Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Gloria L. Jarmon
Deputy Inspector General
for Audit Services

November 2018
A-07-16-06068

Office of Inspector General

https://oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at https://oig.hhs.gov

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief
Date: November 2018
Report No. A-07-16-06068

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.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS REVIEW

Prescription drugs are available to eligible Medicare and Medicaid beneficiaries under both Medicare Part D and the Medicaid prescription drug program. Federal regulations require that each drug have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. Drug manufacturers report the expiration date for each drug to the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) using national drug codes (NDCs).[1] In turn, for Medicaid CMS defines a drug's termination date as the date the drug was withdrawn from the market or, if the drug is no longer distributed, the shelf life of the last lot sold. In this report, we refer to drugs whose termination dates have passed (for either of these two circumstances) as "terminated drugs."

This audit is a followup to a previous Office of Inspector General audit,[2] which reported that in calendar years (CYs) 2006 and 2007, CMS accepted prescription drug event (PDE) data totaling $112.1 million for 2,967 terminated drugs. We also reported that, although terminated drugs could be weak, ineffective, or detrimental to beneficiaries' health and although CMS has issued guidance to States to reject claims as invalid for terminated drugs under Medicaid, Federal regulations did not prohibit coverage of those drugs under Medicare Part D. We recommended that CMS issue regulations to prohibit Part D coverage of terminated drugs. CMS did not concur with our recommendation, but it has taken steps since our previous audit to address terminated drug utilization and updated its process for identifying terminated drugs in Part D.

OBJECTIVES

Our objectives 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.

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 Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit.[3] 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

[1] 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.

[2] *Review of Terminated Drugs in the Medicare Part D Program* (A-07-09-03130), Nov. 1, 2010.

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

Medicare, contracts with private prescription drug plans and Medicare Advantage plans (collectively known as "sponsors") to offer prescription drug benefits to eligible individuals. 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. These data provide the necessary detail to enable CMS to process the Part D claims through its system edits.

Medicaid Prescription Drug Coverage

In addition to offering Medicare Part D prescription drug coverage to Medicare beneficiaries, CMS oversees prescription drug coverage for eligible Medicaid beneficiaries through State Medicaid programs. Although drug coverage is an optional benefit under Federal Medicaid law, all States currently provide coverage for outpatient drugs. The State Medicaid programs include the management, development, and administration of systems and data collection necessary to participate in the Medicaid Drug Rebate Program.[4] The Medicaid program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. CMS requires manufacturers to provide it with a list of all covered outpatient drugs, including termination dates for those drugs that have been terminated. CMS then provides this information to the States in quarterly Medicaid drug rebate files, which are one of two data sources that this report will discuss for information on terminated drugs.

In a memorandum to State Medicaid directors, CMS said that States must ensure that claims submitted by pharmacists are not for drugs dispensed after their termination dates. These claims should be rejected as invalid because these drugs cannot be dispensed after they have reached their termination dates.[5]

States generally use the information on terminated drugs from the quarterly Medicaid drug rebate files in their system edits to ensure that terminated drugs are neither dispensed to Medicaid beneficiaries nor paid for by the States.

Terminated Drugs

Generally, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use (21 CFR § 211.137 (a)). The expiration date effectively establishes a shelf life for the drug. For Medicaid, CMS defines a

[4] The Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508, established the Medicaid Drug Rebate Program effective January 1, 1991. The program is set forth in section 1927 of the Act.

[5] Medicaid Drug Rebate Program Release No. 19 (May 18, 1992), page 5.

drug's termination date as the date the drug was withdrawn from the market or, if the drug is no longer distributed, the shelf life of the last lot sold.[6]

CMS Actions Regarding Terminated Drugs in Medicare Part D Since Issuance of Our Previous Report

Since our previous audit,[7] CMS has addressed terminated drug utilization and updated its process for identifying terminated drugs in Medicare Part D. On May 14, 2012, CMS issued program guidance regarding terminated drugs to all sponsors.[8] In accordance with this guidance, effective September 1, 2012, CMS began using FDA's Comprehensive NDC Structured Product Labeling Data Elements file (NSDE file) to edit PDE data. CMS's guidance added that beginning on this effective date, CMS would reject submitted PDE data for (and, therefore, not cover) drugs not listed on the NSDE file or drugs with a Marketing End Date[9] before the date the prescription is filled.[10] For purposes of this report, the NSDE file's Marketing End Date for a drug is synonymous with that drug's termination date.

The NSDE file is created from data that drug manufacturers send to FDA as part of the product listing and reporting process. This file can contain information on various products, including human prescriptions, veterinary drugs, biologic drugs, devices, dietary supplements, medical foods, and cosmetics. In relying on the NSDE file as the basis for the CY 2012 program guidance, CMS was acting consistent with its belief, as expressed in written comments on our previous audit report, that the only authoritative source of data on product expiration dates at the NDC level is data officially submitted by manufacturers to FDA—the NSDE file.

The NSDE file is one of two data sources of information on terminated drugs (the other being the quarterly Medicaid drug rebate files) that this report will discuss.

HOW WE CONDUCTED THIS REVIEW

We reviewed the NSDE file and CMS's quarterly Medicaid drug rebate files to identify terminated drugs. We compared the termination dates from both files to PDE data for

---

[6] Medicaid Drug Rebate Program Notice Release No. 157 (Jan. 6, 2011). Although this definition appears in CMS guidance for the Medicaid Drug Rebate Program, it is synonymous with the term "Marketing End Date" as used in the NSDE file.

[7] *Review of Terminated Drugs in the Medicare Part D Program* (A-07-09-03130), Nov. 1, 2010.

[8] CMS, Center for Medicare, Medicare Plan Payment Group; *Implementation starting September 1, 2012 of PDE Editing using the FDA Online Label Repository* (May 14, 2012), page 1.

[9] The "Marketing End Date," as used in the NSDE file, is the date the product will no longer be available on the market. In most cases, this is the expiration date of the last lot distributed. Drugs that are actively being marketed will not have a Marketing End Date. Drugs that are no longer manufactured may have a future Marketing End Date tied to the expiration of the last lot distributed.

[10] The date the prescription is filled correlates to the date of service in the PDE record.

CYs 2014 and 2015 to identify terminated drug utilization. In addition, we verified termination dates directly with the drug manufacturers for 30 terminated drugs.

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.

FINDINGS

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 $31,933,291 in gross drug costs for 3,705 terminated drugs in CYs 2014 and 2015.[11]

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 (as reported by drug manufacturers) often did not match. In fact, we determined through analysis and by contacting drug manufacturers directly for 30 terminated drugs that (1) the quarterly Medicaid drug rebate files often—but not always—contained more accurate data on termination dates than did the NSDE file and (2) termination dates for two-thirds of the drugs we analyzed were in the quarterly Medicaid drug rebate files earlier than they were in the NSDE file.

CMS continued to accept some PDE data for terminated drugs in CYs 2014 and 2015 because it did not compare the information on termination dates in its quarterly Medicaid drug rebate files with the information in the NSDE file to better ensure the accuracy of the termination dates that CMS used in its administration of the Part D program. Moreover, CMS did not investigate the discrepancies that existed between these two data sources with respect to termination dates.

In addition to identifying discrepancies between the two data sources, we found that CMS did not update its system edits in a timely manner. Specifically, although FDA updated the NSDE file each business day, CMS updated its system edits with the NSDE file from the 15th of each month on the first day of the following month. The NSDE file that CMS used to update its system edits was therefore always at least 2 weeks old, which meant that PDE data for

[11] Of the 3,705 terminated drugs identified in this report, 8 of these drugs had been identified as terminated in our previous audit report (A-07-09-03130).

terminated drugs could have been accepted, and the drugs paid for, during that 2-week timelag.

The Medicare Part D program continued to cover some terminated drugs that were dispensed to beneficiaries. Those medications could have been weak, ineffective, or detrimental to beneficiaries' health.

FEDERAL REQUIREMENTS AND GUIDANCE RELATED TO TERMINATED DRUGS

Federal regulations say that Medicare Part D sponsors must have established quality assurance measures, including obtaining "[r]epresentation that network providers are required to comply with minimum standards for pharmacy practice as established by the States" (42 CFR § 423.153(c)(1)). Statutes and regulations governing State pharmacy practices generally prohibit or limit dispensing drugs after their expiration dates.

Each drug must have an expiration date to ensure that the drug meets certain standards, including for strength and quality, at the time of its use (21 CFR § 211.137 (a)). The expiration date effectively establishes a shelf life for the drug. For Medicaid, CMS defines a drug's termination date as the date the drug was withdrawn from the market or, if the drug is no longer distributed, the shelf life of the last lot sold.[12] This definition is essentially synonymous with FDA's definition of Marketing End Date.[13]

In a memorandum to Medicare Part D sponsors,[14] CMS stated that effective September 1, 2012, it would begin to use FDA's NSDE file to edit PDE data. Specifically, CMS stated that it would reject any submitted PDE data that meets all of the following conditions:

- a drug coverage status code of "C" (which signifies that the drug is covered under Part D),

- dates of service on or after September 1, 2012, and

[12] Medicaid Drug Rebate Program Notice Release No. 157 (Jan. 6, 2011). Although this definition appears in CMS guidance for the Medicaid Drug Rebate Program, it is synonymous with the term "Marketing End Date" as used in the NSDE file.

[13] The "Marketing End Date," as used in the NSDE file, is the date the product will no longer be available on the market. In most cases, this is the expiration date of the last lot distributed. Drugs that are actively being marketed will not have a Marketing End Date. Drugs that are no longer manufactured may have a future Marketing End Date tied to the expiration of the last lot distributed.

[14] CMS, Center for Medicare, Medicare Plan Payment Group; *Implementation starting September 1, 2012 of PDE Editing using the FDA Online Label Repository* (May 14, 2012), page 1.

- NDC not listed in the NSDE file or NDC listed in NSDE file with a Marketing End Date before the date of service.[15]

CMS ACCEPTED SOME PRESCRIPTION DRUG EVENT DATA FOR TERMINATED DRUGS

CMS Accepted Prescription Drug Event Data for Drugs Identified as Terminated in Either of the Two Data Sources

CMS has made improvements to prevent terminated drug utilization in Medicare Part D. However, according to information that appeared in either the NSDE file or the quarterly Medicaid drug rebate files, CMS accepted PDE data totaling $31,933,291 in gross drug costs for 3,705 terminated drugs for CYs 2014 and 2015.

For each of these data sources, we compared the termination dates to the dates on which CMS accepted the corresponding PDE data and identified:

- $22,564,231 in accepted PDE data for 2,752 drugs that were listed as terminated in only the quarterly Medicaid drug rebate files,

- $5,280,114 in accepted PDE data for 474 drugs that were listed as terminated in only the NSDE file, and

- $4,088,946 in accepted PDE data for 479 drugs that were listed as terminated in both the quarterly Medicaid drug rebate files and the NSDE file.

Vulnerabilities in CMS's Process for Updating Its System Edits To Identify and Reject Coverage of Terminated Drugs in the Medicare Part D Program

Although CMS had information on termination dates from its Medicaid drug rebate files, it relied solely on the NSDE file to identify and reject coverage of Part D claims for terminated drugs. If CMS had compared the two information sources, it would have seen that the termination dates in these two sources were not always the same. Additionally, CMS did not update its system edits in a timely manner.

Quarterly Medicaid Drug Rebate Files Not Used To Verify Termination Dates Reported by Manufacturers

Although CMS maintained the quarterly Medicaid drug rebate files and provided them to the States to assist them in administering their Medicaid prescription drug programs, it did not use

[15] The "Marketing End Date," as used in the NSDE file, is the date the product will no longer be available on the market. In most cases, this is the expiration date of the last lot distributed. Drugs that are actively being marketed will not have a Marketing End Date. Drugs that are no longer manufactured may have a future Marketing End Date tied to the expiration of the last lot distributed.

the information in this data source to verify that manufacturers had accurately reported termination dates. CMS did not compare the information on termination dates in its quarterly Medicaid drug rebate files to the information in the NSDE file. And according to CMS officials, CMS also did not investigate discrepancies between its quarterly Medicaid drug rebate files and the NSDE file, including discrepancies in termination dates. A thorough comparison of information on termination dates in these two data sources and an investigation of identified discrepancies would have allowed CMS to identify, as we did, $22,564,231 in PDE data that it had accepted for 2,752 drugs that were listed as terminated in the quarterly Medicaid drug rebate files but not in the NSDE file.

A process for the routine comparison of information from both data sources, combined with a process to investigate discrepancies in termination dates, would have helped ensure that all terminated drugs were identified and then removed from coverage under Medicare Part D.

System Edits Not Updated in a Timely Manner

Although FDA updated the NSDE file each business day, CMS uploaded a new NSDE file into its system edits monthly. CMS used the NSDE file that FDA created on the 15th of each month to update its system edits on the first day of the following month. By updating its own data only once a month and using an NSDE file that was at least 2 weeks old, CMS created the possibility that PDE data for terminated drugs could be accepted, and the drugs paid for under Medicare Part D, during the timelag between CMS's receipt of the NSDE file and its use of that file to update its system edits.

Example of Part D Payments Made for One Terminated Drug Whose Termination Date Was Properly Reported on the Medicaid Drug Rebate File

The figure on the following page and the bullets below show the timelines and effects of these vulnerabilities for one specific terminated drug:

- The drug's termination date of October 31, 2013, was first published on the quarterly Medicaid drug rebate file for the fourth quarter of CY 2013. That date was not reported on the NSDE file until more than 1 year later (February 15, 2015).

- Under CMS's current process, the October 31, 2013, termination date did not appear in its system edits until March 1, 2015 (the first day of the month following the date on which that termination date first appeared on the NSDE file).

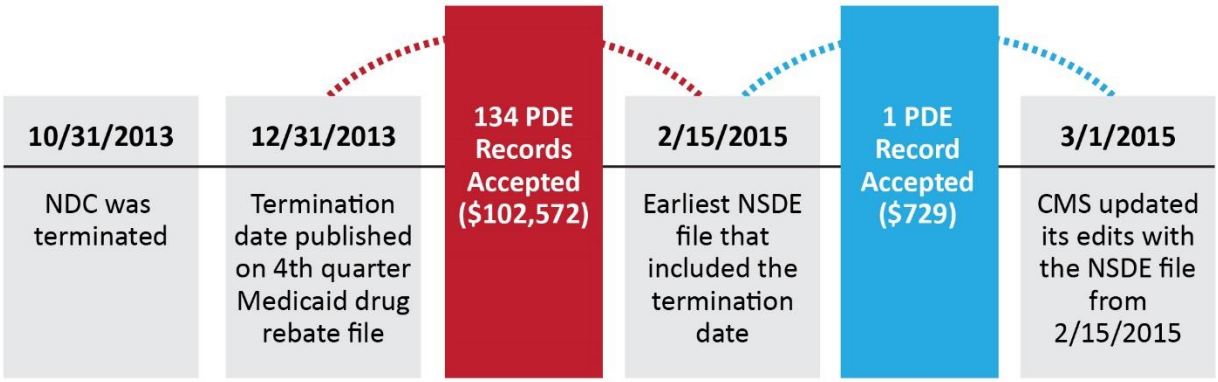
- Consequently, CMS accepted a PDE record with a date of service of February 20, 2015, for this terminated drug.

Of particular note in this example is that versions of the NSDE file published before February 15, 2015, did not include this drug's October 31, 2013, termination date. Thus, even if CMS's controls had included updating its system edits each business day with the most recent NSDE

file, those controls would not have been able to prevent acceptance of any PDE data submitted between the termination date and the February 15, 2015, date on which this drug's termination date first appeared on the NSDE file.

We estimate that if CMS had incorporated the quarterly Medicaid drug rebate files into its process for identifying terminated drugs and implemented a process for the comparison of termination dates from both data sources, its system edits would have had the drug's termination date earlier and would have rejected payment for 135 PDE records (including the record for February 20, 2015) totaling $103,301 in gross drug costs.

Figure: Prescription Drug Event Records Accepted After Publication of Termination Date on a Medicaid Drug Rebate File



Differences in Data Sources' Information Regarding Terminated Drugs

Both data sources—the NSDE file and the quarterly Medicaid drug rebate files—drew from data provided by the drug manufacturers, but the information regarding terminated drugs in each differed substantially.

A comparison of the quarterly Medicaid drug rebate files and the NSDE file revealed that, of the 7,138 unique drugs that had a termination date and that appeared in one or both data sources, only 1,404 (20 percent) had the same termination dates in *both* data sources. The other 5,734 drugs had discrepancies in the information: either both data sources listed a particular drug as terminated but showed different termination dates or one data source listed a termination date and the other did not.

Of the 1,404 drugs for which both data sources showed the same termination dates, 956 (68 percent) were listed as terminated more promptly in the quarterly Medicaid drug rebate files than they were in the NSDE file. The termination dates were reported more promptly in the NSDE file—the data source that CMS described as the only authoritative source—for 154 (11 percent) of the 1,404 drugs. Termination dates for the remaining 294 (21 percent) drugs were reported at approximately the same time in both data sources.

See Appendix B for a more detailed summary of these discrepancies. According to officials from CMS and FDA, neither agency has conducted a review of the discrepancies between the quarterly Medicaid drug rebate files and the NSDE file.

Quarterly Medicaid Drug Rebate Files Were Generally More Accurate Than FDA's NSDE File

After we identified the extent of the discrepancies regarding information on terminated drugs in these two data sources, we contacted 14 manufacturers directly and verified the termination dates, by NDC, for 30 different terminated drugs. Those 30 terminated drugs represented 21 percent of the terminated drug utilization (in dollar value associated with PDE data that CMS accepted after the associated drugs' termination dates) that we identified for CYs 2014 and 2015.

On the basis of our comparison of the termination dates provided by these manufacturers and the information in the two data sources, we determined that the quarterly Medicaid drug rebate files correctly classified all 30 drugs as terminated and that the termination dates in the rebate files matched the dates that were provided to us by the manufacturers. However, the NSDE file classified only 13 of the 30 drugs as terminated, and only 4 of those 13 drugs had termination dates that matched the manufacturers' dates (and that also matched the dates in the quarterly Medicaid drug rebate files). See Appendix C.

IMPACT OF TERMINATED DRUGS ON BENEFICIARY HEALTH AND SAFETY

Because CMS did not compare the information on termination dates between the two data sources and did not investigate any of the discrepancies, Medicare Part D continued to cover some terminated drugs that were dispensed to beneficiaries. These drugs had all expired or been pulled from the market. Those medications could have been weak, ineffective, or detrimental to beneficiaries' health.

In one example, manufacturers withdrew from the market the opioid pain reliever propoxyphene (Darvon and Darvocet), effective November 19, 2010,[16] because of concerns that the drug threatened "serious toxicity to the heart." The effective date of this drug's withdrawal from the market was its termination date. Medicare Part D incorrectly accepted 118 PDE records for this drug after its termination date. Moreover, 44 NDCs associated with this drug did not have termination dates listed on the August 11, 2017, NSDE file—nearly 7 years after propoxyphene was withdrawn from the market. The controls that CMS had put in place during our audit period would not have prevented CMS from accepting PDE data for these NDCs.

[16] This was before our audit period, which began on January 1, 2014.

RECOMMENDATIONS

We recommend that CMS continue to strengthen its internal controls to ensure that all PDE data for terminated drugs are rejected by:

- working with FDA to verify the accuracy of drug termination dates, to include comparing the information on termination dates in its quarterly Medicaid drug rebate files with the information in the NSDE file, investigating discrepancies between the two data sources, and verifying termination dates with the drug manufacturers when discrepancies are identified; and

- updating its system edits with a new NSDE file on a more timely basis to reduce the likelihood of timelags that could lead to acceptance of PDE data for terminated drugs and payment for those drugs.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our second recommendation and said that it would update its system edits with a new NSDE file on a more timely basis. CMS did not concur 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 NDC 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. CMS referenced its partnership with FDA and said that it would make that agency aware of this report.

CMS separately provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, appear as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing CMS's comments, we maintain that our findings and recommendations remain valid. We recognize that FDA is the expert authority and source for NDC listing information for Medicare Part D. However, drug manufacturers submit information to CMS for use in its Medicaid Drug Rebate Program, and as this report points out, that information sometimes differs from the information in FDA's NDSE file. CMS stated that for terminated drug utilization in Part D, it is not appropriate for CMS to investigate and address discrepancies in information between the two data sources. But for the Medicaid Drug Rebate Program, CMS has directed the States to reject drugs dispensed after their termination dates as shown in the quarterly Medicaid drug rebate files (footnote 5). Therefore, we continue to assert that it is CMS's responsibility to use the information in the Medicaid drug rebate files to help identify differences between the two data sources as part of its administration of Part D and to continue to work in partnership with FDA to ensure the accuracy of both drug files.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the NSDE file and CMS's quarterly Medicaid drug rebate files to identify terminated drugs. We compared the termination dates from both files to PDE data for CYs 2014 and 2015 (January 1, 2014, through December 31, 2015) to identify terminated drug utilization. (Our previous audit[17] reviewed PDE data for CYs 2006 and 2007.)

Our audit objectives did not require an understanding or assessment of CMS's complete internal control structure. We limited our internal control review to obtaining an understanding of the changes that CMS incorporated into its controls since our previous audit for identifying and rejecting terminated drugs.

We conducted our audit from August 2016 to August 2018.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations and CMS guidance, as well as CMS's policies and procedures pertaining to terminated drugs;

- held discussions with CMS officials to gain an understanding of relevant policies, procedures, and guidance regarding terminated drugs;

- identified a population of terminated drugs from the quarterly Medicaid drug rebate files for CYs 2014 and 2015;

- identified a population of terminated drugs from the NSDE file published on September 16, 2016;

- compared the population of terminated drugs from both data sources with PDE data submitted by sponsors in CYs 2014 and 2015;

- compared information on terminated drugs as shown in the quarterly Medicaid drug rebate files to information on these drugs in the NSDE file published on September 16, 2016, to determine whether there were discrepancies in the identification of terminated drugs, termination dates, or both (Appendix B);

- contacted 14 drug manufacturers and verified the termination dates, by NDC, for 30 different terminated drugs, which represented 21 percent of the terminated drug

[17] *Review of Terminated Drugs in the Medicare Part D Program* (A-07-09-03130), Nov. 1, 2010.

utilization (in dollar value associated with PDE data that CMS accepted after the associated drugs' termination dates) that we identified for CYs 2014 and 2015 and compared those dates to the termination dates as reported in the two data sources (Appendix C); and

- discussed the results of our review with and provided detailed data on our findings to CMS officials on December 19, 2017.

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 B: COMPARISON OF TERMINATION DATES IN THE TWO DATA SOURCES

Dates of termination for terminated drugs are reported in both the quarterly Medicaid drug rebate files and the NSDE file. Table 1 below compares information on terminated drugs as it appears in these two data sources. We downloaded the NSDE file used in this analysis from the FDA website on September 16, 2016. We compared that file's information on terminated drugs to the information in the quarterly Medicaid drug rebate files (referred to as "Medicaid" in this Table) for the first quarter of CY 2010 through the fourth quarter of CY 2015.

Table 1: Agreements and Discrepancies Between the Two Data Sources Regarding Terminated Drugs and Termination Dates

Drugs listed as terminated in one or both data sources:	7,138[18]	
-Drugs terminated in Medicaid but not in NSDE file		2,892
-Drugs terminated in NSDE file but not in Medicaid		1,331
-Drugs terminated in both data sources		2,915
Drugs with termination dates in both data sources:	2,915	
-Drug termination dates did not match		1,511
-Drug termination dates matched		1,404

Of the 7,138 drugs listed as terminated in one or both data sources from Table 1, we identified 1,404 drugs whose termination dates were the same in both data sources. Table 2 shows the data sources in which the termination dates for these 1,404 drugs were first reported.

Table 2: Comparison of Drugs With Matching Termination Dates Between the Two Data Sources

Drugs with matching termination dates:	1,404	
-Medicaid-listed termination dates before NSDE		956
-NSDE-listed termination dates before Medicaid		154
-Termination dates listed about the same time		294

[18] These are unique human prescription drugs for which there was Medicare Part D spending during our audit period and that appeared in either or both data sources.

APPENDIX C: OFFICE OF INSPECTOR GENERAL VERIFICATION OF TERMINATION DATES

For 30 terminated drugs (Appendix A), we contacted 14 manufacturers and verified the accuracy of the termination dates that were listed in the NSDE file and the quarterly Medicaid drug rebate files. The quarterly Medicaid drug rebate files classified all 30 drugs as terminated, and the termination dates in the quarterly files matched the manufacturers' dates. However, as shown in Table 3 on the next page, only 13 of the 30 drugs were also classified as terminated in the NSDE file. Furthermore, only 4 of those 13 drugs had termination dates that matched the manufacturers' termination dates (and that also matched the termination dates that appeared in the quarterly Medicaid drug rebate files).

Table 3: Comparison of Termination Dates as Shown on Medicaid Quarterly Drug Rebate Files, in NSDE File, and as Verified by Drug Manufacturers

Drug	Total Drug Costs	Termination Date in the Quarterly Medicaid Drug Rebate Files	Termination Date in the NSDE File	Manufacturer-Verified Termination Date
1	$306,035	12/31/2013	9/30/2014	12/31/2013
2	196,857	9/30/2015	11/10/2015	9/30/2015
3	1,044,879	11/30/2013	8/10/2015	11/30/2013
4	415,771	11/30/2013	No Termination Date	11/30/2013
5	390,327	5/31/2014	No Termination Date	5/31/2014
6	344,204	1/31/2014	No Termination Date	1/31/2014
7	304,035	6/30/2013	3/30/2016	6/30/2013
8	318,914	6/30/2014	No Termination Date	6/30/2014
9	223,657	7/31/2013	No Termination Date	7/31/2013
10	188,545	4/30/2014	No Termination Date	4/30/2014
11	181,090	6/30/2014	No Termination Date	6/30/2014
12	176,263	6/30/2014	No Termination Date	6/30/2014
13	172,812	11/30/2014	11/30/2014	11/30/2014
14	166,526	10/31/2013	8/10/2015	10/31/2013
15	167,548	5/31/2014	No Termination Date	5/31/2014
16	167,287	5/31/2014	No Termination Date	5/31/2014
17	166,783	9/30/2012	9/30/2012	9/30/2012
18	158,715	6/30/2013	8/10/2015	6/30/2013
19	160,746	12/31/2013	2/03/2015	12/31/2013
20	146,607	1/31/2015	No Termination Date	1/31/2015
21	137,514	7/31/2014	8/31/2015	7/31/2014
22	140,310	8/31/2013	No Termination Date	8/31/2013
23	135,112	4/02/2014	2/03/2015	4/01/2014[19]
24	131,748	9/30/2012	9/30/2012	9/30/2012
25	131,692	12/31/2013	No Termination Date	12/31/2013
26	118,070	7/31/2015	No Termination Date	7/31/2015
27	115,477	12/31/2014	No Termination Date	12/31/2014
28	113,935	8/31/2014	8/31/2014	8/31/2014
29	113,332	8/31/2012	No Termination Date	8/31/2012
30	103,958	7/31/2013	No Termination Date	7/31/2013

Note: We have highlighted cells in this Table to call attention to two issues that this report has discussed: (1) differences in termination dates between the quarterly Medicaid drug rebate files and the NSDE file and (2) drugs classified as terminated in the quarterly Medicaid drug rebate files but not so classified in the NSDE file.

[19] For this drug, the termination date provided by the manufacturer was within 1 day of the termination date reported in the quarterly Medicaid drug rebate file. We consider this difference immaterial; therefore, we categorize all 30 drugs as having manufacturer-verified termination dates that matched the termination dates that appeared in the quarterly Medicaid drug rebate files.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: SEP - 7 2018

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS's Enhanced Controls Did Not Always Prevent Terminated Drug Utilization in Medicare Part D (A-07-16-06068)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report regarding the prevention of terminated drug utilization in the Medicare Part D program for calendar years 2014 and 2015. CMS remains committed to making necessary enhancements to its oversight of the Medicare Part D program to ensure plans cover, and beneficiaries receive, prescription drugs in accordance with Federal law, regulation, and guidance.

As OIG notes, CMS has made improvements to its process for identifying terminated drugs in Medicare Part D since the OIG's previous audit in 2010.[1] On September 1, 2012, CMS began using the Food and Drug Administration's (FDA) Comprehensive National Drug Code Structured Product Labeling Data Elements (NSDE) file to help ensure that drugs not listed with FDA or terminated prior to the date of service were not covered by Medicare Part D. In addition, CMS reiterated our guidance that Part D plans are to report discrepancies with the NSDE file directly to the FDA. These improvements helped CMS save more than $80 million on costs in terminated drugs over a two-year period since OIG last examined this issue.

CMS maintains that the FDA is the expert authority and source for national drug code listing information for the Part D program and does not consider it appropriate or administratively feasible for CMS to investigate and address discrepancies in information between the Medicaid drug rebate files and the FDA NSDE file. As appropriate, CMS will continue to support ongoing efforts by both the FDA and Part D plans to ensure NSDE file accuracy.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

We recommend that CMS continue to strengthen its internal controls to ensure that all PDE data for terminated drugs are rejected by working with FDA to verify the accuracy of drug

[1] HHS OIG, *Review of Terminated Drugs in the Medicare Part D Program* (A-07-09-03130), November 2010. Accessible at https://oig.hhs.gov/oas/reports/region7/70903130.pdf.

termination dates, to include comparing the information on termination dates in its quarterly Medicaid drug rebate files with the information in the NSDE file, investigating discrepancies between the two data sources, and verifying termination dates with the drug manufacturers when discrepancies are identified.

CMS Response

CMS does not concur with OIG's recommendation. While CMS remains committed to strengthening our internal controls to ensure that prescription drug event data for terminated drugs are rejected, CMS maintains that the FDA is the expert authority and source for national drug code listing information in its NSDE file. CMS does not consider it appropriate or administratively feasible for CMS to investigate and address discrepancies in information between the Medicaid drug rebate files and the FDA NSDE file. CMS recognizes the importance of its partnership with the FDA and will make FDA aware of this report.

OIG Recommendation

We recommend that CMS continue to strengthen its internal controls to ensure that all PDE data for terminated drugs are rejected by updating its system edits with a new NSDE file on a more timely basis to reduce the likelihood of time lags that could lead to acceptance of PDE data for terminated drugs and payment for those drugs.

CMS Response

CMS concurs with OIG's recommendation. CMS will update its system edits with a new NSDE file on a more timely basis going forward.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.