DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

February 2, 2011

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

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs (A-14-09-00302)

The attached final report provides the results of our review of the oversight of the prescriber identifier field in Prescription Drug Event data for Schedule II drugs.

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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-14-09-00302 in all correspondence.

Attachment

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

OVERSIGHT OF THE PRESCRIBER IDENTIFIER FIELD IN PRESCRIPTION DRUG EVENT DATA FOR SCHEDULE II DRUGS

Daniel R. Levinson
Inspector General

February 2011
A-14-09-00302

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

BACKGROUND

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 program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

To provide prescription drug benefits under Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with private entities called Part D sponsors that act as payers and insurers. The sponsors must provide a minimum set of prescription benefits, referred to as the "basic" benefit. Sponsors may offer these benefits through a standalone prescription drug plan or as part of a managed care plan, known as a Medicare Advantage Prescription Drug Plan.

Pursuant to section 1860D-15(c)(1)(C) and (d)(2) of the Act and 42 CFR § 423.322(a), sponsors must submit the information necessary for CMS to carry out Part D payment provisions for the coverage year. Sponsors submit Prescription Drug Event (PDE) records as part of the required information. PDE data are used for payment purposes, as well as for quality monitoring, program integrity, and oversight. Sponsors complete the PDE record using information provided by the pharmacy responsible for filling the prescription. In calendar year (CY) 2007, a PDE record contained 37 fields. The prescriber identifier (ID) field is filled by a number identifying the prescriber (physician, dentist, or other licensed person) who is permitted to write prescriptions. The prescriber ID field should generally contain one of four types of identification: a Drug Enforcement Administration (DEA) number, a National Provider Identifier, a Unique Physician Identification Number, or a State license number.

The Controlled Substances Act established five schedules based on the medical use acceptance and the potential for abuse of the substance or drug. The Attorney General has the authority to reclassify a substance or drug. Schedule II drugs have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused. Except in emergency situations or when dispensed directly by a practitioner other than a pharmacist to an ultimate user, Schedule II prescription drugs may not be dispensed without a practitioner's written prescription.

OBJECTIVE

Our objective was to determine whether PDE records for Schedule II drugs contained valid prescriber IDs and whether CMS and sponsors performed any edits on the prescriber ID field.

SUMMARY OF FINDINGS

For CY 2007, the Schedule II gross drug costs for approximately 228,000 PDE records with invalid prescriber ID totaled approximately $20.6 million. With limited guidance and edits in place for the prescriber ID field, CMS and the sponsors have not identified these invalid prescriber IDs in the PDE records. Additionally, through our separate analysis of three

Schedule II drugs that are most often reported in investigations, we were unable to identify the top prescribers for oxycodone, Ritalin, and methadone.

RECOMMENDATION

We recommend that CMS:

- issue specific guidance requiring sponsors to include a valid DEA number on both standard and nonstandard format PDE records involving Schedule II drugs and

- implement an edit to reject PDE records for Schedule II drugs when the prescriber ID field contains an invalid prescriber ID number.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS did not concur with our recommendations. CMS indicated as it begins to implement additional safeguards related to the prescriber ID, it must continue to balance its dual interests in monitoring program vulnerabilities with ensuring that Medicare beneficiaries have access to critical medications. CMS stated that the use of the DEA number is not suitable as a single ID because only a fraction of PDE volume involves Schedule II drugs.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We respect CMS's need to balance monitoring program vulnerabilities with beneficiaries' access to medications. Accordingly, we modified our first recommendation. Implementing this recommendation would not have any impact on Medicare beneficiaries' access to critical medications. Establishing the National Provider Identifier as a standardized prescriber ID for PDE records is important, but it is also important to require that sponsors include a valid DEA number on PDE records involving Schedule II drugs. The DEA number is the only ID type that indicates whether prescribers are registered to prescribe Schedule II drugs and is necessary for the effective monitoring of aberrancies in the PDE data related to Schedule II drugs.

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INTRODUCTION

BACKGROUND

Medicare Part D

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 program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage. To provide prescription drug benefits under Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with private entities called Part D sponsors that act as payers and insurers. The sponsors must provide a minimum set of prescription benefits, referred to as the "basic" benefit. Sponsors may offer these benefits through a standalone prescription drug plan or as part of a managed care plan, known as a Medicare Advantage Prescription Drug Plan.

Prescription Drug Event Data

Pursuant to section 1860D-15(c)(1)(C) and (d)(2) of the Act and 42 CFR § 423.322(a), sponsors must submit the information necessary for CMS to carry out Part D payment provisions for the coverage year. Sponsors submit Prescription Drug Event (PDE) records as part of the required information. PDE data are used for payment purposes, as well as for quality monitoring, program integrity, and oversight. A PDE record contains the prescription drug cost, payment information, identification numbers of entities or people involved (such as a physician, pharmacy, and beneficiary), and specific drug provided for each Part D prescription drug transaction.

Sponsors complete the PDE record using information provided by the pharmacy responsible for filling the prescription. In calendar year (CY) 2007, a PDE record contained 37 fields. The prescriber identifier (ID) field is filled by a number identifying the prescriber (physician, dentist, or other licensed person) who is permitted to write prescriptions.[1] The prescriber ID field should generally contain one of four types of identification: a Drug Enforcement Administration (DEA) number, a National Provider Identifier (NPI), a Unique Physician Identification Number (UPIN), or a State license number. The prescriber ID qualifier field shows the ID type that is entered in the prescriber ID field. In May 2008, CMS indicated that it prefers that sponsors use the NPI to complete the prescriber ID field.[2]

For prescription drug claims submitted in the NCPDP standard format, the common industry format, CMS requires that an entry be made in the prescriber ID field.[3] However, an entry is

[1] CMS, *Updated Instructions: Requirements for Submitting Prescription Drug Event Data*, April 27, 2006.

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

[3] CMS memorandum, "National Provider Identifier (NPI) Implementation for Prescription Drug Events (PDEs)," April 16, 2007.

optional in the prescriber ID field for those prescription drug claims transmitted to the sponsor in any format other than the NCPDP standard format. Examples of a nonstandard format include a claim submitted by a beneficiary or a paper claim submitted by a provider. Approximately 2 percent of all the 2007 PDE data was submitted in a nonstandard format.

Controlled Substances

The Controlled Substances Act[4] established five schedules based on the medical use acceptance and the potential for abuse of the substance or drug. Schedule I, which include drugs or substances that have no currently accepted medical use and a high potential for abuse, is the most restrictive, and Schedule V is the least restrictive. The Attorney General has the authority to reclassify a substance or drug.

Schedule II drugs have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused.[5] Except in emergency situations or when dispensed directly by a practitioner other than a pharmacist to the ultimate user, Schedule II prescription drugs may not be dispensed without a practitioner's written prescription.[6] Schedule II drugs include drugs such as oxycodone and morphine.

A physician must register with the DEA to prescribe controlled substances. In addition, a physician has to be authorized to prescribe controlled substances by the State where he or she practices.[7] Therefore, some physicians are not registered to prescribe Schedule II drugs.

Abuse of Controlled Substances Related to Health Care Fraud

The abuse of controlled substances impacts both the Medicare program and the Medicaid program. For example, the Government Accountability Office (GAO) recently reported on fraud and abuse related to controlled substances in Medicaid. Its report noted that some physicians overprescribed controlled substances to beneficiaries. Its report also identified payments for drug claims that were prescribed by providers who were deceased, as well as by providers who were excluded[8] from doing business in Federal health care programs.[9] The report concluded that the abuse of controlled substances is a concern for Federal health care programs.

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[4] 21 U.S.C. §§ 801-971.

[5] 21 U.S.C. § 812(b)(2).

[6] 21 U.S.C. § 829(a).

[7] Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Practitioner's Manual: An Informational Outline of the Controlled Substances Act*, 2006 edition.

[8] 42 CFR § 1001.1901. An excluded provider cannot receive payment from Medicare, Medicaid, or other Federal programs. CMS will not pay for items or services ordered or prescribed by an excluded provider, including prescriptions. See also CMS, *Part D Manual*, chap. 9, § 50.2.6.3.3. Sponsors are required to deny claims for drugs prescribed or provided by an excluded provider.

[9] GAO, *Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States*, GAO-09-957, September 9, 2009.

We learned that several physicians have been found guilty of fraudulently prescribing Schedule II drugs. These illegal practices included but were not limited to prescribing without a legitimate doctor's office visit, prescribing without a legitimate medical purpose, and collusion with the pharmacy. In at least one case, a patient died because a physician illegally prescribed controlled substances.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether PDE records for Schedule II drugs contained valid prescriber IDs and whether CMS and sponsors performed any edits on the prescriber ID field.

Scope

We limited our review to all PDE records for Schedule II drugs with dates of service during CY 2007, which covered approximately $1.6 billion in gross drug costs. We included both NCPDP standard and nonstandard formatted PDE records for which prescriber IDs were a DEA number, an NPI, or a UPIN. We excluded records for which the prescriber ID number type was a State license because these records made up only 1.2 percent of the total CY 2007 PDE records and because we were unable to obtain information containing valid State license numbers.

Because our objective did not require an assessment of the internal control structure, we did not perform such a review of CMS or any sponsor. We limited our review of internal controls to obtaining an understanding of how CMS and the 10 selected sponsors maintained and monitored PDE records of Schedule II drugs. We also did not independently verify the validity of the responses to the questionnaires that we sent.

We performed our fieldwork at the Baltimore, Maryland, Centers for Medicare & Medicaid Audits office and at Coventry (a sponsor) in Harrisburg, Pennsylvania, from January 2009 through April 2010.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations and CMS guidance;
- interviewed CMS officials about the guidance governing (1) the PDE data, (2) the oversight program to control fraud, waste, and abuse, and (3) any concerns with PDE data or compliance plans;
- obtained CY 2007 PDE data;
- identified the Schedule II drugs and analyzed the prescriber ID field that either had a DEA number, an NPI, or a UPIN;

- determined that the prescriber ID was invalid when its field had a number that
    - was not listed in the DEA, NPI, and UPIN databases,
    - did not correspond to a prescriber with the authority to prescribe a Schedule II drug,
    - was identified as belonging to a pharmacy[10] (by comparing all prescriber IDs to the NCPDP Pharmacy database that contained NPI and DEA numbers of pharmacy providers to determine whether the prescriber ID belonged to a pharmacy), or
    - was not recorded (a blank field);
- determined the total number of PDE records and gross drug costs for CY 2007 Schedule II drugs and total number of PDE records and gross drug costs for CY 2007 Schedule II drugs associated with invalid prescriber IDs;
- obtained information from the selected sponsors on their monitoring and oversight of the PDE data, specifically the edits performed on the prescriber ID field within the PDE record;
- judgmentally selected 10 sponsors, which collectively processed approximately 76 percent of gross drug costs for the invalid and blank prescriber IDs that we identified;[11]
- interviewed officials of the 10 selected sponsors regarding their monitoring and oversight of their PDE data;
- consulted with law enforcement to identify three Schedule II drugs frequently involved in health care investigations (i.e., oxycodone, Ritalin, and methadone); and
- attempted to determine the top 10 prescribers for those three Schedule II drugs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

[10] The NCPDP Pharmacy database contains information about the retail pharmacies in the United States and Puerto Rico classified as chains, independents, and franchises.

[11] CMS's *Updated Instructions: Requirements for Submitting Prescription Drug Event Data*, April 27, 2006, section 7.2.3, defines gross drug costs as the sum of the following six 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 due to other payer amount.

FINDINGS AND RECOMMENDATIONS

We determined that not all PDE records for Schedule II drugs contained valid prescriber IDs. For CY 2007, the Schedule II gross drug costs for approximately 228,000 PDE records with invalid prescriber IDs totaled approximately $20.6 million.[12] Both CMS and sponsors performed edits on the prescriber ID qualifier and prescriber ID fields. However, these edits did not detect or prevent invalid prescriber IDs. Neither CMS nor the sponsors identified these invalid prescriber IDs in the PDE records. Additionally, through our separate analysis of three Schedule II drugs, we were unable to identify the top prescribers for the three Schedule II drugs that we analyzed using CY 2007 PDE records.

INVALID PRESCRIBER IDENTIFIERS

All Schedule II Drugs in Calendar Year 2007

For CY 2007, the Schedule II gross drug costs for approximately 228,000 PDE records with invalid prescriber ID totaled approximately $20.6 million. The types of invalid prescriber IDs fell into four categories. The gross drug costs for PDE records with a prescriber ID not listed in the DEA, NPI, or UPIN databases were approximately $13.0 million. The CY 2007 Schedule II gross drug costs for PDE records with a prescriber ID (i.e., DEA numbers[13]) that did not indicate that the prescriber had the authority to prescribe a Schedule II drug were approximately $4.1 million. The CY 2007 Schedule II gross drug costs for PDE records with pharmacy prescriber IDs were approximately $3.2 million. The CY 2007 Schedule II gross drug costs for PDE records without any prescriber ID, i.e., blank data fields, were approximately $307,000.

Three Specific Schedule II Drugs

We were unable to identify high volume prescribers for oxycodone, Ritalin, and methadone. Those were the three drugs we established in discussions with law enforcement officials that had a high risk of being abused. Specifically, for oxycodone and Ritalin, we were unable to identify the top two prescribers because of invalid prescriber IDs. For methadone, we were unable to identify the second top prescriber because of invalid prescriber IDs.[14] The invalid prescriber IDs used for these drugs were AA0000000 and 99999999.

[12] Of the approximately 228,000 PDE records that had invalid prescriber IDs, 16,000 (7 percent) were nonstandard format records and 212,000 (93 percent) were standard format records.

[13] We were unable to determine whether the prescriber had the authority to prescribe Schedule II drugs for those PDE records that utilized a UPIN or an NPI in the prescriber ID field.

[14] The results of our separate analysis of oxycodone, Ritalin, and methadone have been shared with both the Office of Inspector General's Office of Investigations and CMS for potential further investigation.

INSUFFICENT EDITS

Centers for Medicare & Medicaid Services Guidance

Pursuant to section 1860D-4(c)(1)(D) of the Act, sponsors are required to have a program to control fraud, waste, and abuse. CMS's *Prescription Drug Benefit Manual*, chapter 9, provides guidance for sponsors in the areas of fraud, waste, and abuse in the Part D program. However, this guidance does not advise the sponsors to monitor the validity of the prescriber ID field in the PDE record to control fraud, waste, and abuse in the Part D program.

In chapter 9, the guidance on fraud, waste, and abuse as it relates to the prescriber and the prescription drug claims is limited. CMS recommends that sponsors comply with applicable criminal statutes such as the Controlled Substance Act, have written policies and procedures to identify prescribers that are excluded or deceased, and monitor claims to determine excessive prescribing of controlled substances.[15]

Centers for Medicare & Medicaid Services Edits

CMS had edits in place to ensure the accuracy of PDE records submitted in the standard format. A PDE record is organized into three levels: file level (provides information to identify the submitter); batch level (provides information to identify the drug or managed care plan); and detail level (includes the information from each PDE record). Two systems perform the checks of the data: the Prescription Drug Front-End System performs the edits at the file and batch levels, and Drug Data Processing System (DDPS) performs the edits at the detail level.

During CY 2007, the DDPS performed edits related to the prescriber ID and prescriber ID qualifier field to determine only whether the prescriber ID field was filled and the prescriber ID qualifier field contained one of the four qualifier codes. If these edits detected errors, the sponsor received an error report and was responsible for correcting and resubmitting the PDE data. Although CMS had edits in place, these edits did not check the validity of the prescriber ID field and whether a prescriber ID indicated that the prescriber had the authority to prescribe Schedule II drugs. Of the four types of identification used in the prescriber ID field, a DEA number is the only identifier that documents that the prescribers are registered to prescribe Schedule II drugs.

Sponsor Edits

Most selected sponsors stated that their monitoring efforts included edits such as checking the logical format of the prescriber ID number. However, the selected sponsors did not perform any other edits to determine invalid prescriber IDs. Other edits might include comparisons to a database to determine if DEA numbers are valid. In addition, we noted prescriber ID logical format errors still existed in the sponsors' submitted CY 2007 PDE records.

[15] CMS, *Prescription Drug Benefit Manual*, chapter 9, April 25, 2006.

CONCLUSION

Having a valid prescriber ID in the PDE record is a valuable program integrity safeguard. Without the valid information from the sponsors, in particular the prescriber ID number, CMS and its Part D contractors cannot properly monitor and oversee the Part D program to detect, prevent, and control fraud, waste, and abuse. Without this information, CMS and its Part D contractors might not be able to monitor excessive prescribing patterns, determine whether a prescription was written by an excluded or deceased provider, or identify those physicians who illegally prescribe Schedule II drugs.

RECOMMENDATIONS

We recommend that CMS:

- issue specific guidance requiring sponsors to include a valid DEA number on both standard and nonstandard format PDE records involving Schedule II drugs and

- implement an edit to reject PDE records for Schedule II drugs when the prescriber ID field contains an invalid prescriber ID number.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS did not concur with our recommendations. CMS indicated as it begins to implement additional safeguards related to the prescriber ID, it must continue to balance its dual interests in monitoring program vulnerabilities with ensuring that Medicare beneficiaries have access to critical medications.

CMS stated that the use of the DEA number is not suitable as a single ID because only a fraction of PDE volume involves Schedule II drugs. CMS will evaluate its authority to mandate the use of the NPI as the standardized prescriber ID through rulemaking. In response to our second recommendation, CMS stated that it did not know whether on implementation of the single ID, it would be feasible to reject PDE records for Schedule II drugs. However, CMS acknowledged the need to strengthen its requirements related to prescriber ID numbers and indicated that it is planning to institute new edits to check that the format of the prescriber ID is correct. CMS added that if it implements a requirement for the single prescriber ID, it would also expect to implement a process for verifying the accuracy of that number.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We respect CMS's need to balance monitoring program vulnerabilities with beneficiaries' access to medications. Accordingly, we modified our first recommendation. Implementing this recommendation would not have any impact on Medicare beneficiaries' access to critical medications.

While establishing the NPI as a standardized prescriber ID for PDE records is important, it is also important to require that sponsors include a valid DEA number on PDE records involving Schedule II drugs. The DEA number is the only ID type that indicates whether prescribers are registered to prescribe Schedule II drugs and is necessary for the effective monitoring of aberrancies in PDE data related to Schedule II drugs.

With respect to CMS's plans to implement new edits to check the format of the prescriber ID, we note that such edits alone are not sufficient to ensure that PDE data include a valid prescriber ID. We found instances in which the prescriber ID would pass a format check but the ID was not a valid number. For example, the prescriber ID number associated with the largest number of prescriptions for oxycodone and Ritalin was AA0000000. This number would have passed a format check.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 1 0 2010

TO: Daniel R. Levinson
Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs (A-14-09-00302)

Thank you for the opportunity to review and comment on the subject OIG draft report, which provides the results of the OIG's review of the oversight of the prescriber identifier (ID) field in Prescription Drug Event (PDE) data for Schedule II drugs. The objective of the study was to determine whether PDE records for Schedule II drugs contained valid prescriber IDs and whether the Centers for Medicare & Medicaid Services (CMS) and sponsors performed any edits on the prescriber ID field. The OIG used data from calendar year 2007 to conduct the study.

CMS shares the OIG's concern regarding the potential for abuse of controlled substances in Federal health care programs. As CMS begins to implement additional safeguards related to the prescriber ID, we must continue to balance our dual interests in monitoring program vulnerabilities with ensuring that Medicare beneficiaries have access to critical medications. For the reasons stated below, we do not concur with either of the OIG's recommendations.

OIG Recommendation

The OIG recommends that CMS issue specific guidance to plan sponsors regarding PDE records involving Schedule II drugs that requires sponsors to complete the prescriber ID field with a valid Drug Enforcement Administration (DEA) number for both standard and nonstandard format PDE records.

CMS Response

CMS does not concur with this recommendation. While CMS recognizes the need to move to the use of a standardized prescriber ID for PDE records, we believe use of the DEA number is not suitable as the single ID because only a fraction of the PDE volume involves Schedule II drugs. Therefore, CMS will evaluate our authority to mandate use of the National Provider Identifier (NPI) as the standardized prescriber identifier for PDE records, and expects to

undertake rulemaking as necessary to address the use of that single prescriber ID for PDE records.

OIG Recommendation

The OIG recommends that CMS implement an edit to reject PDE records for Schedule II drugs when the prescriber ID field contains an invalid prescriber ID number.

CMS Response

CMS does not concur with the recommendation to reject PDE records that do not contain a valid prescriber ID because we believe it is premature. As noted above, CMS is still considering the issue of the use of the NPI as the standardized prescriber ID for PDE records, and, thus, we do not know at this time whether, upon implementation of that single ID through rulemaking as appropriate, it would be feasible to reject PDE records for Schedule II drugs as the OIG recommends. However, we agree that we should work toward strengthening our requirements related to prescriber ID numbers. To that end, CMS plans to institute new edits to check that the format of the prescriber ID is correct on PDEs. Second, to the extent we implement a requirement for the use of a single prescriber ID, we would also expect to implement a process for verifying the accuracy of that number.

CMS appreciates the effort that went into this report. Again, we thank the OIG for the opportunity to review and comment on this draft report.