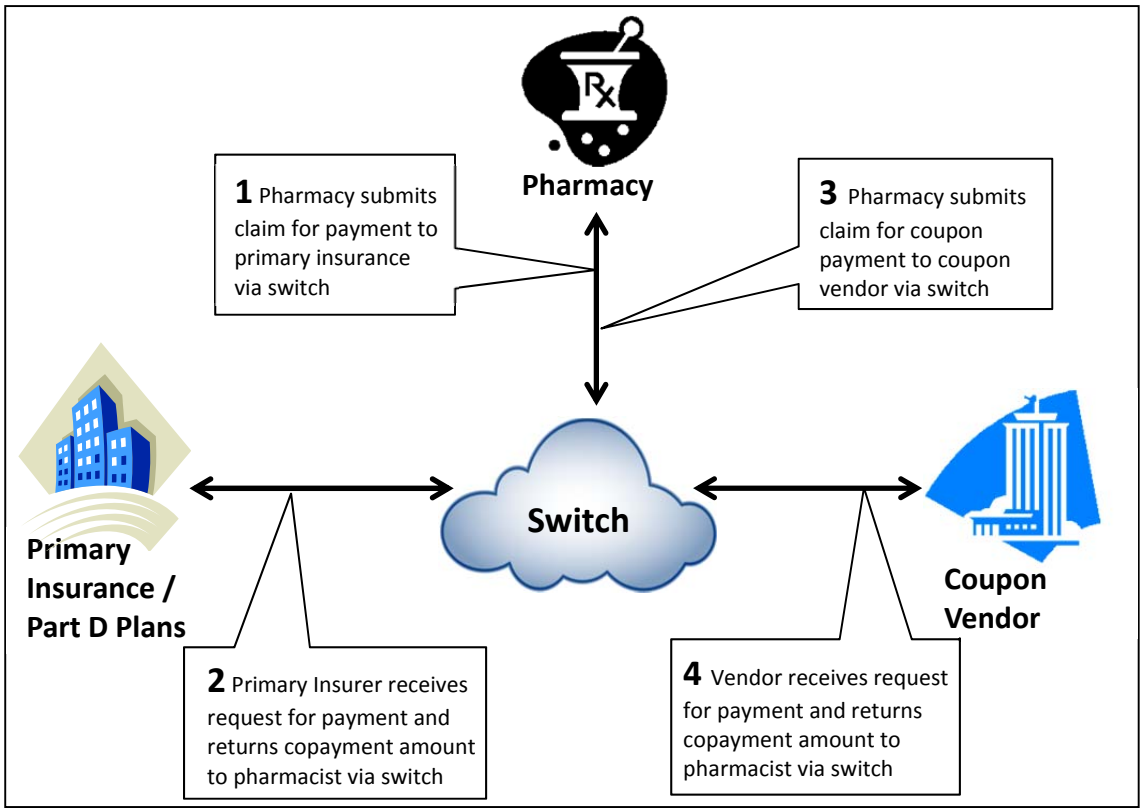
correctly because they do not audit claims processing edits. Only 30 percent of manufacturers surveyed report having auditing practices in place to analyze claims processing edits. These audits may include reviews of processes used to identify and reject claims for Part D beneficiaries or retrospective reviews that assess the number of coupons processed and rejected as a result of the edits.

Part D plans and other entities cannot identify copayment coupons within pharmacy claims

It is difficult for entities other than manufacturers to identify coupons as they are processed through the pharmacy claims transaction system or after they are adjudicated. Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers. This vulnerability impedes other entities, including Part D plans, other primary insurers, and pharmacies, from preventing the use of coupons for drugs paid for by Part D and oversight entities, like CMS and OIG, from monitoring the use of coupons.

Primary insurers, including Part D plans, cannot identify coupons as they are processed or after they are adjudicated because of the way coupons are processed. Coupons are typically processed as secondary insurance claims, after a patient's primary insurance claim, including Part D, has been processed. Because of this, Part D plans, like other primary insurers, cannot identify when a coupon is used. See Figure 5, on the next page, for an illustration of how, as a coupon claim is processed, it is not submitted to primary insurers.

Figure 5: Transmission of Information Among Payers and Entities Coordinating Coupon Claims Processing



Source: OIG analysis of interview responses, 2013.

Further, specific coupon formats may be difficult, or impossible, for pharmacists dispensing to beneficiaries on behalf of Part D plans to identify as coupon claims are processed through the pharmacy claims transaction system. When pharmacies cannot identify coupons, they do not know to attempt to verify Part D enrollment to prevent the use of coupons to purchase drugs paid for by Part D. Coupon formats that are difficult to identify include electronic coupons, debit cards, and direct reimbursements. Electronic coupons may be difficult for pharmacists to identify because they are automatically applied as prescriptions are submitted through the pharmacy claims transaction system rather than being presented by patients at the point of sale as with print coupons. Debit card coupons may be difficult to identify because patients may use them to pay their copayments without handing the card to the pharmacist. Finally, direct reimbursements cannot be identified by pharmacists because they are offered directly to patients and processed outside of the pharmacy claims transaction system.

It is also difficult to identify coupons after they are adjudicated. As previously stated, it not always possible to distinguish coupon claims from secondary insurance claims because both manufacturers and insurers use

BINs to route claims within the pharmacy claims transaction system. Manufacturers currently do not disclose the BINs associated with their coupons to outside entities. Compiling an accurate and comprehensive list of BINs that route coupon claims without manufacturer involvement would be challenging because coupons expire and BINs, while typically on print coupons, are not generally found on other coupon formats. Because BINs that route coupon claims are not distinguishable from BINs that route insurance claims, entities that conduct oversight, such as CMS and OIG, cannot analyze pharmacy claims to determine whether manufacturer safeguards to prevent the use of coupons for drugs paid for by Part D are effectively stopping the coupons.

CONCLUSION AND RECOMMENDATION

The anti-kickback statute prohibits knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a Federal health care program. Pharmaceutical manufacturers may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by Medicare Part D or any other Federal health care program.

Pharmaceutical manufacturers report that they employ safeguards directed at preventing the use of copayment coupons for drugs paid for by Part D. All surveyed manufacturers provide notices to beneficiaries and pharmacists that coupons may not be used in Federal health care programs for at least one of the coupon formats they offer. In addition, most surveyed manufacturers have implemented pharmacy claims edits to prevent coupons from being processed for drugs paid for by Part D.

However, manufacturers' edits may not reliably prevent coupons from being processed for drugs paid for by Part D. In particular, most manufacturers' claims edits only approximate Part D coverage using proxy data that may be unreliable. Additionally, the proxy data that are currently available may not be obtained by all manufacturers.

In addition to potentially implicating the anti-kickback statute, manufacturers' use of coupons to reduce the cost-sharing obligations for drugs paid for by Medicare Part D could impose costs on Part D plans, on the Part D program, and ultimately on Part D beneficiaries. While coupons provide an immediate financial benefit to beneficiaries by reducing their out-of-pocket costs, they may increase the cost of prescription drugs for Part D plans.[35] Coupons may increase costs for Part D plans because they may encourage the purchase of more expensive brand-name drugs instead of less expensive alternative treatments, such as generic drugs.

To protect themselves from excessive costs, Part D plans may have an interest in preventing the use of coupons for drugs paid for by their plans.

[35] Manufacturers that desire to assist Federal health care program beneficiaries who cannot afford their copayments have the option of donating to independent charities that provide copayment support without regard for the particular medication a patient may be using. For OIG's guidance specifically related to such charities, see OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf, and OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf.

However, a lack of coupon transparency impedes Part D plans from distinguishing coupon claims from secondary insurance claims as they are processed. Because entities other than manufacturers cannot identify coupons within pharmacy claims, Part D plans cannot implement their own edits to stop coupon claims as they are processed.

Concurrently with the issuance of this report, OIG is issuing a Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons. This document affirms that the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that sponsor copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.

Improving the reliability of pharmacy claims edits and making coupons transparent within pharmacy claims will likely require the coordination and cooperation of multiple stakeholders within the pharmacy claims transaction process, including CMS. For this reason, pharmaceutical manufacturers may engage industry stakeholders, including CMS, in an effort to identify a solution to ensure that coupons are not used for drugs paid for by Part D.

We recommend that CMS:

Cooperate with industry stakeholder efforts to identify a solution to prevent coupons from being used to purchase drugs paid for by Part D

As the oversight entity of the Part D program and the custodian of Part D enrollment data, CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claims edits and make coupons transparent. For example, CMS could consider all options to facilitate verification of Part D enrollment status before a coupon is processed. Or CMS could explore the possibility of making any feasible changes to the Part D program to facilitate Part D enrollment verification. Additionally, CMS could explore with all involved entities how best to make coupons universally identifiable and transparent in pharmacy claims transactions.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS specifically noted that it concurs with our recommendation to work with relevant stakeholders to improve the reliability of pharmacy claims edits that facilitate verification of Part D enrollment and to explore how best to make coupons universally identifiable and transparent in pharmacy claims data.

For the full text of CMS's comments, see Appendix B.

APPENDIX A

Discussion on Data Collection and Analysis

We collected information about pharmaceutical manufacturer safeguards directed at preventing the use of coupons for drugs paid for by Medicare Part D through a survey of manufacturers and a review of copayment coupon safeguards. We collected information about other vulnerabilities associated with coupon use from interviews with staff at organizations involved in the pharmacy claims processing system.

Drug Selection. We selected the top 100 Part D-covered brand-name drugs by cost that have copayment coupons for the study. These 100 drugs with coupons represent approximately 59 percent of all Part D drug costs.

To select the top 100 Part D-covered brand-name drugs with coupons, we first identified brand-name drugs that were paid for by Part D as of June 2012 using Prescription Drug Event (PDE) data and First DataBank data.[36, 37] Using these data, we matched the NDCs for brand-name drugs in First DataBank data to NDCs in PDE data. Because multiple NDCs exist for a single brand-name drug, we collapsed brand-name drugs by the HICL_SEQNO identifier.[38] Next, we summed the total cost for each drug in PDE data by the HICL_SEQNO and the brand name. We then ranked each drug by its total cost.

Next, we compiled a list of 520 coupons from www.internetdrugcoupons.com as of December 2012. Internet Drug Coupons publishes a list of pharmaceutical manufacturer coupons and is recognized by the industry as a reliable listing for coupons.

Finally, we matched the list of coupons to the list of the Part D-covered brand-name drugs. We selected the first 100 Part D-covered brand-name drugs—ranked by total drug cost—with coupons. Because coupons are offered by drug and generally are not unique by package size, dosage form, or route of administration, we matched the common brand name for the drugs associated with these coupons to the brand names and the HICL_SEQNO identifiers in First DataBank.

[36] The PDE data represent each purchase of a Part D drug by a beneficiary and contain the National Drug Code (NDC), a universal identifier that specifies the pharmaceutical manufacturer, drug name, dosage form, strength, and package size.

[37] First DataBank data provide product information, including drug name, standard therapeutic class, and whether the drug is a brand-name drug or a generic drug.

[38] The HICL_SEQNO identifies a drug's unique combination of active ingredients, irrespective of the package size, dosage form, route of administration, or strength.

Survey of Pharmaceutical Manufacturers. In May 2013, we conducted an online survey of the 34 pharmaceutical manufacturers of the top 100 Part D-covered brand-name drugs with copayment coupons.

We identified these manufacturers through information on the coupons and Internet searches. We also asked manufacturers to verify this information. We made one followup attempt by email. We received 30 complete surveys, an 88-percent response rate.

The survey asked manufacturers to provide responses about the safeguards in place for the coupons they offer. We asked manufacturers to report the coupon formats they offer and distribution methods through which patients obtain coupons. We also asked manufacturers about the types of safeguards they have in place for each coupon format they offer. We asked them questions about coupon safeguards directed to Part D beneficiaries, safeguards directed to pharmacists, and safeguards within the pharmacy claims transaction system. We did not ask manufacturers to specify the particular safeguards in place for each of the top 100 Part D-covered brand-name drugs.

We analyzed survey responses to identify specific manufacturer safeguards and determine the extent to which manufacturers surveyed had safeguards in place. For each type of safeguard identified, we calculated the number of manufacturers using the safeguard for at least one of their coupon formats. We also calculated the number of manufacturers with each safeguard by coupon format.

OIG Review of Coupon Safeguards. We reviewed copayment coupon safeguards for a subset of the top 100 Part D-covered brand-name drugs with coupons to determine whether safeguards directed to beneficiaries and pharmacies existed. OIG attempted to obtain 50 coupons, and we reviewed safeguards for the 40 coupons that we obtained. The coupons we attempted to obtain were associated with 24 manufacturers, all of which were included in the population of manufacturers that OIG surveyed. We reviewed coupon safeguards that manufacturers had in place from February to June 2013.

We reviewed and determined the extent to which manufacturers had safeguards directed to beneficiaries on the Internet, over the telephone, and on the print coupons. For safeguards on the Internet and over the telephone, we determined whether: (1) there was a notice about coupon use in Federal health care programs and (2) the notice was triggered by an eligibility question for Part D coverage. For safeguards on the coupons, we determined whether there was a notice directed to beneficiaries about coupon use in Federal health care programs. For each of these safeguards,

we calculated the number of manufacturers using it and identified vulnerabilities.

We reviewed and determined the extent to which manufacturers had safeguards directed to pharmacists on the coupons. For these safeguards, we determined whether: (1) there was a general notice on the coupons about coupon use in Federal health care programs and (2) there was a specific notice on the coupons that pharmacists will not submit a claim to a Federal health care program for the prescription with the coupons. We considered a general notice to be any other language directed to pharmacists stating that Federal health care beneficiaries are ineligible to use coupons. We considered a specific notice to be any language that indicates the pharmacist agrees or certifies that he or she will not submit a claim for reimbursement under any Federal health care program or certifies that the patient is not enrolled in any Federal health care program. For each of these safeguards, we calculated the number of manufacturers using the safeguard and identified vulnerabilities.

As part of our review, we attempted to obtain the coupons for which we reviewed safeguards. For coupons available online, we attempted to download coupons and obtained 40 of them. For coupons available over the telephone, we attempted to receive coupons through the mail but obtained none of them.

Structured Interviews. We conducted structured interviews with staff at organizations involved in the pharmacy claims transaction process, including pharmacists, coupon vendors, a switching company, and NCPDP, regarding their experience processing pharmacy claims and coupon claims. We conducted these interviews from February to August 2013.

We reviewed structured interview responses to understand other vulnerabilities associated with coupon use. In particular, we discussed the pharmacy claims transaction system and the extent to which coupons are identifiable within it. We also reviewed interview responses to identify vulnerabilities in current safeguards.

APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 30 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs" (OEI-05-12-00540)

The Centers for Medicare & Medicaid Services (CMS) appreciate the opportunity to provide comments on the above mentioned draft report. This draft report assesses the vulnerability of the Part D program to the use of manufacturer's copayment coupons. We are also concerned about the appropriate use of manufacturer's copayment coupons and agree with the OIG that the use of manufacturer's coupons to reduce cost-sharing obligations for drugs paid for by Medicare Part D could impose costs on Part D plans, the Part D program, and ultimately Part D beneficiaries.

OIG Recommendation

The CMS should cooperate with industry stakeholder efforts to identify a solution to prevent coupons from being used to purchase drugs paid for by Part D.

Specifically, the OIG noted that CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claim edits, including considering all options and any feasible changes to the Part D program, to facilitate verification of Part D enrollment status before a coupon is processed. The OIG also suggested that CMS could explore with all involved entities how best to make coupons universally identifiable and transparent in pharmacy claims transactions.

CMS Response

The CMS concurs with the recommendation to work with all relevant stakeholders to find a meaningful solution to prevent inappropriate use of manufacturers' copayment coupons for drugs paid for by Part D. CMS concurs with OIG's suggested recommendation to work with relevant stakeholders to improve the reliability of pharmacy claim edits that facilitate verification of Part D enrollment and to explore how best to make coupons universally identifiable and transparent in pharmacy claims data.

Thank you for the opportunity to review and comment on the draft OIG report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Laura Kordish, Deputy Regional Inspector General.

Melissa Baker served as the team leader for this study, and Jonathan Jones served as the lead analyst. Central office staff who provided support include Clarence Arnold and Meghan Kearns.

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