



March 2, 2011

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

FROM: /Diann M. Saltman/ for
George M. Reeb
Acting Deputy Inspector General for Audit Services

SUBJECT: Review of Erectile Dysfunction Drugs in the Medicare Part D Program
(A-07-10-03143)

The attached final report provides the results of our review of erectile dysfunction 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 contact me at (410) 786-7104 or through email at George.Reeb@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-07-10-03143 in all correspondence.

Attachment

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
ERECTILE DYSFUNCTION DRUGS
IN THE MEDICARE PART D PROGRAM**



Daniel R. Levinson
Inspector General

March 2011
A-07-10-03143

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

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. Under Part D, which began January 1, 2006, individuals entitled to benefits under Medicare Part A or enrolled in Medicare 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 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.

Medicare Part D Excluded Drugs

The MMA requires that a drug meet the definition of a Part D drug to be covered by the Part D program. Certain drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Effective January 1, 2007, P.L. No. 109-91, section 103, amended section 1860D-2(e)(2)(A) of the Act to exclude from the statutory definition of a Part D drug "... a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration" (FDA). An erectile dysfunction (ED) drug meets the definition of a Part D drug when it is prescribed for medically accepted indications other than sexual or erectile dysfunction (such as pulmonary hypertension) for which the drug has been approved by FDA.

OBJECTIVE

Our objective was to determine the extent to which CMS accepted PDE data that sponsors submitted for ED drugs used for the treatment of sexual or erectile dysfunction.

SUMMARY OF FINDING

Of approximately \$133 billion in gross drug costs included in sponsors' PDE data for calendar years (CY) 2007 and 2008, CMS accepted PDE data totaling \$3,107,200 in gross drug costs for ED drugs approved only for the treatment of sexual or erectile dysfunction. Pursuant to Federal requirements, Part D should not have covered these drugs.

According to CMS officials, the software edit in place in CMS's Medicare Drug Data Processing System during our audit period enabled CMS to identify and reject PDE data that sponsors submitted for ED drugs prescribed for the treatment of sexual or erectile dysfunction. However, according to the officials, the edit did not prevent CMS from accepting PDE data for some ED drugs in CY 2007 and most of CY 2008 because the Part D program used an incomplete list of excluded drugs as the basis for the edit. Although the officials indicated that CMS had updated its list of ED drugs in CY 2008, CMS accepted PDE data for some ED drugs during our entire audit period.

RECOMMENDATIONS

We recommend that CMS:

- determine whether it can impose financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction 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 ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction,
 - regularly disseminating this list to all sponsors, and
 - periodically updating the edit used to reject PDE data for ED drugs used for the treatment of sexual or erectile dysfunction.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our first recommendation and described corrective actions it was taking. For our second recommendation, CMS concurred that it should strengthen internal controls but did not concur that it should (1) collaborate with FDA to create and maintain a comprehensive list of ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction and (2) regularly disseminate the list to sponsors. CMS's comments appear in their entirety as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

Nothing in CMS's comments has caused us to change our findings or recommendations. As the administrator of the Medicare Part D program, CMS has the primary responsibility to ensure that sponsors are administering their Part D plans appropriately. Therefore, we continue to recommend that CMS regularly disseminate a list of ED drugs approved by FDA for the treatment of sexual or erectile dysfunction to all sponsors to ensure compliance within the Part D program.

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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 Medicare Part A or enrolled in Medicare 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 under Medicare Part D.

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 (CY) 2007 and 2008, sponsors submitted final PDE data totaling approximately \$133 billion in gross drug costs. CMS's *PDE Instructions: Requirements for Submitting Prescription Drug Event Data*, section 7.2.3, defines 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 sponsors' actual costs 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.²

Medicare Part D Excluded Drugs

The MMA requires that a drug meet the definition of a Part D drug to be covered by the Part D program. Certain drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.³

Effective January 1, 2007, P.L. No. 109-91, section 103, amended section 1860D-2(e)(2)(A) of the Act to exclude from the statutory definition of a Part D drug "... a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other

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

² 42 CFR § 423.343.

³ Section 1860D-2(e)(2); see also 42 CFR § 423.100.

than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration” (FDA). An erectile dysfunction (ED) drug meets the definition of a Part D drug when it is prescribed for medically accepted indications other than sexual or erectile dysfunction (such as pulmonary hypertension) for which the drug has been approved by FDA.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine the extent to which CMS accepted PDE data that sponsors submitted for ED drugs used for the treatment of sexual or erectile dysfunction.

Scope

The audit covered approximately \$133 billion in gross drug costs reflected in sponsors’ final PDE data for CYs 2007 and 2008.

We limited our internal control review to CMS’s policies and procedures for preventing Part D reimbursement of ED drugs used for the treatment of sexual or erectile dysfunction. CMS was unable to provide us with a list of such ED drugs. Therefore, we relied on FDA for this information. We did not review the accuracy or completeness of the PDE data.

We conducted our audit from November 2009 to September 2010.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and program guidance;
- interviewed CMS officials responsible for administering the Part D program;
- obtained from FDA a list of ED drugs;
- obtained the PDE data for the ED drugs for which the only indication approved by FDA was the treatment of sexual or erectile dysfunction; and
- shared the results of our review with CMS officials on September 29, 2010.

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 RECOMMENDATIONS

Of approximately \$133 billion in gross drug costs included in sponsors' PDE data for CYs 2007 and 2008, CMS accepted PDE data totaling \$3,107,200 in gross drug costs for ED drugs approved only for the treatment of sexual or erectile dysfunction.⁴ Pursuant to Federal requirements, Part D should not have covered these drugs.

According to CMS officials, the software edit in place in CMS's Medicare Drug Data Processing System during our audit period enabled CMS to identify and reject PDE data that sponsors submitted for ED drugs prescribed for the treatment of sexual or erectile dysfunction. However, according to the officials, the edit did not prevent CMS from accepting PDE data for some ED drugs in CY 2007 and most of CY 2008 because the Part D program used an incomplete list of excluded drugs as the basis for the edit.

ERECTILE DYSFUNCTION DRUG COSTS

Under the MMA, a drug must meet the definition of a Part D drug to be covered by the Part D program.⁵ The MMA excludes from Part D coverage "... a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration." Effective January 1, 2007, ED drugs are classified as Part D drugs under 42 CFR § 423.100 only when they are used for the treatment of conditions other than sexual or erectile dysfunction.

For CYs 2007 and 2008, sponsors submitted and CMS accepted 28,521 PDE records totaling \$3,107,200 in gross drug costs for ED drugs approved only for the treatment of sexual or erectile dysfunction. (See Appendix A for a list of these drugs.) For example, sponsors submitted PDE records totaling \$3,021,475 in gross drug costs for the drug Viagra (national drug code (NDC) 00069-4220-30).⁶ FDA had not approved Viagra for the treatment of any condition other than sexual or erectile dysfunction at the time of our audit.

INADEQUATE CONTROLS

CMS did not reject all PDE records associated with drugs used for the treatment of sexual or erectile dysfunction because its edit was not adequate. According to CMS officials, the software edit in place in CMS's Medicare Drug Data Processing System during our audit period enabled CMS to identify and reject PDE data that sponsors submitted for ED drugs prescribed for the treatment of sexual or erectile dysfunction. However, according to the officials, the edit did not prevent CMS from accepting PDE data for some ED drugs in CY 2007 and most of CY 2008 because the Part D program used an incomplete list of excluded drugs as the basis for the edit.

⁴ We acknowledge that sponsors may elect to cover ED drugs as a supplemental benefit. However, PDE data for these drugs were not included in our review.

⁵ Section 1860D-2(e) of the Act.

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

Although the officials indicated that CMS had updated its list of ED drugs in CY 2008, CMS accepted PDE data for some ED drugs during our entire audit period.

RECOMMENDATIONS

We recommend that CMS:

- determine whether it can impose financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction 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 ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction,
 - regularly disseminating this list to all sponsors, and
 - periodically updating the edit used to reject PDE data for ED drugs used for the treatment of sexual or erectile dysfunction.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our first recommendation and described corrective actions it was taking. For our second recommendation, CMS concurred that it should strengthen internal controls and said that it has taken action on implementing PDE edits to reject ED drugs in its systems. However, CMS did not concur that it should (1) collaborate with FDA to create and maintain a comprehensive list of ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction and (2) regularly disseminate the list to sponsors. CMS said that it is updating NDC-based PDE edits on a weekly basis to reject ED drugs and added that “Part D sponsors are aware of the requirement that ED drugs are excluded and our existing PDE edits eliminate the need for an additional drug list.” CMS’s comments appear in their entirety as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

Nothing in CMS’s comments has caused us to change our findings or recommendations. As the administrator of the Medicare Part D program, CMS has the primary responsibility to ensure that sponsors are administering their Part D plans appropriately. CMS officials informed us during the audit that edits were in place during the period of review to reject ED drugs in its systems. Moreover, in its comments, CMS stated that it is updating these edits on a weekly basis. However, the edits in place during the period of review were not entirely successful in preventing CMS from accepting PDE data for the ED drugs listed in Appendix A. Therefore, we continue to recommend that CMS regularly disseminate a list of ED drugs approved by FDA for the treatment of sexual or erectile dysfunction to all sponsors to ensure compliance within the Part D program.

APPENDIXES

**APPENDIX A: SUMMARY OF MEDICARE PART D ERECTILE DYSFUNCTION DRUGS
USED FOR THE TREATMENT OF SEXUAL OR ERECTILE DYSFUNCTION**

National Drug Code	Trade Name	Questioned Costs for 2007	Questioned Costs for 2008	Total Questioned Costs
00002-4462-10	Cialis tablets		\$681	\$681
00002-4462-34	Cialis tablets		2,574	2,574
00002-4463-30	Cialis tablets	\$2,906		2,906
00002-4464-30	Cialis tablets	14,414		14,414
00002-4465-34	Cialis tablets		1,811	1,811
00009-5181-01	Caverject impulse powder for injection	850		850
00009-5182-01	Caverject impulse alprostadil for injection	17,340		17,340
00009-7686-04	Caverject sterile powder for injection	998		998
00069-4200-30	Viagra tablets	5,791		5,791
00069-4210-30	Viagra tablets	20,585		20,585
00069-4210-66	Viagra tablets	603		603
00069-4220-30	Viagra tablets	1,804,916	1,216,559	3,021,475
00069-4220-66	Viagra tablets	4,556		4,556
00085-1901-01	Levitra tablets	2,214		2,214
00085-1934-01	Levitra tablets	9,174		9,174
00085-1945-01	Levitra tablets	342		342
62541-0120-06	Muse suppositories	145		145
62541-0140-06	Muse suppositories	741		741
Total		\$1,885,575	\$1,221,625	\$3,107,200

APPENDIX B: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



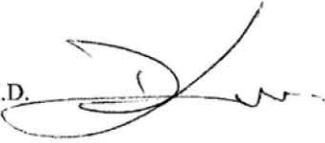
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN 0 5 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D.
Administrator 

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Erectile Dysfunction Drugs in the Medicare Part D Program" (A-07-10-03143)

Thank you for the opportunity to review and comment on the subject draft report. This report finds that the Centers for Medicare & Medicaid Services (CMS), during the period from 2007 and 2008 did not reject prescription drug event (PDEs) for drugs used for Erectile Dysfunction (ED) due to an incomplete drug filter.

The OIG recommendations and CMS responses are provided below.

OIG Recommendation

CMS should determine whether it can impose financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction.

CMS Response

The CMS concurs with the OIG's recommendation and will examine the feasibility of imposing financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction. Our determination regarding the feasibility of imposing financial adjustments in this situation will be based on whether it is appropriate and cost effective to reopen the final payment determinations for Calendar Year (CY) 2007 and/or CY 2008 to recover the costs of claims for drugs used for the treatment of sexual or erectile dysfunction paid in those years.

OIG Recommendation

CMS should strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by collaborating with the Food and Drug Administration (FDA) to create and maintain a comprehensive list of ED drugs that have been approved by FDA

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for the treatment of sexual or erectile dysfunction and regularly disseminate this list to all sponsors.

CMS Response

The CMS concurs with the OIG's recommendation to strengthen internal controls, and CMS has already taken action on implementing PDE edits to reject ED drugs in our systems and is updating these National Drug Code (NDC) based edits on a weekly basis. Therefore, we do not concur with the OIG that CMS and FDA should create a list of ED drugs to be sent to our sponsors. Part D sponsors are aware of the requirement that ED drugs are excluded and our existing PDE edits eliminate the need for an additional drug list. We believe that the creation and distribution of such a list would not further enhance the efficacy of our existing PDE edits in preventing Medicare payment for ED drugs.

OIG Recommendation

CMS should strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by periodically updating the edit used to reject PDE data for ED drugs used for the treatment of sexual or erectile dysfunction.

CMS Response

The CMS concurs with this recommendation, and acted on it in 2008 when we developed additional system functionality to update NDC edits on a weekly basis. We implemented this functionality in 2009, and have continued to update NDC edits since then.

We again thank you for the opportunity to review and comment on the OIG subject draft report.