

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CMS'S IMPLEMENTATION OF A 2014
POLICY CHANGE RESULTED IN
IMPROVEMENTS IN THE REPORTING OF
COVERAGE GAP DISCOUNTS UNDER
MEDICARE PART D**

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**January 2020
A-07-16-06067**

Office of Inspector General

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Report in Brief

Date: January 2020

Report No. A-07-16-06067

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

The Coverage Gap Discount Program (CGDP) made manufacturer discounts equal to 50 percent of the negotiated price of applicable, covered Part D drugs available to Medicare Part D beneficiaries during calendar years (CYs) 2011 through 2018. During CYs 2013 and 2014, Coverage Gap discounts totaled more than \$4.5 billion and \$4.7 billion, respectively.

The size and complexity of the CGDP make the accuracy of the data it uses of paramount importance. If the Centers for Medicare & Medicaid Services (CMS) has not identified all Prescription Drug Event (PDE) records for which Coverage Gap discounts should have been invoiced, Medicare Part D beneficiaries may overpay for their prescription drugs at the point of sale.

Our objective was to determine whether CMS ensured that Medicare Part D sponsors accurately reported all Coverage Gap discounts.

How OIG Did This Audit

We reviewed the Food and Drug Administration's (FDA's) Comprehensive National Drug Code Structured Product Labeling Data Elements file (NSDE file) to identify applicable Part D drugs. Using these applicable drugs, we examined the PDE data for CYs 2013 and 2014 to identify potentially missed Coverage Gap discounts that should have been reported.

CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D

What OIG Found

Although CMS generally ensured that Part D sponsors accurately reported Coverage Gap discounts, we identified instances in which sponsors should have reported these discounts but did not. Specifically, for CYs 2013 and 2014, we identified \$1.1 million in Coverage Gap discounts that should have been invoiced to manufacturers but were not because the discounts were not reflected in the PDE records submitted by sponsors. This amount reflects (1) PDE records associated with drugs that, as Part D sponsors validated, should have had—but did not have—Coverage Gap discounts totaling \$658,396 and (2) PDE records with an estimated \$406,755 in missed Coverage Gap discounts that were still being reviewed by sponsors. With respect to the PDE records associated with the \$658,396 amount, Part D beneficiaries overpaid for their prescription drugs by \$363,287 at the point of sale.

These discrepancies occurred because CMS did not always have the sponsor information it needed. For that reason, CMS was not always able to accurately, and in a timely manner, identify beneficiaries who were in the Coverage Gap. Effective January 1, 2014, CMS began to calculate Coverage Gap discounts for all Employer Group Waiver Plans (EGWPs) using the Defined Standard benefit. (An EGWP is a group Medicare Part D prescription drug plan option that is offered to retirees who receive prescription drug coverage as part of their post-employment benefit package.) This policy change enabled CMS to more easily identify PDEs that should have reflected Coverage Gap discounts. After implementation of the policy change, EGWPs more accurately reported Coverage Gap discounts.

What OIG Recommends and CMS Comments

We recommend that CMS (1) verify that Part D sponsors adjusted PDE records for \$658,396 in validated Coverage Gap discounts and, of this amount, instruct the sponsors to remit \$363,287 to the beneficiaries; and (2) research the remaining records for which we estimated missed Coverage Gap discounts totaling \$406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to the beneficiaries.

CMS concurred with our recommendations and described the actions that it had taken or planned to take to address them.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Medicare Part D Coverage Gap Discount Program (CGDP) was enacted into law as part of the Patient Protection and Affordable Care Act (ACA)¹ to reduce the out-of-pocket expenses for prescription drugs that Part D beneficiaries pay when they are in the Coverage Gap (commonly referred to as the donut hole). In general, for calendar years (CYs) 2011 through 2018, the discount on an applicable, covered Part D drug (for a beneficiary who was in the Coverage Gap) was 50 percent of the drug cost.² During CYs 2013 and 2014, Coverage Gap discounts paid by drug manufacturers totaled more than \$4.5 billion and \$4.7 billion, respectively.³

The size and complexity of the CGDP make the accuracy of the data it uses of paramount importance. If the Centers for Medicare & Medicaid Services (CMS) has not identified all Prescription Drug Event (PDE) records for which Coverage Gap discounts should have been invoiced, Medicare Part D beneficiaries may overpay for their prescription drugs at the point of sale.

OBJECTIVE

Our objective was to determine whether CMS ensured that Medicare Part D sponsors accurately reported all Coverage Gap discounts.

BACKGROUND

Medicare Part D Prescription Drug Coverage

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Act by establishing the Medicare Part D prescription drug benefit.⁴ Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage. CMS, which administers Medicare, contracts with private prescription drug plans (PDPs) and Medicare Advantage plans (collectively known as “sponsors”) to offer prescription drug benefits to eligible individuals.

¹ P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively referred to as “ACA.”

² Under the provisions of the Social Security Act (the Act) § 1860D-2(d)(1)(A) [42 U.S.C. 1395w-102], sponsors negotiate drug prices with manufacturers.

³ 2016 HHS [U.S. Department of Health and Human Services] *Budget in Brief*, page 64 (2014 data), and 2015 HHS *Budget in Brief*, page 58 (2013 data).

⁴ P.L. No. 108-173 § 101, the Act § 1860D-1(a), 42 U.S.C. § 1395w-101(a).

Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit PDE data, including drug cost and payment information, to CMS.

Reporting of Marketing Categories

Drug manufacturers are required to submit drug listing information, which includes a drug's National Drug Code (NDC)⁵ and marketing category, to the Food and Drug Administration (FDA).⁶ Marketing category and other drug listing information is included on FDA's NDC Structured Product Labeling Data Elements file (NSDE file), which is publicly available. For purposes of the CGDP, applicable Part D drugs are those that have NDCs on the NSDE file with a marketing category of New Drug Application (NDA), NDA Authorized Generic, or Biologic License Application (BLA).^{7, 8}

Medicare Part D Coverage Gap Discount Program

Part D beneficiaries who have met their deductible and exceeded the initial coverage limit in a CY are said to have entered the Coverage Gap for that year. Before the implementation of the CGDP, a beneficiary was financially responsible for all drug costs once he or she had entered the Coverage Gap and until the beneficiary's true out-of-pocket (TrOOP) expenses had reached the out-of-pocket threshold.⁹

The CGDP reduces the out-of-pocket expenses that eligible beneficiaries pay once they enter the Coverage Gap for applicable, covered Part D drugs. Under the ACA, manufacturers that have signed a CGDP Agreement provide a discount on applicable drugs to applicable beneficiaries who are in the Coverage Gap.^{10, 11} The discount is applied to the portion of the

⁵ NDCs can be reported at several different levels of detail. Prescription drugs reviewed for this audit and discussed in this report use 11-digit NDCs.

⁶ The marketing category identifies applicable drugs for the CGDP.

⁷ Generic drugs are also listed on the NSDE file with a marketing category of Abbreviated New Drug Application.

⁸ For CYs 2011 through 2018, biosimilar drugs were not eligible for a Coverage Gap discount, but biologics were eligible. Both are approved under a BLA. Biologics are medical products that are produced from living organisms or that contain components of living organisms; they include a wide variety of products such as gene and cell therapies and vaccines. A biosimilar is a brand-name product with similar characteristics to those of an already existing biologic but, unlike a generic drug, is not identical to that biologic.

⁹ The out-of-pocket threshold is sometimes referred to as the catastrophic coverage threshold.

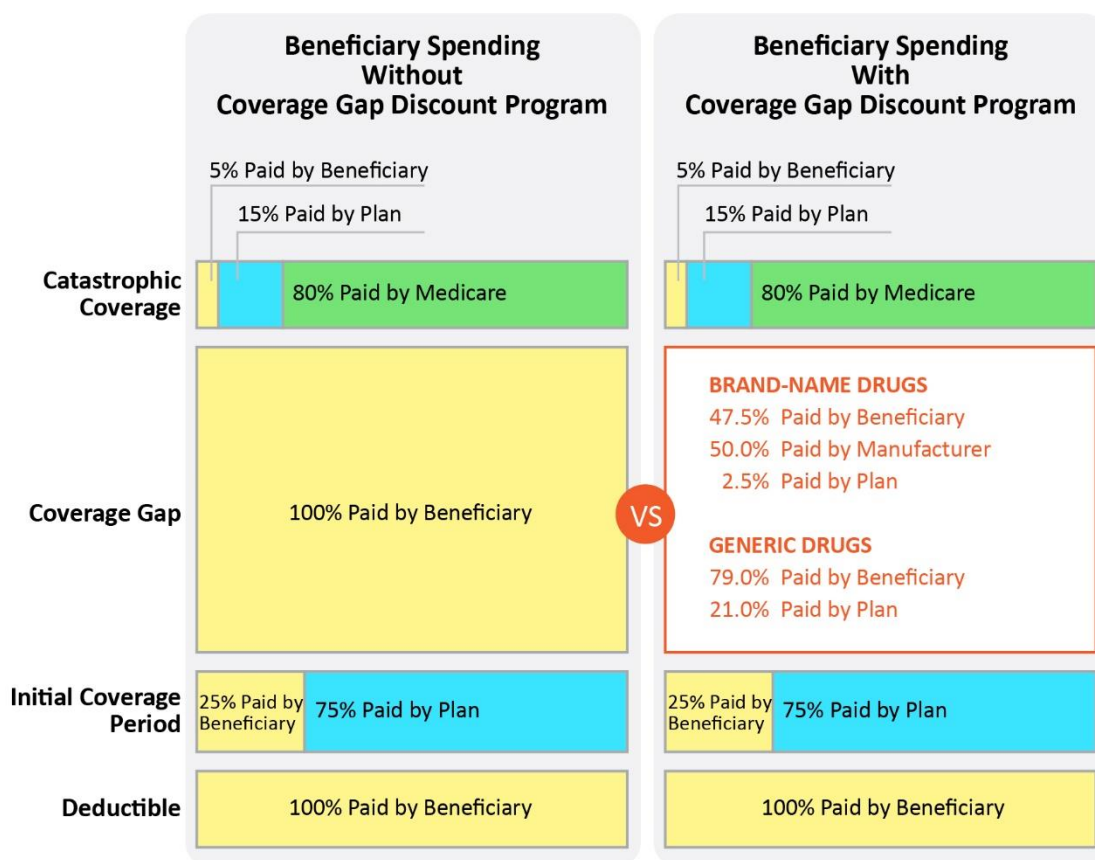
¹⁰ The term "applicable drug" means a covered Part D drug approved under an NDA or licensed under BLAs (the Act § 1860D-14A(g)(2)(A)).

¹¹ The Act § 1860D-14A [42 U.S.C. 1395w-114A]. The term "applicable beneficiary" means an individual who has entered the Coverage Gap, who is not entitled to a low-income subsidy, and is not enrolled in a qualified retiree prescription drug plan. The low-income subsidy provides for extra help with prescription drug costs for eligible beneficiaries whose income and resources are limited.

drug cost falling in the Coverage Gap and excludes supplemental benefits, dispensing fees, and vaccine administration fees.

For CY 2013, the first year of our audit period, the Part D Defined Standard benefit included a beneficiary deductible of \$325, an initial coverage limit of \$2,970 for total gross covered drug costs, and an out-of-pocket threshold of \$4,750 in TrOOP costs.¹² Thus, the Coverage Gap for that year was \$2,970 to \$4,750. Figure 1 below illustrates the components of the Part D Defined Standard benefit with information on payors' liability under two scenarios: without and with the CGDP for CY 2013. Specific coverage parameters vary by Part D plan, but the benefits must be actuarially equivalent to the Defined Standard benefit.

Figure 1: Comparison of Payors' Liability for Prescription Drugs in the Coverage Gap Under the Medicare Part D Defined Standard Benefit in CY 2013, Without and With the Medicare Coverage Gap Discount Program in Place



¹² The Medicare Part D Defined Standard benefit was included in the Act § 1860D-2 [U.S.C. 1395w-102] for CY 2006, and CMS updates the parameters for each subsequent year. Enhanced Alternative plans offer supplemental benefits that may exceed the Defined Standard benefit.

The ACA and the Bipartisan Budget Act of 2018¹³ include provisions for Medicare Part D and drug manufacturers to cover an increasing percentage of beneficiaries' costs for prescription drugs while they are in the Coverage Gap. Starting in CY 2019, beneficiaries in a Defined Standard benefit plan will pay 25 percent for all applicable, covered drugs while these beneficiaries are in the Coverage Gap.

Program Responsibilities for Sponsors, CMS, and Drug Manufacturers

Sponsors, CMS, and drug manufacturers each have responsibilities for carrying out the CGDP. See Figure 2, which depicts the CGDP payment process, later in this section.

Sponsors are the focal point of the CGDP process at the point of sale. Specifically, sponsors are responsible for calculating the Coverage Gap discount on behalf of the drug manufacturers; providing information on the amount paid by the beneficiary and total reimbursement to the pharmacy; paying the calculated discount amounts to the pharmacies (thus reducing the amounts that beneficiaries pay at the point of sale); and reporting Coverage Gap discount amounts to CMS, which, as explained below, invoices the manufacturers for the discounts.

- For the discount to be provided at the point of sale to beneficiaries, sponsors determine (1) that the drug is an applicable drug (footnote 10), (2) that the beneficiary is eligible for the discount,¹⁴ (3) that the beneficiary is wholly or partially in the Coverage Gap at the time of the pharmacy claim, and (4) the amount of the discount.
- After the beneficiary receives the discount at the point of sale, sponsors are responsible for recording the amount of the discount that the beneficiary received and for including this information on the PDE record that is ultimately reported to CMS.

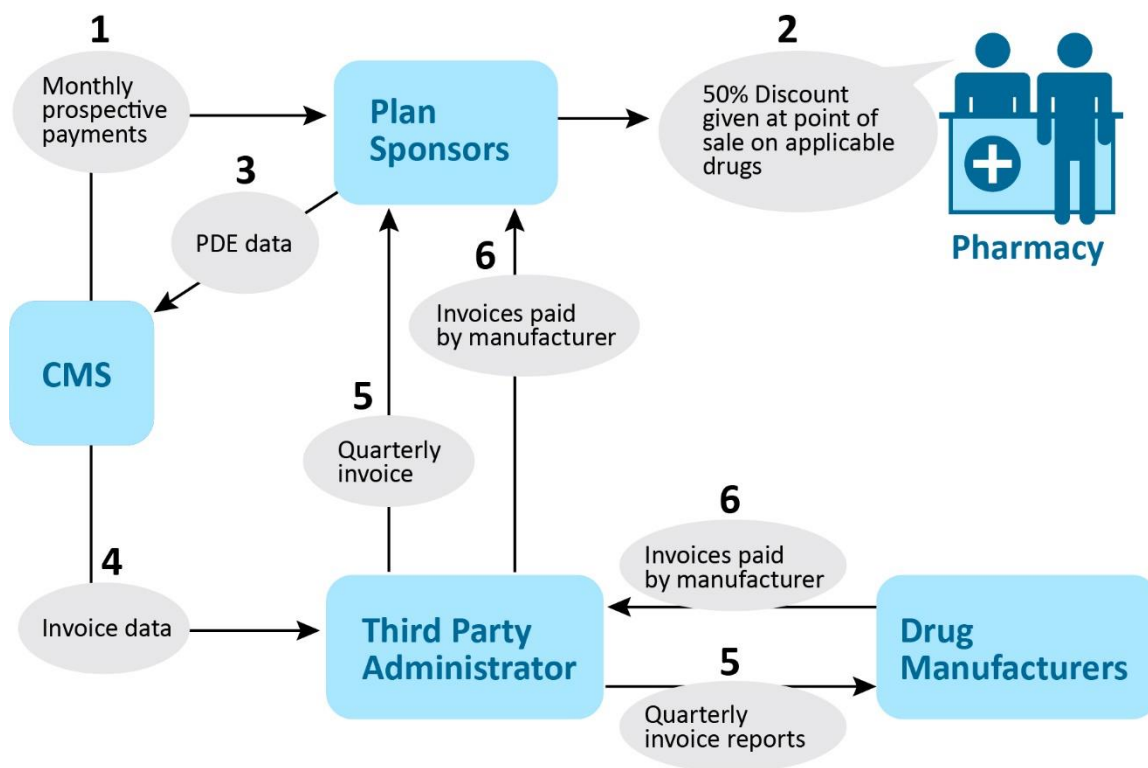
CMS is responsible for invoicing drug manufacturers for Coverage Gap discounts and for monitoring manufacturer and sponsor compliance with CGDP requirements (as stated in the drug manufacturers' agreements with CMS). CMS is also responsible for making monthly Part D prospective payments to sponsors for providing prescription drug benefits to Medicare beneficiaries, which includes payments for providing Coverage Gap discounts to beneficiaries. The prospective payments are calculated using information such as the number of non-low-income-subsidy beneficiaries. CMS is also responsible for aggregating and validating the discount amounts that sponsors have paid and reported on the PDE records. Upon aggregating the amount of the discounts that sponsors have paid at the point of sale, CMS sends this information to its third-party administrator, which invoices the manufacturers and sponsors on a quarterly basis.

¹³ The Bipartisan Budget Act of 2018, P.L. No. 115-123 (Feb. 9, 2018).

¹⁴ Beneficiaries are eligible for Coverage Gap discounts when they are (1) enrolled in a qualified prescription drug plan, (2) not entitled to an income-related subsidy under the Act § 1860D-14(a), (3) and not enrolled in a qualified retiree prescription drug plan.

Drug manufacturers are responsible for maintaining up-to-date drug listing information with FDA (as stated in their agreements with CMS) and, upon receipt of invoices from CMS’s third-party administrator, for reimbursing the sponsors by remitting to them the discounts for applicable drugs that the sponsors paid on the manufacturers’ behalf at the point of sale.

Figure 2: Illustration of the Coverage Gap Discount Program Payment Process



Employer Group Waiver Plans

An Employer Group Waiver Plan (EGWP) is a group Medicare Part D prescription drug plan option that is offered to retirees who receive prescription drug coverage as part of their post-employment benefit package. Entities that seek to offer a Part D EGWP must enter into a contract with CMS and comply with all Part D requirements unless those requirements have been specifically waived or modified. Examples of waived requirements include open-enrollment timeframes, service area restrictions, provision of information on a website (e.g., listing the current formulary or formulary changes), and provision of certain information to CMS.

Like other Part D sponsors, EGWPs are permitted to offer supplemental Part D drug coverage that is more generous than the Part D Defined Standard benefit. However, unlike other Part D sponsors, EGWPs do not submit annual bid proposals because CMS stated that such a requirement would hinder the design of, offering of, or enrollment in employer-sponsored

coverage.¹⁵ This difference is important because annual bid proposals to CMS are required to include the proposed plan benefit structure as well as information on any proposed additional supplemental Part D coverage. CMS must be able to distinguish between the Defined Standard benefit and supplemental benefits to calculate Coverage Gap discounts.

Because EGWPs do not submit bid proposals, CMS could not easily distinguish supplemental Part D coverage from non-Medicare drug coverage offered by EGWPs in CY 2013; this had the potential to affect CMS's ability to ensure that Part D sponsors had accurately reported all Coverage Gap discounts. As a result of a policy change starting in CY 2014, CMS defined any supplemental benefit offered by an EGWP as a non-Medicare benefit. This meant that Coverage Gap discounts for EGWPs are calculated based solely on the Defined Standard benefit.¹⁶

HOW WE CONDUCTED THIS AUDIT

We reviewed the NSDE file to identify applicable Medicare Part D drugs. We then examined the PDE data for CYs 2013 and 2014 to identify potentially missed Coverage Gap discounts related to these drugs that should have been reported by sponsors and invoiced to drug manufacturers. Specifically, we used the September 27, 2016, NSDE file to identify 1,659,946 PDE records for CYs 2013 and 2014 for which Coverage Gap discounts were not reported on PDE data even though the applicable Part D beneficiaries appeared to be in the Coverage Gap. We provided these records to CMS, which reviewed the records and determined that most of them did not qualify for Coverage Gap discounts. (See Appendix A.) CMS then provided the remaining 137,852 records to the applicable Part D sponsors; both CMS and the sponsors reviewed the records to determine whether Coverage Gap discounts should have been reported by sponsors and invoiced.

For the PDE records that, according to the sponsors' validation, should have included discounts, the sponsors calculated the missed Coverage Gap discount amounts as well as the effects of these missed discounts on Part D beneficiaries.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains details of our audit scope and methodology.

¹⁵ CMS, Center for Medicare; *Update on Employer Group Waiver (EGWP) Supplemental Benefits and Coverage Gap Policies for 2013 and 2014* (Jan. 25, 2013), page 5.

¹⁶ Federal regulations (42 CFR § 423.100) define "supplemental benefits" as benefits offered by Medicare Part D plans, other than employer group health or waiver plans, that meet the requirements of 42 CFR § 423.104(f)(1)(ii).

FINDINGS

Although CMS generally ensured that Part D sponsors accurately reported Coverage Gap discounts, we identified instances in which sponsors should have reported these discounts but did not. Specifically, for CYs 2013 and 2014, we identified approximately \$1.1 million¹⁷ in Coverage Gap discounts that should have been invoiced to manufacturers but were not because the discounts were not reflected in the PDE records. Of this amount, Medicare Part D beneficiaries overpaid for their prescription drugs by \$363,287 at the point of sale.

Discounts were not reflected in the PDE records because CMS did not always have the sponsor information it needed. For that reason, CMS was not always able to accurately, and in a timely manner, identify beneficiaries who were in the Coverage Gap. The unidentified Coverage Gap discounts were predominantly related to EGWPs. Because EGWPs do not submit annual bid proposals, CMS did not always have the information necessary to calculate Coverage Gap discounts for CY 2013. Effective January 1, 2014, CMS began to calculate Coverage Gap discounts for all EGWPs using the Defined Standard benefit. This policy change enabled CMS to more easily identify PDEs that should have reflected Coverage Gap discounts.

FEDERAL REQUIREMENTS AND GUIDANCE FOR COVERAGE GAP DISCOUNTS

The Act authorizes CMS to implement the CGDP and requires drug manufacturers to provide “applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer” (the Act § 1860D-14A(b)(1)(A)). The term “applicable beneficiary” means an individual who has entered the Coverage Gap, who is not entitled to a low-income subsidy, and is not enrolled in a qualified retiree prescription drug plan.

Effective January 1, 2011, the CGDP made manufacturer discounts available to applicable Medicare Part D beneficiaries receiving applicable Part D drugs while in the Coverage Gap. For CY 2013 and 2014, the discount on each applicable, covered Part D drug was 50 percent of an amount equal to the negotiated price.¹⁸

COVERAGE GAP DISCOUNTS NOT INVOICED

Although CMS generally ensured that Part D sponsors accurately reported Coverage Gap discounts, CMS did not identify all instances in which discounts should have been reported on behalf of applicable beneficiaries who were in the Coverage Gap and who were entitled to discounts. The majority of the instances of unreported Coverage Gap discounts involved EGWPs.

¹⁷ Specifically, we identified \$1,065,151 in Coverage Gap discounts.

¹⁸ The Act § 1860D-14A(g)(4)(A). Beginning after plan year 2018, the discount on each applicable drug will rise to 70 percent.

For CYs 2013 and 2014, we identified 30,926 PDE records totaling approximately \$1.1 million in Coverage Gap discounts that should have been invoiced to manufacturers but were not. These PDE records did not reflect discounts that should have been applied at the point of sale on behalf of applicable beneficiaries who were in the Coverage Gap. Of this amount, Medicare Part D beneficiaries overpaid for their prescription drugs by \$363,287 at the point of sale. These amounts and associated numbers of PDE records are broken out in the table below and in the discussion that follows.

Table: Coverage Gap Discounts That Should Have Been Invoiced but Were Not for PDE Records for Applicable Drugs on the September 27, 2016, NSDE File

Type of Audit Finding	PDE Count	Missed Discount Amount
PDE adjustments validated by sponsor		
EGWPs	27,616	\$566,727*
Non-EGWPs	947	91,669*
Subtotal	28,563	658,396
PDE adjustments pending sponsor validation		
EGWPs	2,065	379,173**
Non-EGWPs	298	27,582**
Subtotal	2,363	406,755
Total	30,926	\$1,065,151

*Medicare Part D sponsors confirmed that Coverage Gap discounts should have been reported, and they adjusted the PDE records for this amount.

**Estimated based on the Part D Defined Standard benefit.

Using the PDE data we provided, CMS reached out to Part D sponsors, which validated that 28,563 PDE records (of the 30,926) were associated with drugs that should have had—but did not have—Coverage Gap discount amounts totaling \$658,396.¹⁹

Of the 28,563 PDE records, 27,616 PDE records with Coverage Gap discounts totaling \$566,727 were submitted by EGWPs; these represented the majority of the unreported discounts. Of these, 108 PDE records (\$59,087 in Coverage Gap discounts) had dates of service in CY 2014, after CMS had updated its policy for calculating Coverage Gap discounts for EGWPs based on the Defined Standard benefit. The remaining 947 PDE records, with Coverage Gap discounts totaling \$91,669, were not submitted by EGWPs. For the 28,563 PDE records, the sponsors calculated that Medicare Part D beneficiaries paid \$363,287 more for their prescription drugs than they should have.

¹⁹ As discussed below, as of the completion of our audit work sponsors were still reviewing the other 2,363 PDE records (of the 30,926).

Following is an example of a PDE record that should have reflected a Coverage Gap discount. A Medicare Part D beneficiary with coverage through an EGWP filled a prescription on June 10, 2013, and paid \$307.63 out of pocket for a drug that had a total cost of \$389.40; the sponsor covered the remaining \$81.77. Upon reviewing this claim, the sponsor determined that a Coverage Gap discount should have been reported. The sponsor adjusted the PDE record to report a Coverage Gap discount of \$59.52 and an updated amount, which the beneficiary should have paid, of \$70.05, which meant that the beneficiary overpaid by \$237.58 (that is, \$307.63 – \$70.05) at the point of sale. The sponsor reported to CMS that it did not originally report a Coverage Gap discount because of a claim processing error in its system for which a coding modification was necessary.

An additional 2,363 PDE records were still being reviewed by sponsors. If it is determined that these PDE records should have been adjusted, we estimated that the missed Coverage Gap discounts for these records totaled \$406,755.

CMS REVISED ITS POLICY RELATED TO THE CALCULATION OF COVERAGE GAP DISCOUNTS FOR EMPLOYER GROUP WAIVER PLANS

Because EGWPs do not submit annual bid proposals, CMS did not always have the information it needed to determine which PDEs should have had Coverage Gap discounts. Effective January 1, 2014, CMS began to calculate Coverage Gap discounts for all EGWPs using the Defined Standard benefit. This policy change enabled CMS to more easily identify PDEs that should have reflected Coverage Gap discounts. After implementation of the policy change, EGWPs more accurately reported Coverage Gap discounts.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- verify that Part D sponsors adjusted PDE records for \$658,396 in validated Coverage Gap discounts and, of this amount, instruct the sponsors to remit \$363,287 to the beneficiaries who overpaid for their prescriptions at the point of sale; and
- research the remaining records for which we estimated missed Coverage Gap discounts totaling \$406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to the beneficiaries.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described the actions that it had taken or planned to take to address them. For our first recommendation, CMS stated that Part D sponsors were able to confirm that the Coverage Gap discounts should have been applied, and they adjusted the PDE records for the amounts we specified. For our second recommendation, CMS said that it has informed the Part D sponsors

that potential Coverage Gap discounts were not applied and has requested that the sponsors take appropriate actions to adjust PDE records accordingly.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, appear in their entirety as Appendix B.

OTHER MATTERS

We identified 6,471 PDE records for drugs that were classified as generic drugs at the times that they were dispensed but that, according to the September 27, 2016, NSDE file, were brand-name drugs (which refers generally to drugs that were approved by an NDA and that were applicable Part D drugs). The initial classification of these drugs as generic appeared to have been in error, and CMS was not able to explain why or how that occurred. Based on the Medicare Part D Defined Standard benefit, sponsors should have submitted PDE records with adjusted Coverage Gap discounts for these brand-name drugs. As a result, CMS (through its third-party administrator) would have invoiced for an additional \$83,136 in Coverage Gap discounts to drug manufacturers.

For example, a beneficiary filled a prescription on December 2, 2013, for NDC 00338004804 (sodium chloride), with a total cost of \$207.19. At that time, the NSDE file listed the drug as having been approved under an Abbreviated New Drug Application, which meant that it was a generic drug. As of September 27, 2016, the NSDE file listed the drug as having been approved under an NDA, which made it an applicable Part D drug. If the NSDE had correctly listed the drug as having been approved under an NDA on the date of service, a Coverage Gap discount of \$103.09 (based on the Defined Standard benefit) would have been reported on the PDE data and invoiced to the manufacturer.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the NSDE file to identify applicable Medicare Part D drugs. Using these applicable drugs, we examined the PDE data for CYs 2013 and 2014 to identify potentially missed Coverage Gap discounts that should have been reported by sponsors and invoiced to drug manufacturers.

Our audit objective did not require an understanding or assessment of the complete internal control structures of CMS, the drug manufacturers, or the sponsors. We limited our internal control audit to obtaining an understanding of the controls that CMS had in place to ensure the accuracy of the data it used to administer the CGDP and to invoice Coverage Gap discounts.

We conducted our audit from August 2016 to May 2019.

METHODOLOGY

To accomplish our objectives, we took the following steps:

- We reviewed applicable Federal laws and regulations and CMS's policies, procedures, and guidance pertaining to the CGDP.
- We held discussions with CMS officials to gain an understanding of relevant policies, procedures, and guidance regarding the CGDP.
- We used the September 27, 2016, NSDE file to:
 - identify 1,659,946 PDE records for CYs 2013 and 2014 for which Coverage Gap discounts were not reported on PDE data even though the applicable Medicare Part D beneficiaries appeared to be in the Coverage Gap and
 - estimate, based on the Part D Defined Standard benefit (footnote 12), the missed Coverage Gap discounts for the applicable Part D drugs associated with these PDE records.
- We asked CMS to review the 1,659,946 PDE records to determine whether the Coverage Gap discounts should have been submitted on PDE records by sponsors and invoiced to manufacturers.
- We evaluated the information that CMS gave us and determined that most of the 1,659,946 PDE records appropriately did not reflect Coverage Gap discounts. PDE records to which Coverage Gap discounts were not applicable included:

- PDE records associated with beneficiaries who, because they were eligible to receive low-income subsidies, did not qualify for participation in the CGDP;
 - PDE records associated with prescriptions for which beneficiaries did not pay anything out of pocket for the applicable Part D drugs;
 - PDE records associated with compound drugs, which are not eligible for Coverage Gap discounts; and
 - PDE records associated with beneficiaries for whom Medicare was the secondary payer for their prescription drug coverage.
- For the 137,852 PDE records that CMS’s initial review identified as possibly qualifying for Coverage Gap discounts, both CMS and the applicable Part D sponsors reviewed the records to determine whether Coverage Gap discounts should have been invoiced to manufacturers. This review by CMS and the sponsors identified 106,926 PDE records that did not qualify for Coverage Gap discounts, primarily because the records involved co-pay-to-co-pay straddle claims.²⁰
 - For the remaining 30,926 PDE records (of the 137,852), sponsors:
 - validated that 28,563 PDE records should have had Coverage Gap discount amounts;
 - adjusted and calculated, for each of the validated PDE records, the missed discount amounts as well as the effects of these missed discounts on Part D beneficiaries; and
 - stated that they would continue to review the remaining 2,363 PDE records.
 - We discussed our findings with, and provided detailed data on our findings to, CMS officials on December 7, 2018, and April 12, 2019.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

²⁰ CMS uses the term “co-pay-to-co-pay straddle claims” to refer to scenarios in which Part D beneficiaries have co-pays in both the initial coverage phase and the Coverage Gap. In such scenarios, the Coverage Gap discount does not apply.



APPENDIX B: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

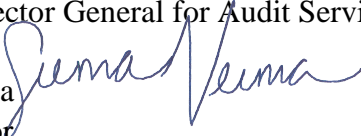
Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DATE: November 26, 2019

TO: Gloria L. Jarmon
Deputy Inspector General for Audit Services

FROM: Seema Verma 
Administrator

SUBJECT: The Office of Inspector General (OIG) Draft Report: CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D (A-07-16-06067)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on OIG's audit on Coverage Gap discounts in the Part D program. CMS is committed to ensuring Part D beneficiaries eligible for Coverage Gap discounts do not overpay for their prescription drugs.

The Coverage Gap Discount Program (CGDP) reduces beneficiaries' out of pocket expenses for Part D drugs once they enter the Coverage Gap, which is the point when Part D beneficiaries have exceeded the initial coverage limit in a calendar year. Part D sponsors, CMS, and drug manufacturers each play a role in ensuring the CGDP is effectively implemented. Sponsors are responsible for calculating the Coverage Gap discount on behalf of drug manufacturers and determining which beneficiaries are eligible for this benefit. CMS is responsible for invoicing drug manufacturers for Coverage Gap discounts based on information received from sponsors through Prescription Drug Event (PDE) records and for monitoring manufacturer and sponsor compliance with CGDP requirements. Finally, drug manufacturers are responsible for maintaining up-to-date drug listing information and for reimbursing sponsors by remitting to them the discounts for applicable drugs. It is important to note that CMS invoiced drug manufacturers correctly based on the information received from plan sponsors. The issues identified by OIG are due to plan sponsors not submitting the appropriate information to CMS via PDE records.

OIG's audit estimated that approximately \$1.1 million in Coverage Gap discounts should have been submitted on PDEs, but were not during 2013 and 2014. This represents about 0.01 percent of the \$9.3 billion submitted on PDEs for Coverage Gap discounts during these years, and virtually all of these instances were with Employer Group Waiver Plans (EGWPs). CMS notes that the OIG figure is likely an overestimate, as OIG estimated potential Coverage Gap discounts based on a defined standard benefit design and not the plans' actual benefit designs, under which a prescription could incur a lower Coverage Gap discount than under the defined standard or not fall within the Coverage Gap at all. As acknowledged by the OIG, a PDE reporting change for

EGWPs in 2014 largely addressed the issue. CMS will continue to monitor Coverage Gap discounts to ensure that beneficiaries have access to affordable Part D drugs.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

Verify that Part D sponsors adjusted PDE records for \$658,396 in validated Coverage Gap discounts, and, of this amount, instruct the sponsors to remit \$363,287 to the beneficiaries who overpaid for their prescriptions at the point of sale.

CMS Response

CMS concurs with this recommendation. As OIG notes, Part D sponsors were able to confirm that the Coverage Gap discounts should have been applied, and they adjusted the PDE records for this amount. Consistent with CMS' policies, procedures, and operations, we will instruct Part D sponsors to remit the amounts to beneficiaries.

OIG Recommendation

Research the remaining records for which we estimated missing Coverage Gap discounts totaling \$406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to the beneficiaries.

CMS Response

CMS concurs with this recommendation. CMS informed Part D sponsors that potential Coverage Gap discounts were not applied and requested sponsors take appropriate actions to adjust PDE records accordingly. Consistent with CMS' policies, procedures, and operations, CMS will continue to monitor Part D sponsors to ensure adjusted PDE records are accurately submitted and, where applicable, instruct Part D sponsors to remit amounts to beneficiaries.