



November 1, 2010

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of Terminated Drugs in the Medicare Part D Program (A-07-09-03130)

The attached final report provides the results of our review of terminated drugs in the Medicare Part D program.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Robert A. Vito, Acting Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Robert.Vito@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-07-09-03130 in all correspondence.

Attachment

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
TERMINATED DRUGS IN
THE MEDICARE PART D PROGRAM**



Daniel R. Levinson
Inspector General

November 2010
A-07-09-03130

Office of Inspector General

<http://oig.hhs.gov>

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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.

EXECUTIVE SUMMARY

BACKGROUND

Prescription Drug Coverage

The Centers for Medicare & Medicaid Services (CMS) contracts with private prescription drug plans and Medicare Advantage plans (collectively known as sponsors) to offer prescription drug benefits to eligible individuals under Medicare Part D. Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit prescription drug event (PDE) data, including drug cost and payment information, to CMS. Sponsors are required to submit final PDE data within 6 months after the end of the coverage year.

CMS also offers prescription drug coverage through the States to eligible Medicaid beneficiaries. Most States administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The Medicaid prescription drug 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 a list of all covered outpatient drugs, including their termination dates. CMS provides this information to the States on quarterly Medicaid drug tapes.

Terminated Drugs

Pursuant to 21 CFR § 211.137, 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. The expiration date effectively establishes a shelf life for the drug. A drug's termination date is defined by CMS as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that the Food and Drug Administration (FDA) or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal. In this report, we refer to drugs whose termination dates have passed as "terminated drugs."

State pharmacy practice statutes and regulations generally prohibit or limit dispensing drugs after their expiration dates. Although CMS has issued guidance to States prohibiting payment for terminated drugs under Medicaid, no guidance or regulation prohibits payment for terminated drugs under Medicare Part D.

OBJECTIVE

Our objective was to determine the extent to which CMS accepted PDE data submitted by sponsors for terminated drugs.

SUMMARY OF FINDING

Of approximately \$115 billion in gross drug costs included in sponsors' PDE data for calendar years 2006 and 2007, CMS accepted PDE data totaling \$112,104,483 in gross drug costs associated with 2,967 terminated drugs. Terminated drugs are discontinued drugs that have

passed their shelf life or drugs that have been pulled from the market for health or safety reasons. Such medications could be weak, ineffective, or detrimental to beneficiaries' health. However, Federal regulations do not specifically prohibit coverage of terminated drugs under the Medicare Part D program.

RECOMMENDATION

We recommend that CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs and, in the interim, publish a list of these drugs on its Web site.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS did not concur with our finding or recommendation. CMS questioned our reliance on the termination dates reported by drug manufacturers for use in the Medicaid program and disagreed that terminated drugs were actually dispensed to Medicare beneficiaries. CMS also expressed its belief that the only authoritative source of data on product expiration dates at the national drug code level is information officially submitted by manufacturers to FDA. CMS concluded that establishing a new regulatory requirement without more complete information from FDA would not solve the problem.

CMS's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

The termination dates that we used were the same dates that CMS provided to States for use in determining whether drugs were eligible for reimbursement under the Medicaid drug rebate program. Our audit found that the PDE data that CMS accepted indicated that terminated drugs were dispensed to Part D beneficiaries. Given that CMS directed States to reject Medicaid drug claims on the basis of the termination dates reported by manufacturers, CMS should prohibit Part D coverage of terminated drugs on the same basis. Accordingly, our recommendation remains unchanged.

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INTRODUCTION

BACKGROUND

Medicare Part D Prescription Drug Coverage

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit.¹ Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage. The Centers for Medicare & Medicaid Services (CMS), which administers 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 prescription drug event (PDE) data to CMS. PDE data include drug cost and payment information to enable CMS to administer the Part D benefit. Pursuant to 42 CFR § 423.343(c)(1), sponsors must submit final PDE data to CMS within 6 months after the end of the coverage year. For calendar years 2006 and 2007, sponsors submitted final PDE data totaling approximately \$115 billion in gross drug costs. CMS's *PDE Instructions: Requirements for Submitting Prescription Drug Event Data*, section 7.2.3, define gross drug costs as the sum of the following PDE payment fields: covered plan-paid amount, noncovered plan-paid amount, patient-pay amount, low-income cost-sharing payment, other true out-of-pocket costs, and patient liability reduction as a result of another payer amount.

Sections 1860D-14 and 15 of the Act provide that CMS pay sponsors for Part D benefits prospectively based in part on information in the sponsors' approved annual bids. After the close of the coverage year, CMS is responsible for reconciling the prospective payments with the actual costs incurred by sponsors and for determining the amount that each sponsor will owe to or receive from Medicare for the plan year. CMS's reconciliations are based on sponsors' final PDE data.

Medicaid Prescription Drug Coverage

In addition to offering Part D prescription drug coverage to Medicare beneficiaries, CMS offers drug coverage through the States to eligible Medicaid beneficiaries pursuant to Title XIX of the Act. Most States administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.² The Medicaid prescription drug 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 a list of all covered outpatient drugs, including their termination dates. CMS provides this information to the States on quarterly Medicaid drug tapes.

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

² The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act.

Terminated Drugs

Pursuant to 21 CFR § 211.137, 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. The expiration date effectively establishes a shelf life for the drug. A drug's termination date is defined by CMS as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that the Food and Drug Administration (FDA) or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal.³ In this report, we refer to drugs whose termination dates have passed as "terminated drugs."

State pharmacy practice statutes and regulations generally prohibit or limit dispensing drugs after their expiration dates. Federal regulations provide that Part D plans must comply with minimum State pharmacy practice standards (42 CFR § 423.153(c)(1)). In addition, the *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, § 70.1.3, states that a pharmacy's act of dispensing expired drugs constitutes fraud, waste, or abuse.

Although CMS has issued guidance to States prohibiting payment for terminated drugs under Medicaid, no guidance or regulation prohibits payment for terminated drugs under Medicare Part D.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine the extent to which CMS accepted PDE data submitted by sponsors for terminated drugs.

Scope

The audit scope covered approximately \$115 billion in gross drugs costs reflected in sponsors' final PDE data for calendar years 2006 and 2007.

The objective of our audit did not require us to review CMS's internal control structure. We did not review the accuracy or completeness of the PDE data.

We conducted our audit from August 2008 to February 2009.

Methodology

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We interviewed CMS officials responsible for administering the Part D program.

³ *Medicaid Drug Rebate Operational Training Guide*, page F7 (Sept. 2001); Medicaid Drug Rebate Program Release No. 19, page 5.

- We obtained from CMS a list of drugs and their termination dates reported by the drug manufacturers that participated in the Medicaid drug rebate program. We then obtained the PDE data for all drugs that were dispensed after their termination dates.
- For the 12 terminated drugs with the highest gross drug costs included in sponsors' PDE data, we confirmed the accuracy of the termination dates with the drug manufacturers. These drugs represented 52 percent of the total Part D gross drug costs associated with terminated drugs.
- We shared the PDE data associated with terminated drugs with CMS officials.

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 finding and conclusions based on our audit objective.

FINDING AND RECOMMENDATION

Of approximately \$115 billion in gross drug costs included in sponsors' PDE data for calendar years 2006 and 2007, CMS accepted PDE data totaling \$112,104,483 in gross drug costs associated with 2,967 terminated drugs.⁴ Terminated drugs are discontinued drugs that have passed their shelf life or drugs that have been pulled from the market for health or safety reasons. Such medications could be weak, ineffective, or detrimental to beneficiaries' health. However, Federal regulations do not specifically prohibit coverage of terminated drugs under the Medicare Part D program.

TERMINATED DRUG COSTS

Pursuant to the provisions of the MMA, a drug must meet the definition of a Part D drug to be covered by the Part D program.⁵ This definition generally requires that FDA approve the drug. FDA requires that drug products undergo testing to assess their stability. The results of stability testing are used in determining appropriate storage conditions and expiration dates. Federal regulations (21 CFR § 211.137) require that a drug product meet applicable standards of identity, strength, quality, and purity at the time of use and bear the expiration date determined during stability testing.

For calendar years 2006 and 2007, CMS accepted sponsors' PDE data totaling \$112,104,483 in gross drug costs for drugs that were dispensed after their termination dates. For example, one sponsor submitted a PDE record for the drug Cozaar (national drug code (NDC)

⁴ Of the 2,967 terminated drugs that we identified, 17 drugs totaling \$3,354,998 in gross drug costs were also classified as less than effective. We are addressing less-than-effective drugs in another report (A-07-09-04138).

⁵The Act, § 1860D-2(e).

00006-0952-58).⁶ This drug was dispensed on November 1, 2006, with a gross drug cost of \$141. However, the drug manufacturer had reported to CMS that the drug was discontinued and that the expiration date was August 31, 2006. Thus, on the date that it was dispensed, the drug had passed its shelf life. For calendar years 2006 and 2007, CMS accepted PDE data totaling \$11,621,242 in gross drug costs for this drug after its termination date.

Federal regulations do not specifically prohibit coverage of terminated drugs under the Part D program.

POTENTIAL QUALITY-OF-CARE IMPLICATIONS

Beneficiaries who are prescribed and dispensed terminated drugs are taking drugs that by definition have expired or have been pulled from the market for health or safety reasons. Such medications could be weak, ineffective, or detrimental to beneficiaries' health.

RECOMMENDATION

We recommend that CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs and, in the interim, publish a list of these drugs on its Web site.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS did not concur with our finding or recommendation. CMS questioned our reliance on the termination dates reported by drug manufacturers for use in the Medicaid program and said that these dates are collected to establish "the last date that rebates will be due to the Medicaid program. In discussions with Medicaid staff we have learned that these dates are not infrequently subject to change" CMS also expressed its belief that the only authoritative source of data on product expiration dates at the NDC level is data officially submitted by manufacturers to FDA.

In addition, CMS disagreed that terminated drugs were actually dispensed to Medicare beneficiaries and said that our report more likely indicated imprecise pharmacy billing practices. CMS explained that pharmacies bill for an NDC that does not always precisely correlate with the actual product being dispensed.

CMS stated that if FDA made information regarding terminated drugs transparent and widely available, pharmacies would incorporate appropriate edits into their systems, payers would reject claims for these drugs, and CMS could establish edits that would reject PDE claims for these drugs. CMS concluded that establishing a new regulatory requirement without more complete information from FDA would not solve the problem.

CMS's comments are included in their entirety as the Appendix.

⁶ An NDC is a unique, three-segment identification number.

OFFICE OF INSPECTOR GENERAL RESPONSE

The termination dates that we used were the same dates that CMS provided to States for use in determining whether drugs were eligible for reimbursement under the Medicaid drug rebate program. In accordance with Medicaid Drug Rebate Program Release No. 19, States must “assure that claims submitted by pharmacists are not for drugs dispensed after the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date.”

Our audit found that the PDE data that CMS accepted indicated that terminated drugs were dispensed to Part D beneficiaries. We acknowledge that a pharmacy could potentially bill for an NDC that does not precisely correlate with the product dispensed. However, when a pharmacy bills for a terminated drug, CMS should reject the PDE data, as well as the sponsor’s payment, for that drug. Regardless of pharmacy billing practices, CMS is responsible for ensuring that drugs dispensed to Part D beneficiaries are safe and effective.

Although FDA plays an important role in drug safety, it does not obtain termination dates from drug manufacturers or track expiration dates. Given that CMS directed States to reject Medicaid drug claims on the basis of the termination dates reported by manufacturers, CMS should prohibit Part D coverage of terminated drugs on the same basis. Accordingly, our recommendation remains unchanged.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

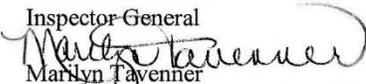
Centers for Medicare & Medicaid Services

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Administrator
 Washington, DC 20201

DATE: JUN 25 2010

TO: Daniel R. Levinson
 Inspector General

FROM: 
 Marilyn Tavenner
 Acting Administrator and Chief Operating Officer

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Terminated Drugs in the Medicare Part D Program" (A-07-09-03130)

Thank you for the opportunity to review and comment on this OIG draft report reviewing "terminated drugs" in the Medicare Part D Program. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's concern for ensuring that Medicare beneficiaries are not receiving drugs that could be weak, ineffective or detrimental to beneficiaries' health. We strongly agree that we do not want Medicare beneficiaries receiving expired or outdated drugs. As noted in the report, States already regulate pharmacy practice and generally prohibit or limit dispensing of expired drugs. We rarely see evidence to indicate that pharmacies are dispensing outdated drugs to Medicare beneficiaries and we believe that pharmacists generally adhere to the practice of dispensing drugs that are not outdated.

We note that the data source used in the report methodology is likely flawed, and cannot be relied upon as a proxy for identifying the dispensing of outdated products. The data submitted by manufacturers to the Medicaid program on "terminated drugs", i.e., the reported expiration date of the last lot of drugs produced, is collected for the purpose of establishing the last date that rebates will be due to the Medicaid program. In discussions with Medicaid staff we have learned that these dates are not infrequently subject to change, in certain cases by more than a year. We believe that the only authoritative source of data on final product expiration dates at the national drug code (NDC) level is data officially submitted by manufacturers to the Food and Drug Administration (FDA). If this information were made publicly available, all parties that utilize NDC data – commercial databases, pharmacies and pharmacy software vendors, plan benefit managers and other Part D sponsor processors, and CMS systems – could consistently apply edits to any terminated codes.

The CMS does not concur with the OIG's interpretation that their study supports the finding that terminated drugs were actually dispensed to Medicare beneficiaries, and instead believes the report most likely supports a finding of imprecise pharmacy billing practices based on lack of timely access to updated coding data. The OIG report uses a finding of pharmacies billing for outdated 11-digit NDC as a proxy for actually outdated drug products being dispensed at the pharmacy counter. In actuality, in the constantly changing world of NDCs, real-time electronic

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pharmacy billing with 11-digit NDCs does not always precisely correlate with the actual product being dispensed. For example, it is not uncommon for a pharmacy to bill using an NDC for the correct drug product but the incorrect package size. The Cozaar example offered by the OIG represents a classic situation where the manufacturer discontinued one package size (100 tablet) and created a new NDC for the new package size (90 tablet). Only the last 2 digits on the 11-digit Cozaar NDC differ. In this example, the billing of the terminated NDC most likely represented the pharmacies failure to update the precise NDC in their billing systems to reflect the new package size and not that the pharmacy dispensed outdated drugs. Although ideally, with timely access to updated data, pharmacies would always use the exact NDC to match the product dispensed to the patient, it is important to recognize that such discrepancies do not support a finding that outdated drugs were dispensed.

While we disagree that the OIG report supports the finding that pharmacies dispensed, and Medicare beneficiaries received, outdated drugs, we recognize that pharmacies should be billing with the correct NDCs and believe that transparent data on outdated NDCs could assist with eliminating the use of outdated NDCs on pharmacy claims transactions and any potential risk of payment for actual outdated drugs. We believe this information must be provided by the FDA so that commercial databases, pharmacies, payers and CMS will have the same access to the same authoritative information.

OIG Recommendation

CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs and, in the interim, publish a list of these drugs on its Web site.

CMS Recommendation

The CMS does not concur with this recommendation. For the reasons discussed above, we believe that a permanent solution requires the FDA to make such information on drug products transparent and widely available. If this information is available from the FDA, we believe that pharmacies will incorporate appropriate edits in their systems, payers will reject claims for outdated NDCs and CMS could establish prescription drug event (PDE) reject edits for the same NDCs. Establishing a new regulatory requirement without the availability of more complete information from the FDA will not solve the issue but could create more confusion and inconsistencies. Furthermore, it would not be appropriate for CMS to publish a program-specific list of terminated drug NDCs because the FDA, not CMS, is the authoritative source that collects and should make this information available to the public.

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