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CMS ENSURED NEARLY ALL PART D DRUG RECORDS CONTAINED VALID PRESCRIBER IDENTIFIERS IN 2016

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CMS Ensured Nearly All Part D Drug Records Contained Valid Prescriber Identifiers in 2016

Why OIG Did This Review

Prescriber identifiers are a valuable program integrity safeguard. They enable the Centers for Medicare & Medicaid Services (CMS) and Part D plan sponsors to determine if legitimate practitioners have prescribed drugs for enrollees. Plan sponsors are required to include prescriber identifiers on the Part D prescription drug event (PDE) records they submit to CMS. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires that, beginning in 2016, pharmacy claims for covered Part D drugs must contain valid prescriber National Provider Identifiers (NPIs). Additionally, the law requires the Secretary of the Department of Health and Human Services to establish procedures for determining the validity of these prescriber NPIs. The law also requires the Office of Inspector General (OIG) to submit to Congress a report on the effectiveness of these procedures no later than January 1, 2018. This evaluation report fulfills OIG's MACRA mandate.

How OIG Did This Review

We compared the prescriber NPIs on calendar year 2016 PDE records submitted to CMS for covered drugs to the NPIs in CMS's National Plan and Provider Enumeration System (NPPES) file. NPPES is the system of record for health care providers' NPIs. We considered prescriber NPIs to be invalid if (1) they did not appear in the NPPES file, or (2) they appeared in the NPPES file but had been deactivated before January 1, 2015, and remained deactivated through 2016. We reviewed CMS documentation and its responses to a questionnaire regarding its procedures to determine the validity of Part D prescriber NPIs.

What OIG Found

Of the 1.5 billion PDE records that plan sponsors submitted to CMS for covered drugs in 2016, we found only 147 records that contained invalid prescriber identifiers. These records represented $19,122 in Part D payments. The 147 PDE records were associated with 70 invalid prescriber identifiers, which accounted for a small percentage (0.005) of the 1.4 million unique prescriber identifiers on the PDE records in our review. Specifically, 1 invalid NPI was not listed in the NPPES file, and the remaining 69 invalid NPIs had been deactivated more than 1 year prior to the dates of service on associated PDE records.

Key Takeaways

- **Nearly all PDE records for Part D drug claims in 2016 contained valid prescriber NPIs.**
- **System edits that CMS has in place are effective in ensuring the validity of the vast majority of Part D prescriber NPIs.**

CMS has system edits in place to review PDE records to determine whether prescriber identifiers are valid NPIs. These edits reject PDE records (1) that do not contain a prescriber identifier that is an NPI in CMS's current NPPES file and (2) where the date of service is more than 1 year after a prescriber NPI has been deactivated. Regarding the one NPI that was not listed in the NPPES file noted above, CMS stated that this invalid identifier had bypassed its PDE system editing and that CMS is in the process of determining if its edit logic can be modified. For the PDE records associated with the 69 deactivated prescriber NPIs noted above, the dates of service occurred during a time when the date-of-service edit was operating as an informational edit rather than a reject edit. This suggests that CMS accepted these PDE records because the edit flagged—rather than rejected—these records. This edit was changed to a reject edit in May 2016. Additionally, CMS has provided plan sponsors with the procedures they should follow to ensure the validity of prescriber NPIs.

What OIG Concludes

The system edits that CMS currently has in place to check PDE records are effective in ensuring the validity of the vast majority of Part D prescriber NPIs.

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OBJECTIVES

1. To determine the extent to which invalid National Provider Identifiers (NPIs) were used as prescriber identifiers on Part D prescription drug event (PDE) records for calendar year 2016.
2. To identify how the Centers for Medicare & Medicaid Services (CMS) ensures the validity of prescribers' NPIs on claims for covered Part D drugs.

BACKGROUND

Previous Office of Inspector General (OIG) work has emphasized that prescriber identifiers on PDE records submitted to CMS by Part D plan sponsors are a valuable program integrity safeguard. These identifiers enable CMS and Part D plan sponsors to determine who prescribed covered drugs for Medicare enrollees. Prescriber identifiers on PDE records can be used to determine if legitimate practitioners have prescribed drugs for enrollees, including during post-payment reviews and investigations. Since OIG's prior work on prescriber identifiers was issued, CMS has made efforts to strengthen prescriber requirements to protect the integrity of the Part D program.

This study fulfills the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) mandate for OIG to evaluate the effectiveness of the procedures used to validate Part D prescriber NPIs and provide a report of the results of the evaluation to Congress no later than January 1, 2018.[1]

Medicare Part D Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Part D to provide an optional prescription drug benefit for all Medicare beneficiaries. Private companies, called plan sponsors,[2] administer the benefit through Part D drug plans. Plan sponsors provide Part D benefits to enrollees and process claims for prescriptions submitted by network pharmacies at the point of sale. Plan sponsors later submit PDE records based on these claims to CMS for payment calculations. In 2016, 43 million Medicare beneficiaries were enrolled in Medicare Part D

[1] P.L. 114-10 (April 16, 2015) § 507.

[2] For the purpose of this report, we use the term "plan sponsors" to refer to stand-alone Medicare prescription drug plan sponsors and Medicare Advantage prescription drug plan sponsors. We use the term "Part D plans" to refer to both of these sponsors' plans.

plans, and total Part D program expenditures (excluding administrative expenses) were $99.5 billion.[3]

Part D Prescription Drug Events

Pursuant to §1860D-15(c)(1)(C) and (d)(2) of the Social Security Act, all Part D plan sponsors must submit certain data and information to CMS as a condition of payment. Part D plans submit an electronic record to CMS for each covered prescription filled by their enrollees. This electronic record, the PDE record, contains drug cost and payment data fields as well as prescriber identifier fields that enable CMS to administer the Part D benefit. Plan sponsors submitted 1.5 billion PDE records to CMS in 2016.

Prescriber Identifier Requirements

Part D plan sponsors are required to include prescriber identifiers on the PDE records they submit to CMS.[4] Specifically, as of January 1, 2013, CMS required sponsors to submit an active and valid NPI to identify the prescriber on a PDE record (allowing for a group NPI in cases where the prescriber had not yet obtained an individual NPI). Beginning May 6, 2013, the "Prescriber ID" field on the PDE record must contain the individual NPI of the prescriber.[5, 6]

MACRA Requirements. Section 1860D-4(c) of the Social Security Act, as amended by section 507 of MACRA, requires that, beginning in plan year 2016, i.e., calendar year, pharmacy claims for covered Part D drugs must contain a valid prescriber NPI.[7] MACRA section 507 requires the Secretary of the Department of Health and Human Services to establish procedures for determining the validity of the prescriber NPIs included on Part D drug claims. Appendix A provides the full text of section 507 of MACRA.

National Provider Identifier. The administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 mandated that the Secretary of the Department of Health and Human Services adopt a standard unique health identifier for health care

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[3] *2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Washington, D.C. July 13, 2017. Accessed at http://www.cms.hhs.gov/reportstrustfunds/ on September 13, 2017.

[4] 42 CFR § 423.120(c)(5)(i). Beginning January 1, 2016, see 42 CFR § 423.120(c)(6)(i).

[5] CMS, *Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields*, October 1, 2012.

[6] According to CMS, a group NPI is permitted in the Prescriber ID field in limited circumstances to accommodate states of emergency.

[7] P.L. 114-10 (April 16, 2015) § 507.

providers.[8, 9] Individuals and organizations apply for and acquire a unique 10-digit NPI through CMS's National Plan and Provider Enumeration System (NPPES). Since May 23, 2008, NPIs have been used in Medicare to identify health care providers on all covered electronic health care transactions.

Related OIG Work

In a June 2010 report, OIG found that Medicare drug plans and enrollees paid pharmacies $1.2 billion in 2007 for more than 18 million prescription drug claims that contained invalid prescriber identifiers.[10] At the time of the study, the NPI was not required to be reported in the Prescriber ID field on Part D drug claims, and less than 4 percent of drug claims contained NPIs. OIG recommended that CMS conduct periodic reviews to ensure the validity of Part D prescriber identifiers, and that CMS require Part D plan sponsors to identify invalid prescriber identifiers on Part D drug claims and flag those claims for review. CMS concurred with and implemented OIG's recommendations.

Additionally, a February 2011 OIG report found that in 2007 Schedule II gross drug costs for PDE records with invalid prescriber identifiers totaled approximately $20.6 million.[11] This amount represented approximately 228,000 PDE records for Schedule II drugs that contained invalid prescriber identifiers. OIG recommended that CMS (1) require sponsors to include a valid DEA number on all PDE records involving Schedule II drugs and (2) implement an edit to reject PDE records for Schedule II drugs that contain an invalid prescriber identifier number. CMS implemented the second but not the first recommendation. CMS stated that it pursued requiring only valid prescriber NPIs on PDE records. In addition, CMS stated that section 507 of MACRA reinforced this approach by also requiring only valid prescriber NPIs on Part D pharmacy claims.

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[8] P.L. 104-191 (August 21, 1996) § 262(a), amending § 1173 of the Social Security Act.

[9] Beginning May 23, 2005, providers were able to start applying for an NPI. CMS, *MLN Matters,* Number MM4320, January 1, 2006. Accessed at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4320.pdf on June 20, 2017.

[10] OIG, *Invalid Prescriber Identifiers on Medicare Part D Drug Claims* (OEI-03-09-00140), June 2010.

[11] The Controlled Substances Act (21 U.S.C. § 812) established five drug schedules based on the medical use acceptance and the potential for abuse of a 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. OIG, *Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs* (A-14-09-00302), February 2011.

METHODOLOGY

Data Collection and Analysis

We focused this review on determining the extent to which invalid prescriber NPIs were used on Part D PDE records submitted to CMS for covered drugs for 2016. We used data from three sources to conduct this review: (1) CMS's Part D PDE records, (2) CMS's NPPES data, and (3) CMS's responses to an information request.

Prescriber Identifiers on PDE Records. From CMS's Part D PDE data, we created a file of PDE records with dates of service from January 1, 2016, to December 31, 2016. We excluded PDE records for noncovered and over-the-counter drugs from our analysis.[12] After these exclusions, the file contained 1.5 billion PDE records. In addition, we obtained from CMS a copy of the NPPES file, which contains information for both active and deactive NPIs.

To determine whether NPIs in the prescriber identifier field on PDE records were valid, we compared prescriber NPIs to the NPPES file. We considered prescriber NPIs on PDE records to be valid if they were active in 2016, or if they were active at any point during 2015 to allow time for prescription refills in 2016. We considered prescriber NPIs to be invalid if (1) they did not appear in the NPPES file or (2) they appeared in the NPPES file but had been deactivated before January 1, 2015, and remained deactivated through 2016.

We calculated the number of PDE records for 2016 that contained invalid NPIs and calculated total Part D payments for these PDE records. We summed four payment fields to calculate total Part D payments for PDE records with invalid prescriber identifiers: "Ingredient Cost Paid," "Dispensing Fee Paid," "Total Amount Attributed to Sales Tax," and "Vaccine Administration Fee."

We examined the characteristics of the invalid prescriber NPIs such as an NPI having an inappropriate length or format. In addition, we examined whether invalid prescriber NPIs were associated with certain Part D sponsors, drug codes, or pharmacies.

CMS's Procedures to Ensure Validity of Prescriber Identifiers. To determine the procedures that CMS has established to validate Part D prescriber NPIs, we developed and provided a self-administered questionnaire to CMS staff. As part of the questionnaire, we requested

[12] The value "C" in the "Drug Coverage Status Code" field on the PDE record indicates a Part D-covered drug. The value "E" in this field indicates an enhanced alternative drug, i.e., a non-Part D, noncovered drug; the value "O" indicates an over-the-counter drug.

that CMS provide documentation of all policies and procedures it has in place to ensure that Part D prescriber NPIs are valid. We reviewed CMS's responses and the associated documentation and summarized CMS's policies and procedures for determining the validity of Part D prescriber NPIs.

Limitations

We did not validate the accuracy of the NPPES data file that we used to verify prescriber identifiers on PDE records.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Nearly all PDE records for Part D drug claims in 2016 contained valid prescriber identifiers

MACRA required that, beginning in 2016, pharmacy claims for covered Part D drugs contain valid prescriber NPIs. Of the 1.5 billion PDE records that plans submitted to CMS for covered drugs in 2016, we found only 147 PDE records that contained invalid prescriber identifiers. These 147 PDE records with invalid prescriber identifiers represented $19,122 in Part D payments. Individually, the PDE payments ranged from a minimum of $1.48 for a 4 days' supply of Prednisone tablets to a maximum of $7,947.88 for a 90 days' supply of Fosrenol.

These 147 PDE records were associated with 70 invalid prescriber identifiers, which accounted for a small percentage (0.005) of the 1.4 million unique prescriber identifiers on the PDE records in our review. The number of PDE records associated with each of these invalid prescriber identifiers ranged from 1 to 17 records.

One invalid prescriber NPI was not listed in the NPPES database

One of the 70 invalid prescriber identifiers on 2016 PDE records did not match to any NPI contained in the NPPES database. This invalid identifier appeared in the expected length and format of an NPI,[13] but it contained an incremental sequence of numbers in the first nine positions of the identifier. This invalid NPI was used on three PDE records to identify the prescriber as well as the pharmacy that filled the enrollee prescription.

In response to our inquiry about this invalid identifier, CMS reported that the invalid identifier had bypassed CMS's PDE system editing. Prescriber identifier editing was bypassed because the same identifier was used in the prescriber identifier and service provider identifier fields on the PDE records. An exception to prescriber identifier editing exists to accommodate states of emergency in which a pharmacy may serve as both prescriber and service provider on a PDE record. At this point, the PDE records would have undergone further editing to check the validity of the service provider identifier. In this case, however, the service provider editing was bypassed because the PDE records were for vaccines, which are typically administered by an individual practitioner rather than dispensed as a prescription by a pharmacy. CMS stated that it is in the process of determining if its edit logic can be modified. If not, CMS

[13] NPIs are 10-digit numbers beginning with a 1, 2, 3 or 4.

stated that it will perform data analysis and exclude PDEs with invalid NPIs during the Part D payment reconciliation process.

Sixty-nine invalid prescriber NPIs were deactivated more than 1 year prior to dates of service on PDE records

Sixty-nine of the seventy invalid NPIs had been deactivated in NPPES prior to January 1, 2015. These NPIs were used as prescriber identifiers on 144 PDE records from 2016, but they had been deactivated between March 2009 and December 2014. For the purpose of this review, we considered prescriber NPIs to be valid if they were active in 2016 or if they were active at any point during 2015, to allow for prescription refills in 2016.

On average, the 69 NPIs had been deactivated 3 years prior to the dates of service on the PDE records. Assigned NPIs may be deactivated when, for example, a health care provider dies or when a provider goes out of business. The earliest deactivation date among these NPIs was March 3, 2009—7 years prior to the May 4, 2016, date of service on the PDE record that contained this invalid prescriber NPI.

Three plan sponsors accounted for half of the PDE records that contained invalid prescriber NPIs

Forty Part D plan sponsors each submitted at least one PDE record for 2016 that contained an invalid prescriber NPI. Of these plan sponsors, 3 submitted half (74 of 147) of the PDE records that contained invalid prescriber identifiers. One plan sponsor submitted 46 PDE records that were associated with 16 different invalid prescriber NPIs.

Additionally, while some prescription drug codes and pharmacies appeared in the PDE data more frequently than others, no individual drug code or pharmacy represented a considerable portion of the PDE records that contained invalid prescriber NPIs.

CMS has system edits to reject PDE records with invalid prescriber identifiers

CMS has system edits in place to review Part D prescriber information on PDE records submitted by Part D plan sponsors. Two edits are used specifically to determine whether prescriber identifiers on PDE records are valid NPIs. Edit 833 is a reject edit used to determine whether the prescriber identifier on a PDE record is an individual NPI in CMS's

current NPPES file.[14] Our analysis of 2016 PDE records for covered drugs identified one invalid prescriber identifier that did not match to any NPI contained in CMS's NPPES file. As noted above, in response to our inquiry about this invalid identifier, CMS reported that this identifier had bypassed CMS system editing and that it is in the process of determining if its edit logic can be modified.

CMS's Edit 834 rejects PDE records in which the date of service is more than 1 year after the prescriber NPI has been deactivated.[15] CMS allows the date of service on a PDE record to be within 1 year of the NPI deactivation date to accommodate State prescribing laws that permit refills up to 1 year after a prescriber has died. However, from February 9, 2014, through May 7, 2016, CMS had modified Edit 834 to function as an informational edit rather than a reject edit, due to State laws that allow for prescriptions beyond the 1-year time period. As noted above, we found 69 prescriber NPIs on the PDE records reviewed that had been deactivated in NPPES prior to January 1, 2015. The dates of service on the 144 PDE records associated with these 69 prescriber NPIs were between January 4, 2016, and May 7, 2016. This suggests that CMS accepted these PDE records because Edit 834 was operating as an informational edit during this time.

CMS has provided plan sponsors with the procedures they should follow to ensure the validity of prescriber NPIs

CMS issued a memorandum[16] on June 1, 2015, to all plan sponsors in which it described its existing Part D claims procedures with respect to prescriber NPIs and the changes to prescriber NPI requirements under section 507 of MACRA.

In the memorandum, CMS outlined the current Part D claims procedures of the National Council for Prescription Drug Programs. These procedures support the following actions regarding prescriber NPIs:

- A Part D sponsor communicates at point of sale to the pharmacy whether or not a submitted prescriber NPI is active and valid.

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[14] If Edit 833 triggers, the PDE record is rejected, and the message reported to the plan sponsor is, "The submitted Prescriber ID is not found on the CMS NPPES NPI table." CMS, *Updates to Prescriber ID Editing on the Prescription Drug Event (PDE) Record*, April 7, 2016.

[15] If Edit 834 triggers, the PDE record is rejected, and the message reported to the plan sponsor is, "The submitted Prescriber ID is not active on the CMS NPPES NPI table for the given DOS [Date of Service]." CMS, *Updates to Prescriber ID Editing on the Prescription Drug Event (PDE) Record*, April 7, 2016.

[16] CMS, *Medicare Part D Prescriber Enrollment Requirement Update*, June 1, 2015.

- A sponsor pays a claim if the sponsor determines that the prescriber NPI is active and valid.
- If the sponsor communicates that the prescriber NPI is not active and valid, but the pharmacy corrects the NPI or confirms that the NPI is active and valid because the pharmacy has so determined through more up-to-date information, the sponsor pays the claim.

In the memorandum, CMS stated that, in addition to these existing procedures, it interpreted section 507 of MACRA to mean that beginning January 1, 2016, a Part D sponsor cannot pay a claim that the sponsor determines does not have an active and valid prescriber NPI unless the pharmacy corrects the NPI or confirms that it is active and valid.

Also, CMS has issued additional memoranda to Part D plan sponsors describing the system edits that CMS has in place to ensure the validity of prescriber NPIs on PDE records.

CONCLUSION

Section 507 of MACRA requires that, beginning in 2016, pharmacy claims for covered Part D drugs must contain valid prescriber NPIs. In addition, the law requires the Secretary of the Department of Health and Human Services to establish procedures for determining the validity of Part D prescriber NPIs. The law also requires OIG to submit to Congress a report on the effectiveness of these procedures no later than January 1, 2018. This evaluation report fulfills OIG's MACRA mandate.

Based on an analysis of Medicare Part D PDE records for covered drugs submitted to CMS for 2016, we found that nearly all PDE records contained valid prescriber NPIs. Of the 70 invalid prescriber identifiers, 1 NPI was not listed in the NPPES database, and the remaining 69 had been deactivated more than 1 year prior to dates of service on PDE records. However, CMS currently has an edit in place to reject PDE records with dates of service of more than 1 year after a prescriber NPI has been deactivated. For the PDE records associated with the 69 deactivated prescriber NPIs noted above, the dates of service occurred during a time when the edit was operating as an informational edit rather than a reject edit.

We conclude that the system edits that CMS currently has in place are effective in ensuring the validity of the vast majority of Part D prescriber NPIs on PDE records. To address cases similar to the invalid prescriber identifier we found that was not in NPPES, CMS reported that it will consider revising its edit logic or, if that is not possible, ensure that PDEs with invalid NPIs are excluded during the Part D payment reconciliation process.

APPENDIX A: SECTION 507 OF MACRA

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114-10

SEC. 507. REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.

Section 1860D-4(c) of the Social Security Act (42 U.S.C. 1395w-104(c)) is amended by adding at the end the following new paragraph:

(4) REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

(A) IN GENERAL.— For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA-PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) PROCEDURES.—

(i) VALIDITY OF PRESCRIBER NATIONAL PROVIDER IDENTIFIERS.—The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) INFORMING BENEFICIARIES OF REASON FOR DENIAL.— The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) REPORT.—Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

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