



August 16, 2010

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

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of Less-Than-Effective Drugs in the Medicare Part D Program
(A-07-09-04138)

The attached final report provides the results of our review of less-than-effective 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-07-09-04138 in all correspondence.

Attachment

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
LESS-THAN-EFFECTIVE DRUGS IN
THE MEDICARE PART D PROGRAM**



Daniel R. Levinson
Inspector General

August 2010
A-07-09-04138

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.

Less-Than-Effective Drugs

Less-than-effective drugs are drugs that the Food and Drug Administration (FDA) approved before the Drug Amendments of 1962 (P.L. No. 87-781) and that FDA subsequently found to be less than effective. When FDA finds a lack of substantial evidence that a pre-1962 drug is effective for all intended uses, it publishes a notice in the Federal Register concerning its proposal to withdraw approval of the drug. At that time, the manufacturer of the drug or an identical, related, or similar drug may request a hearing and provide FDA with documentation of the effectiveness of the drug product before FDA makes a final determination. A drug for which FDA has proposed withdrawing approval is considered less than effective until the manufacturer can prove its effectiveness. The Federal Register notice is the only notice that a drug is less than effective; FDA does not publish a list of less-than-effective drugs.

For the Medicare Part D program, CMS determines which drugs are less than effective principally by consulting two commercially available databases. CMS's Drug Data Processing System subjects sponsors' PDE records to an edit designed to reject less-than-effective drugs. According to CMS officials, this edit rejected 5.3 million PDE records during calendar years 2006 and 2007.

For the Medicaid drug rebate program, CMS relies on drug manufacturers to identify their less-than-effective drugs by reviewing FDA's Federal Register notices. CMS requires manufacturers to provide a list of all covered outpatient drugs and to identify any less-than-effective drugs. CMS provides this information to the States on quarterly Medicaid drug tapes.

OBJECTIVE

Our objective was to determine the extent to which CMS accepted PDE data submitted by sponsors for less-than-effective 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 \$43,307,536 in gross drug costs associated with less-than-effective drugs. Pursuant to Federal requirements, Part D should not have covered these drugs. We identified no other unallowable utilization of less-than-effective drugs in Medicare Part D.

The edit in CMS's Drug Data Processing System identified and rejected the vast majority of sponsors' PDE data associated with less-than-effective drugs. However, the edit did not identify and reject PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. CMS officials stated that the Medicare Part D and Medicaid drug rebate programs shared information on less-than-effective drugs on an ad hoc basis and that the two programs' lists of less-than-effective drugs did not always agree. There is no definitive list of less-than-effective drugs.

According to CMS officials, CMS modified the edit in the Drug Data Processing System in such a way that the edit now identifies and rejects PDE data for most of the less-than-effective drugs that we identified.

RECOMMENDATIONS

We recommend that CMS:

- determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs and
- strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by:
 - collaborating with FDA to create and maintain a comprehensive list of less-than-effective drugs,
 - regularly disseminating this list to all sponsors, and
 - using this list to reject PDE data for less-than-effective drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS agreed with our first recommendation and partially disagreed with our second recommendation. Specifically, CMS disagreed that it should

create a comprehensive, up-to-date list of less-than-effective drugs and routinely verify the accuracy of the list with FDA. CMS also disagreed that it should regularly disseminate the list to sponsors. CMS stated that FDA should be responsible for maintaining and disseminating the list of less-than-effective drugs. CMS added that if FDA produces such a list, CMS would be able to ensure that the correct system edits are in place to reject applicable PDE data. CMS's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge that FDA plays an important role in identifying less-than-effective drugs, and we modified our second recommendation to reflect that role. However, as the administrator of the Medicare Part D program, CMS has the primary responsibility to ensure that sponsors are not paid for less-than-effective drugs and that the drugs being prescribed to beneficiaries are safe and effective. Therefore, we continue to recommend that CMS regularly disseminate a list of less-than-effective drugs to all sponsors to ensure that they are provided with the information necessary to appropriately administer their Part D plans.

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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 pays 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.

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.

Less-Than-Effective Drugs

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.³ This definition generally requires that the Food and Drug Administration (FDA) approve the drug. The definition does not include less-than-effective drugs.

Less-than-effective drugs are drugs that FDA approved before the Drug Amendments of 1962 (P.L. No. 87-781) and that FDA subsequently found to be less than effective. The Drug Amendments required, for the first time, that FDA approve only drugs found to be both safe and effective. The Drug Amendments also required FDA to evaluate the effectiveness of those drugs that it approved before the requirement that drugs be proven effective as a condition of approval (pre-1962 drugs). Pre-1962 drugs were permitted to remain on the market while FDA reviewed evidence of their effectiveness.

When FDA finds a lack of substantial evidence that a pre-1962 drug is effective for all intended uses, it publishes a notice of opportunity for a hearing in the Federal Register concerning its proposal to withdraw approval of the drug. At that time, the manufacturer of the drug or an identical, related, or similar drug may request a hearing and provide FDA with documentation of the effectiveness of the drug product before FDA makes a final determination. A drug for which FDA has proposed withdrawing approval is considered less than effective until the manufacturer can prove its effectiveness to FDA's satisfaction. The Federal Register notice is the only notice that a drug is less than effective; FDA does not publish a list of less-than-effective drugs.

For the Medicare Part D program, CMS determines which drugs are less than effective principally by consulting two databases, First DataBank's National Drug Data File Plus and Medi-Span's Master Drug Data Base.⁴ CMS's Drug Data Processing System⁵ subjects sponsors' PDE records to an edit designed to reject less-than-effective drugs. According to CMS officials, this edit rejected 5.3 million PDE records during calendar years 2006 and 2007.⁶

For the Medicaid drug rebate program, CMS relies on drug manufacturers to identify their less-than-effective drugs by reviewing FDA's Federal Register notices. CMS's rebate agreements require manufacturers to provide CMS with a list of all covered outpatient drugs and to identify any less-than-effective drugs. CMS provides this information to the States on quarterly Medicaid drug tapes.

³ The Act, § 1860D-2(e).

⁴ These commercially available databases are used by both private industry and Government agencies.

⁵ CMS's Drug Data Processing System collects, validates, and stores PDE data received from sponsors.

⁶ According to CMS officials, this number may include duplicate PDE records that resulted when previously rejected records were resubmitted.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine the extent to which CMS accepted PDE data submitted by sponsors for less-than-effective drugs.

Scope

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

We limited our internal control review to CMS's policies and procedures for preventing reimbursement of less-than-effective drugs under the Part D program. 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.
- We created a list of less-than-effective drugs, including identical, related, or similar drugs, by compiling information from FDA, CMS's quarterly Medicaid drug tapes, and First DataBank's National Drug Data File Plus. FDA confirmed the accuracy of our list.
- We based the date that a particular drug was determined to be less than effective on the date that FDA published a notice in the Federal Register. We adjusted these dates for some drugs in accordance with a CMS 2006 memorandum to sponsors.⁷ We then obtained the PDE data for all of the less-than-effective drugs that were dispensed after the effective dates.

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.

⁷ In a December 5, 2006, memorandum to sponsors, CMS stated that because some sponsors had relied on U.S. Pharmacopeia classifications, the sponsors had allowed Medicare Part D coverage of certain less-than-effective drugs. Based on this reliance, CMS allowed coverage of these less-than-effective drugs until February 1, 2007. We did not include drugs subject to this memorandum in our finding. (The U.S. Pharmacopeia is an official standards-setting authority for all prescription and over-the-counter medicines manufactured or sold in the United States.)

FINDING AND RECOMMENDATIONS

Of approximately \$115 billion in gross drug costs included in sponsors' PDE data for calendar years 2006 and 2007, CMS accepted PDE data totaling \$43,307,536 in gross drug costs associated with less-than-effective drugs. Pursuant to Federal requirements, Part D should not have covered these drugs. We identified no other unallowable utilization of less-than-effective drugs in Medicare Part D.

The edit in CMS's Drug Data Processing System identified and rejected the vast majority of sponsors' PDE data associated with less-than-effective drugs. However, the edit did not identify and reject PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. CMS officials stated that the Medicare Part D and Medicaid drug rebate programs shared information on less-than-effective drugs on an ad hoc basis and that the two programs' lists of less-than-effective drugs did not always agree. There is no definitive list of less-than-effective drugs.

According to CMS officials, CMS modified the edit in the Drug Data Processing System in such a way that the edit now identifies and rejects PDE data for most of the less-than-effective drugs that we identified.⁸

LESS-THAN-EFFECTIVE 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. This definition generally requires that FDA approve the drug. The definition does not include less-than-effective drugs.

For calendar years 2006 and 2007, sponsors submitted and CMS accepted 774,990 PDE records totaling \$43,307,536 in gross drug costs associated with less-than-effective drugs. CMS had not identified these drugs as less than effective and therefore did not reject the related PDE records. Under separate cover, we provided details on these drugs to CMS.

CONTROLS TO IDENTIFY LESS-THAN-EFFECTIVE DRUGS

The edit in the Drug Data Processing System enabled CMS to identify and reject the vast majority of PDE data associated with less-than-effective drugs during our audit period. However, the edit did not prevent CMS from accepting PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. CMS officials told us that CMS principally used First DataBank's National Drug Data File Plus and Medi-Span's Master Drug Data Base to identify less-than-effective drugs for system edit purposes. In addition, CMS officials stated that the Medicare Part D and Medicaid drug rebate programs shared information on less-than-effective drugs on an ad hoc basis. However, the officials added that because the two programs receive information from different sources, their lists of less-than-effective drugs did not always agree. There is no definitive list of less-than-effective drugs.

⁸ CMS officials were not able to tell us when the edit in the Drug Data Processing System was modified.

Moreover, CMS identifies less-than-effective drugs on the quarterly Medicaid drug tapes that it provides to the States. In contrast, CMS does not identify less-than-effective drugs for sponsors in the Medicare Part D program. CMS accepted PDE data submitted by sponsors for some drugs that had been accurately identified as less than effective by the Medicaid drug rebate program.

According to CMS officials, CMS modified the edit in the Drug Data Processing System in such a way that the edit now identifies and rejects PDE data for most of the less-than-effective drugs that we identified.

POTENTIAL QUALITY-OF-CARE IMPLICATIONS

Less-than-effective drugs lack substantial evidence of effectiveness for all intended purposes. Although the use of less-than-effective drugs may not cause direct physical harm to Part D beneficiaries, reliance on these drugs could be detrimental when they are used instead of drugs whose effectiveness has been verified.

RECOMMENDATIONS

We recommend that CMS:

- determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs and
- strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by:
 - collaborating with FDA to create and maintain a comprehensive list of less-than-effective drugs,
 - regularly disseminating this list to all sponsors, and
 - using this list to reject PDE data for less-than-effective drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS agreed with our first recommendation and stated that it was in the process of implementing it. CMS partially disagreed with our second recommendation. Specifically, CMS disagreed that it should create a comprehensive, up-to-date list of less-than-effective drugs and routinely verify the accuracy of this list with FDA. CMS also disagreed that it should regularly disseminate the list to sponsors. CMS stated that FDA is the agency tasked with regulatory drug status determinations and, accordingly, should be responsible for maintaining and disseminating the list of less-than-effective drugs. CMS added that if FDA produces such a list, CMS would be able to ensure that the correct system edits are in place to reject applicable PDE data.

CMS also requested that we clarify the description of our list of less-than-effective drugs and include identical, related, or similar drugs in our discussion of less-than-effective drugs.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge that FDA plays an important role in identifying less-than-effective drugs, and we modified our second recommendation to reflect that role. However, as the administrator of the Medicare Part D program, CMS has the primary responsibility to ensure that sponsors are not paid for less-than-effective drugs. Furthermore, CMS has a responsibility to beneficiaries to ensure that the drugs being prescribed through the Part D program are safe and effective. Therefore, we continue to recommend that CMS regularly disseminate a list of less-than-effective drugs to all sponsors to ensure that they are provided with the information necessary to appropriately administer their Part D plans.

As CMS requested, we clarified the description of our list of less-than-effective drugs and included information on identical, related, or similar drugs in this final report.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



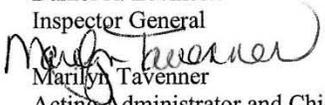
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

 Administrator
 Washington, DC 20201

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DATE: MAY 20 2010

TO: Daniel R. Levinson
Inspector GeneralFROM: 
Marilyn Tavenner
Acting Administrator and Chief Operating Officer

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Less-than-Effective Drugs in the Medicare Part D Program" (A-07-09-04138)

Thank you for the opportunity to review and comment on this OIG draft report aimed at determining the extent to which the Centers for Medicare & Medicaid Services (CMS) has accepted prescription drug event (PDE) data submitted by sponsors for less-than-effective (LTE) drugs. CMS understands the limitations in identifying pre-1962 drugs evaluated under the Food and Drug Administration's (FDA) Drug Efficacy Study Implementation (DESI) program and the impact on the Medicare Part D program and Medicaid Drug Rebate program. CMS also acknowledges the importance of having a publicly available and comprehensive list of all DESI drugs with their respective FDA determination regarding effectiveness.

The CMS supports the report's recommendations to strengthen internal controls as applicable to help ensure that drugs covered by Medicare Part D comply with Federal requirements to the extent that information is available to do so. However, we do not concur that it is our responsibility to publish this comprehensive, up-to-date list of the DESI LTE drugs (and their respective National Drug Codes (NDCs)) including any drugs/NDCs that are identical, related or similar (IRS) to the DESI LTE drugs. Rather, we believe it would be beneficial to all stakeholders to have a complete list of all drugs evaluated under the DESI program, the FDA's DESI determination (e.g., less than effective) for each drug, the Federal Register Notice associated with each determination, and all marketed NDCs associated with the DESI drugs or the drugs IRS to DESI drugs. We believe the FDA is in the best position to accomplish this and encourage the OIG to work with FDA in recommending mechanisms to disseminate comprehensive DESI lists to all stakeholders.

The lack of a complete and accurate listing of all marketed drug products and their NDCs are of ongoing concern to CMS and Part D sponsors since the inception of the Part D program. The fact that it is difficult to identify Federal Register notices associated with DESI products and that these notices are not easily retrievable further complicates the issue. CMS' Drug Data Processing System relies on PDE edits to block claims for drugs that are not coverable under Part

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D. These edits are at the NDC level and therefore require drug information with this level of specificity.

As per the methodology in the draft report, the OIG presented the FDA with a list of LTE drugs compiled using various data sources. CMS would appreciate if you could clarify whether the FDA confirmed that the OIG's list represents both an accurate and complete list of FDA determined DESI LTE drugs. Also, did the OIG inquire whether or not the compiled list represented all marketed NDCs available for LTE drugs or drugs identical, related or similar to DESI LTE drugs? As noted previously, NDC level information is critical to CMS operations. We think it is worth including in your discussion of LTE drugs, a reference to the DESI program and identical, related or similar (IRS) drugs. Interpretation of what constitutes an IRS drug is another source of confusion and possible error that could benefit from the existence of a comprehensive FDA list of DESI drugs. Lastly, was the OIG provided with an explanation from the FDA as to why a comprehensive list of DESI drugs has not yet been made publicly available? If so, it would be informative to include this in the report.

Below is the CMS response to the OIG recommendations in the draft report.

OIG Recommendation

The OIG recommends that CMS determine whether it can impose financial adjustments on sponsors that were paid for furnishing LTE drugs.

CMS Response

The CMS is in the process of determining whether financial adjustments would be appropriate and/or legal given the absence of a list the government can provide to sponsors regarding which drugs are indeed LTE. We, therefore, concur that a determination is needed.

OIG Recommendation

The OIG recommends that CMS strengthen internal controls to help ensure that drugs covered by Medicare part D comply with Federal requirements by:

- A. Creating a comprehensive, up-to-date list of LTE drugs and verifying the accuracy of the list with the FDA on a routine basis;
- B. Regularly disseminating this list (of LTE drugs) to all sponsors, and;
- C. Using the list to reject PDE data for LTE drugs.

CMS Response

- A. CMS does not concur with this recommendation. The FDA is the agency tasked with making regulatory drug status determinations and making this information publicly available. Therefore, CMS believes it is the responsibility of the FDA to produce a

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comprehensive, up-to-date list of the DESI LTE drugs (and their respective NDCs) including any drugs/NDCs that are IRS to the DESI LTE drugs.

- B. CMS does not concur with this recommendation. The FDA is the agency tasked with making regulatory drug status determinations and making this information publicly available. Therefore, the DESI status of drugs evaluated by the FDA as part of the DESI program should be maintained and disseminated by the FDA.
- C. CMS concurs with this recommendation and will be able to ensure the correct system edits are in place to reject applicable PDE data, if the FDA can, and will, produce such a specified up-to-date LTE drug list.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.