Report in Brief

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

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.