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

CMS's Enhanced Controls Did Not Always Prevent Terminated Drug Utilization in Medicare Part D

Why OIG Did This Review

A 2010 OIG audit reported that in calendar years (CYs) 2006 and 2007, the Centers for Medicare & Medicaid Services (CMS) accepted prescription drug event (PDE) data totaling $112.1 million for 2,967 terminated drugs. These are discontinued drugs that have passed their shelf life or that have been withdrawn from the market.

The previous audit reported that, although terminated drugs could be weak, ineffective, or detrimental to beneficiaries' health, Federal regulations did not prohibit coverage of terminated drugs under Medicare Part D. We recommended that CMS issue regulations to prohibit Part D coverage of terminated drugs. CMS has taken steps since our previous audit to address this issue.

Our objectives for the current audit were to determine whether the steps CMS has taken to address terminated drug utilization in Medicare Part D were effective and to determine whether PDE data for terminated drugs continued to be accepted in CYs 2014 and 2015.

How OIG Did This Review

We reviewed the Food and Drug Administration's (FDA) Comprehensive National Drug Code (NDC) Structured Product Labeling Data Elements file (NSDE file) and CMS's quarterly Medicaid drug rebate files and compared the termination dates from both files to PDE data for CYs 2014 and 2015 to identify terminated drug utilization.

What OIG Found

The steps CMS has taken to address terminated drug utilization in Medicare Part D were not entirely effective and, as a result, CMS continued to accept some PDE data for terminated drugs in CYs 2014 and 2015. Although CMS has made improvements to prevent terminated drug utilization in Part D, it accepted PDE data totaling $31.9 million in gross drug costs for 3,705 terminated drugs in CYs 2014 and 2015.

After our previous audit, CMS enhanced its controls to rely on the NSDE file to identify and reject coverage of terminated drugs. However, the quarterly Medicaid drug rebate files also contain drug termination dates by NDC, and we identified in this current audit that the termination dates in those two sources often did not match. In fact, we determined that for 30 terminated drugs, the quarterly Medicaid drug rebate files often—but not always—contained more accurate data on termination dates than did the NSDE file.

CMS did not compare the information on termination dates in its quarterly Medicaid drug rebate files with the NSDE file, did not investigate the discrepancies that existed between these two data sources, and did not update its system edits in a timely manner.

What OIG Recommends and CMS Comments

We recommend that CMS continue to strengthen its internal controls to ensure that all PDE data for terminated drugs are rejected by (1) working with FDA to verify the accuracy of drug termination dates, to include comparing the information on termination dates in its two data sources, investigating discrepancies between the data sources, and verifying termination dates with the manufacturers; and by (2) updating its system edits with a new NSDE file on a more timely basis.

CMS concurred with our second recommendation but not with our first recommendation, stating that although it remains committed to strengthening its internal controls to ensure that PDE data for terminated drugs are rejected, it regards FDA as the expert authority and source for national drug code listing information. CMS added that it does not consider it appropriate or administratively feasible to investigate and address discrepancies in information between the Medicaid drug rebate files and FDA's NSDE file. We maintain that our findings and recommendations remain valid, and we continue to assert that it is CMS's responsibility to use the information in the drug rebate files to identify differences between the two data sources.

The full report can be found at https://oig.hhs.gov/oas/reports/region7/71606068.asp.