



December 23, 2011

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of Excluded Providers in the Medicare Part D Program (A-07-10-06004)

The attached final report provides the results of our review of excluded providers 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, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-07-10-06004 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
EXCLUDED PROVIDERS IN
THE MEDICARE
PART D PROGRAM**



Daniel R. Levinson
Inspector General

December 2011
A-07-10-06004

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 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.

Excluded Providers

Section 1862(e)(1) of the Act and Federal regulations at 42 CFR § 1001.1901 (b)(1) prohibit payment under Medicare, Medicaid, and other Federal health care programs for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs (excluded providers) when the person dispensing the prescription knows or has reason to know of the exclusion until these providers are reinstated. CMS’s *Prescription Drug Benefit Manual*, chapter 9, § 50.2.6.3.3, states that sponsors should (a) review the exclusion list maintained by the U.S. Department of Health and Human Services, Office of Inspector General (OIG), to identify excluded providers and (b) have a process in place to deny claims for prescriptions written by excluded providers.

Pursuant to section 1128 of the Act, OIG established a nationwide program to exclude individuals and entities from participation in Medicare, Medicaid, and other federally funded health care programs. To administer this program, OIG maintains a database of all currently excluded providers called the List of Excluded Individuals/Entities. Monthly, OIG provides updates to CMS. CMS uses the monthly updates to maintain its database of excluded providers, the Medicare Exclusion Database (MED).

Prescriber Identifiers

CMS requires sponsors to enter a prescriber identifier in the PDE record for all pharmacy claims submitted under the Part D program. CMS guidance to sponsors states that sponsors should make all reasonable efforts to use a prescriber’s national provider identifier (NPI) in the prescriber identifier data field. (NPIs are assigned by CMS to identify health care providers and other entities in electronic health care transactions.) Because not all prescribers are required to

have an NPI, CMS guidance also makes provisions for the use of alternative identifiers, such as State license numbers, in this data field.

OBJECTIVE

Our objective was to determine whether CMS accepted PDE data submitted by sponsors for prescriptions written under the Part D program by excluded providers.

SUMMARY OF FINDINGS

Contrary to Federal law, CMS accepted some PDE data submitted by sponsors for prescriptions written under the Part D program by excluded providers and used these PDE data to adjust Medicare Part D payments to sponsors at the end of the plan year. Of approximately \$185 billion in gross drug costs included in sponsors' PDE data for calendar years 2006 through 2008, CMS accepted PDE data with gross drug costs totaling \$15,079,608 for prescriptions written by excluded providers.

Furthermore, CMS accepted PDE data with gross drug costs totaling an additional \$1,985,315 for prescriptions that may have been written by excluded providers. The PDE records for these prescriptions contained State license numbers as prescriber identifiers, but State license numbers are not unique identifiers and may be duplicated from one State to another. Therefore, State license numbers cannot reliably verify that a provider is not excluded.

CMS accepted PDE data submitted by sponsors for prescriptions written by excluded providers because it had inadequate internal controls in place during our review. Specifically, CMS did not provide sponsors with access to the MED to accurately and effectively identify excluded providers. In addition, CMS allowed sponsors to use State license numbers. CMS also did not have an edit in place to reject PDE data submitted by sponsors for prescriptions written by excluded providers.

RECOMMENDATIONS

We recommend that CMS:

- to resolve improper Part D payments made for prescriptions written by excluded providers, reopen and revise calendar year 2006 through 2008 final payment determinations to remove prescriptions written by excluded providers and
- strengthen internal controls to ensure that, in accordance with Federal regulations, prescriptions written by excluded providers are not paid under the Part D program by:
 - researching and incorporating into the MED all of the provider identifiers that CMS allows sponsors to use,
 - providing sponsors with access to the MED and requiring them to use the MED to ensure that prescriptions written by excluded providers are not accepted,

- prohibiting sponsors from using State license numbers in the prescriber identifier field of PDE records, and
- establishing an edit that would reject any PDE data submitted by sponsors for prescriptions written by excluded providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our first recommendation but added that it would explore the feasibility and cost-effectiveness of implementing it. CMS partially concurred with the four parts of our second recommendation and described corrective actions that it had taken or planned to take.

CMS's comments appear in their entirety as the Appendix.

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.

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INTRODUCTION

BACKGROUND

Medicare Part D Prescription Drug Coverage

Title I of the Medicare Prescription Drug Program, 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.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 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 that enables 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) 2006 through 2008, sponsors submitted final PDE data associated with approximately \$185 billion in gross drug costs. CMS defines gross drug costs as the sum of the following PDE payment fields: noncovered plan pay amount; covered plan pay 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, which would include amounts paid by third-party payers such as private group health plans (*Instructions: Requirements for Submitting Prescription Drug Event Data*, section 7.2.3).

Sections 1860D-14 and -15 of the Act require CMS to 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 certain 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.

Excluded Providers

Section 1862(e)(1) of the Act and Federal regulations at 42 CFR § 1001.1901(b)(1) prohibit payment under Medicare, Medicaid, and other Federal health care programs for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs (excluded providers) when the person dispensing the prescription knows or has reason to know of the exclusion until these providers are reinstated. CMS’s *Prescription Drug Benefit Manual*, chapter 9, § 50.2.6.3.3, states that sponsors should (a) review the exclusion list maintained by the U.S. Department of Health and Human Services, Office of Inspector General

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

(OIG), to identify excluded providers and (b) have a process in place to deny claims for prescriptions written by excluded providers.

Pursuant to section 1128 of the Act, OIG established a nationwide program to exclude individuals and entities from participation in Medicare, Medicaid, and other federally funded health care programs. OIG must exclude a provider convicted of a criminal offense related to Medicare or any State health care program, a criminal offense related to patient abuse or neglect, or a felony related to other health care fraud or to the misuse of controlled substances. In addition, OIG, at its discretion, may exclude a provider convicted of a misdemeanor health care fraud offense, a criminal offense related to fraud in non-health-care programs, an obstruction of an investigation, or a misdemeanor controlled substance offense. The effect of an OIG exclusion is that no Federal health care program may pay for any items or services furnished, ordered, or prescribed by an excluded provider when the person dispensing the prescription knows or has reason to know that the prescriber is excluded. OIG can waive an exclusion because a provider is the sole community physician or sole source of essential specialized services in a community.

To administer this program, OIG maintains a database of all currently excluded providers called the List of Excluded Individuals/Entities (LEIE). The LEIE is available on the OIG Web site in two formats: an online searchable database and a downloadable database. The online searchable database allows individuals to search for an excluded provider and to confirm the identity of an individual using a Social Security number (SSN) or employer identification number (EIN). The downloadable database includes an excluded provider's specialty, exclusion dates, and unique physician identifier number (UPIN) but does not include an excluded provider's SSN or EIN. OIG, Office of Investigations, obtains the national provider identifier (NPI) of the excluded providers as well; however, the NPI is not available on the searchable database or the downloadable database.² Monthly, OIG provides updates to CMS that include excluded providers' SSNs and EINs. CMS uses the monthly updates to maintain its database of excluded providers, the Medicare Exclusion Database (MED).

CMS developed the MED to store and allow the retrieval of information that helps Medicare ensure that payments are not made to excluded providers for services furnished during their exclusion periods. The MED identifies the same excluded providers as the LEIE and contains additional identifying information, such as an excluded provider's NPI.

CMS provides the MED files to various entities, including Medicare administrative contractors, fiscal intermediaries, and Medicaid State agencies, involved in administering the Medicare and Medicaid programs under the oversight of CMS. However, CMS does not provide this information to sponsors.

² UPINs were formerly assigned by CMS to identify physicians enrolled in the Medicare program. CMS discontinued the use of UPINs as of June 2007 and replaced them with NPIs. NPIs are assigned by CMS to identify health care providers and other entities for use in electronic health care transactions.

Prescriber Identifiers

Federal regulations at 45 CFR § 162.406 designate the NPI as the standard unique health identifier for electronic health care transactions. Entities that are required to obtain NPI numbers include health plans and health care providers that transmit any health information electronically in connection with transactions covered by Federal regulations (45 CFR § 160.102(a)).

CMS requires sponsors to enter a prescriber identifier in the PDE record for all pharmacy claims submitted under the Part D program. In May 2008, CMS indicated in a memorandum to sponsors that it prefers that sponsors use the NPI to complete the prescriber identifier data field,³ but CMS does not require all prescribers to have an NPI. When the prescriber does not have an NPI or when the pharmacy cannot obtain a prescriber's NPI, the sponsor may substitute an alternative identifier in the prescriber identifier data field. Alternative identifiers that sponsors have used include Drug Enforcement Agency (DEA) numbers, State license numbers, and UPINs.⁴

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether CMS accepted PDE data submitted by sponsors for prescriptions written under the Part D program by excluded providers.

Scope

The audit scope covered approximately \$185 billion in gross drug costs reflected in sponsors' final PDE data for CYs 2006 through 2008.

We limited our internal control review to CMS's policies and procedures for preventing reimbursement of prescriptions written under the Part D program by excluded providers. We did not review the accuracy or completeness of the PDE data.

We conducted our audit from March 2009 to August 2010.

³ CMS memorandum, "Prescriber Identifier on Part D NCPDP [National Council Prescription Drug Program] Pharmacy Claims Transactions," May 1, 2008.

⁴ A DEA number is a unique number assigned by DEA to handlers of controlled substances, including manufacturers, hospitals, pharmacies, and prescribers. A State license number is assigned to health care providers by the various State licensing boards. CMS guidance to sponsors does not include provisions for the use of UPINs as alternative identifiers; however, during our audit period, UPINs were used as prescriber identifiers in some PDE records.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials responsible for the administration of the Part D program and OIG, Office of Investigations, officials responsible for the administration of the LEIE;
- obtained the LEIE database as of May 31, 2009;
- obtained prescriber identifiers associated with excluded providers, including DEA numbers, State license numbers, and additional UPINs not included in the LEIE;
- obtained the PDE records for prescriptions written under the Part D program by excluded providers for CYs 2006 through 2008; and
- discussed our findings with CMS officials on December 16, 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 findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Contrary to Federal law, CMS accepted some PDE data submitted by sponsors for prescriptions written under the Part D program by excluded providers and used these PDE data to adjust Medicare Part D payments to sponsors at the end of the plan year. Of approximately \$185 billion in gross drug costs included in sponsors' PDE data for CYs 2006 through 2008, CMS accepted PDE data with gross drug costs totaling \$15,079,608 for prescriptions written by excluded providers.

Furthermore, CMS accepted PDE data with gross drug costs totaling an additional \$1,985,315 for prescriptions that may have been written by excluded providers. The PDE records for these prescriptions contained State license numbers as prescriber identifiers, but State license numbers are not unique identifiers and may be duplicated from one State to another. Therefore, State license numbers cannot reliably verify that a provider is not excluded.

CMS accepted PDE data submitted by sponsors for prescriptions written by excluded providers because it had inadequate internal controls in place during our review. Specifically, CMS did not provide sponsors with access to the MED to accurately and effectively identify excluded providers. In addition, CMS allowed sponsors to use State license numbers. CMS also did not have an edit in place to reject PDE data submitted by sponsors for prescriptions written by excluded providers.

PRESCRIPTIONS WRITTEN BY EXCLUDED PROVIDERS

Section 1862(e)(1) of the Act and Federal regulations at 42 CFR § 1001.1901(b)(1) prohibit payment under Medicare, Medicaid, and other Federal health care programs for prescriptions written by excluded providers when the person dispensing the prescription knows or has reason to know that the prescriber is excluded until a provider is reinstated.

Contrary to Federal regulations, of approximately \$185 billion in gross drug costs included in sponsors' PDE data during CYs 2006 through 2008, CMS accepted PDE data with gross drug costs totaling \$15,079,608 for prescriptions written by excluded providers. CMS used these PDE data when it reconciled Medicare Part D payments to sponsors at the end of the plan year.

Furthermore, CMS accepted PDE data with gross drug costs totaling an additional \$1,985,315 for prescriptions that may have been written by excluded providers. The PDE records for these prescriptions contained State license numbers in the provider identifier data field. State license numbers may be duplicated from one State to another; therefore, they cannot reliably verify that a provider is not excluded.

INADEQUATE CONTROLS TO PREVENT ACCEPTANCE OF PRESCRIPTIONS WRITTEN BY EXCLUDED PROVIDERS

CMS accepted PDE data submitted by sponsors for prescriptions written by excluded providers because it had inadequate internal controls during our review. Specifically:

- CMS's *Prescription Drug Benefit Manual*, chapter 9, § 50.2.6.3.3, states that sponsors should (a) review the LEIE to identify excluded providers and (b) have a process in place to deny claims for prescriptions written by excluded providers. However, because the LEIE does not currently contain the prescriber identifiers that are generally used in Medicare Part D, sponsors may not have been able to identify prescriptions written by excluded providers as quickly as they could have if they had access to the MED. Sponsors could more effectively identify excluded providers if CMS were to give the sponsors the same access to the MED that other entities, such as Medicare administrative contractors, fiscal intermediaries, and Medicaid State agencies, already have. The MED contains additional identifying information, such as an excluded provider's NPI, that would assist CMS in ensuring that it does not accept PDE data submitted by sponsors for prescriptions written by excluded providers. However, to effectively identify all excluded providers, the MED must contain all of the prescriber identifiers that CMS allows the sponsors to use.
- CMS allowed sponsors to use State license numbers that are not unique and are not listed on the LEIE or MED in the prescriber identifier data field of PDE records. Because State license numbers may be duplicated from one State to another, they are not credible sources for unique prescriber identifiers.

- CMS did not have an edit in place to reject PDE data submitted by sponsors for prescriptions written by excluded providers. Without an edit, CMS had to rely on sponsors to identify and deny claims for prescriptions written by excluded providers.

RECOMMENDATIONS

We recommend that CMS:

- to resolve improper Part D payments made for prescriptions written by excluded providers, reopen and revise CY 2006 through 2008 final payment determinations to remove prescriptions written by excluded providers and
- strengthen internal controls to ensure that, in accordance with Federal regulations, prescriptions written by excluded providers are not paid under the Part D program by:
 - researching and incorporating into the MED all of the provider identifiers that CMS allows sponsors to use,
 - providing sponsors with access to the MED and requiring them to use the MED to ensure that prescriptions written by excluded providers are not accepted,
 - prohibiting sponsors from using State license numbers in the prescriber identifier field of PDE records, and
 - establishing an edit that would reject any PDE data submitted by sponsors for prescriptions written by excluded providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first recommendation but added that it would explore the feasibility and cost-effectiveness of implementing it. CMS partially concurred with our second recommendation and described corrective actions that it had taken or planned to take. A summary of CMS's comments regarding our second recommendation and our responses follows. CMS's comments appear in their entirety as the Appendix.

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.

Controls for Researching and Incorporating All of the Provider Identifiers Into the Medicare Exclusion Database

Centers for Medicare & Medicaid Services Comments

CMS stated that it began providing MED monthly files, which include the NPI among other provider identifying information, to sponsors in July 2011.

Office of Inspector General Response

Although CMS said that it was now providing the MED to sponsors, CMS did not address our recommendation to research and incorporate into the MED all of the provider identifiers that CMS allows sponsors to use. To ensure that sponsors accurately and efficiently identify those prescribers that have been excluded, CMS must ensure that the MED is comprehensive and contains all of the identifiers associated with each excluded provider. We therefore continue to recommend that CMS research and incorporate the missing provider identifiers into the MED.

Controls for Providing Sponsors Access to the Medicare Exclusion Database and Requiring Them To Use It To Identify Excluded Providers

Centers for Medicare & Medicaid Services Comments

CMS said that it communicated system changes and expanded the distribution of the MED files to all sponsors. CMS also stated that it will provide a monthly MED file to all sponsors that signed up to receive it. CMS added that its existing guidance to sponsors instructs them to use the OIG exclusion list (that is, the LEIE) and to use the MED in concert with that list, not in lieu of it.

Office of Inspector General Response

The measures that CMS described in its comments should adequately address this part of our second recommendation.

Controls for Prohibiting Sponsors From Using State License Numbers in the Prescriber Identifier Field of Prescription Drug Event Records

Centers for Medicare & Medicaid Services Comments

CMS stated that it is considering rulemaking to require the exclusive use of the NPI for prescriber identifiers on Part D PDEs.

Office of Inspector General Response

Allowing the use of alternative provider identifiers increases the risk that a sponsor would not appropriately identify and prevent payments associated with an excluded provider. Until CMS implements a rule that requires the exclusive use of the NPI, sponsors will continue to use

alternative provider identifiers that may not be readily identifiable or that may, as in the case of State license numbers, be duplicated from one State to another.

Controls for Establishing an Edit That Would Reject Prescription Drug Event Data Submitted by Sponsors for Prescriptions Written by Excluded Providers

Centers for Medicare & Medicaid Services Comments

CMS agreed that it would be ideal for CMS to establish an edit that would reject any PDE data submitted by sponsors for prescriptions written by excluded providers but would need to determine the efficacy of such an edit.

Office of Inspector General Response

Without an edit in place, CMS is relying on sponsors to identify prescriptions written by excluded providers. This is an unrealistic expectation given the number of sponsors and the variability in the efficacy of their controls. Furthermore, sponsors may not be able to adequately identify excluded providers if they are not receiving and using a comprehensive MED. The edit that we are recommending would be an effective control for denying payments for prescriptions written by excluded providers.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



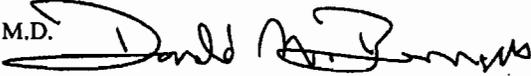
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP 21 2011

TO: Daniel R. Levinson
Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Excluded Providers in the Medicare Part D Program" (A-07-10-06004)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled "*Review of Excluded Providers in the Medicare Part D Program*". The purpose of this audit was to determine whether CMS accepted prescription drug event (PDE) data submitted by sponsors for prescriptions written under the Part D program by excluded providers.

The CMS has taken significant actions in the last few months to ensure that payments under Medicare for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs are not made. In July 2011, CMS began providing Part D plan sponsors with monthly Medicare Exclusion Database (MED) files that reflect the monthly updates provided by OIG to the list of Excluded Individuals/Entities (LIEIE). Unlike the LIEIE, the MED files include excluded providers' National Provider Identifier (NPI)—the prescriber identifier used by Part D plan sponsors on approximately 90 percent of PDEs, greatly facilitating sponsors' ability to ensure they are not improperly paying for drugs prescribed by an excluded provider. In addition, CMS issued guidance to all Part D plan sponsors reminding them of the prohibition against making payments for a prescription written by an excluded provider.

We appreciate the OIG's efforts in working with CMS in identifying vulnerabilities in the Medicare program. Our response to each of the OIG recommendations follows:

OIG Recommendation

To resolve improper Part D payments made for prescriptions written by excluded providers, CMS should reopen and revise calendar year 2006 through 2008 final payment determinations to remove prescriptions written by excluded providers.

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CMS Response

The CMS concurs with this recommendation. The CMS agrees with the OIG's goal to resolve improper Part D payments made for prescriptions written by excluded providers. However, CMS needs to explore whether it is feasible and cost-effective to reopen final payment determinations for calendar years 2006 through 2008 to recover the portion of the estimated \$17 million in gross drug costs for prescriptions written by excluded providers which was paid for by Medicare.

OIG Recommendation

The CMS should strengthen internal controls to ensure that, in accordance with Federal regulations, prescriptions written by excluded providers are not paid under the Part D program.

CMS Response

The CMS partially concurs with this recommendation. Detailed responses to each of this recommendation's sections follow.

(a) By researching and incorporating into the MED all of the providers' identifies that CMS allows sponsors to use.

The CMS began providing MED monthly files to Part D plan sponsors in July 2011. These files contain the following provider identifying information: name, SSN, UPIN, NPI, NSC number, and EIN number. CMS believes that the addition of the NPI will enhance the ability of plan sponsors to identify excluded providers.

(b) By providing sponsors with access to the MED and requiring them to use the MED to ensure that prescriptions written by excluded providers are not accepted.

CMS released a MED newsletter to all Part D plans sponsors. The MED Newsletter communicated system changes and expansion of the distribution of the MED file to all Part D plan Sponsors. The newsletter contained enrollment instructions for Part D plan sponsors to receive monthly MED files as well as information on a web based system that allows users to download provider sanctions and re-instatement files. Plan sponsors who signed up to receive the MED will receive a monthly MED file via a secure connection and gain access to historic MED file information via the MED website. MED files were made available to all participating Part D plan sponsors in July 2011.

In addition, existing guidance requires Part D sponsors to utilize the OIG exclusion list to ensure that prescriptions written by excluded providers are not paid under the part D program. The existing guidance instructs plan sponsors to use the MED in concert with the OIG exclusion list, not in lieu of it.

(c) By prohibiting sponsors from using State license numbers in the prescriber identifier field of PDE records.

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As stated in the 2012 Call Letter issued April 4, 2011, CMS is considering rulemaking to require the exclusive use of the NPI for prescriber identifiers on Part D PDEs.

(d) By establishing an edit that would reject any PDE data submitted by sponsors for prescriptions written by excluded providers.

The CMS agrees that it would be ideal for CMS to establish an edit that would reject any PDE data submitted by sponsors for prescriptions written by excluded providers. However, CMS needs to determine the efficacy of such an edit.

Again, we appreciate the opportunity to comment on this draft report and look forward to working with OIG on this and other issues.