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Providers Used Medicare Part D Eligibility Verification Transactions for Permissible Purposes

REPORT HIGHLIGHTS

December 2024 | A-05-22-00022

Providers Used Medicare Part D Eligibility Verification Transactions for Permissible Purposes

Why OIG Did This Audit

- Providers must use Part D eligibility verification transactions (E1 transactions) for the purposes of billing for a prescription or determining drug coverage billing order.
- An OIG audit of E1 transactions processed during calendar years 2013 through 2015 found that selected providers used E1 transactions for potentially impermissible purposes. In response to the prior audit, CMS officials implemented controls to monitor and help ensure the permissible use of E1 transactions.
- This audit of E1 transactions processed during calendar year 2019 determined whether providers used E1 transactions for the permissible purposes of billing for a prescription or determining drug coverage billing order.

What OIG Found

Providers used E1 transactions for the permissible purposes of billing for a claim or determining drug coverage billing order during our calendar year 2019 audit period. Of the more than 18.8 million E1 transactions covered by our audit, almost 13.5 million matched a prescription drug event (PDE) record. This match gave us reasonable assurance that the providers submitted the transactions for the permissible purpose of obtaining drug coverage information. For the remaining 5.3 million E1 transactions that providers submitted during our audit period but that did not directly match PDE records, we reviewed a statistical sample of 543 E1 transactions submitted by 24 randomly selected providers and determined that providers submitted the transactions for permissible purposes.

What OIG Recommends

Based on the results of this audit and the effectiveness of steps CMS and the Facilitator took during and after our prior audit of E1 transactions to improve provider compliance, we determined that any impermissible use of E1 transactions is not widespread. As a result, this audit report does not include any recommendations.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS AUDIT

Providers – typically pharmacies – use Medicare Eligibility Verification transactions known as E1 transactions to obtain or verify information about individuals' drug coverage on a real-time basis. A prior Office of Inspector General (OIG) audit of 30 non-statistically selected providers found that, during our calendar year (CY) 2013 through 2015 audit period, 25 of the 30 providers used E1 transactions for potentially impermissible purposes.[1] In response to our recommendations, the Centers for Medicare & Medicaid Services (CMS) took steps to help ensure the proper use of these transactions. Among other things, CMS:

- developed a list of approved taxonomy codes (such as those associated with pharmacies, ambulatory care sites, and long-term care facilities) and instructed its contractor to use that list to validate access rights for each submitter of an E1 transaction;[2] and

- instructed the E1 Transaction Facilitator (a CMS contractor) to send guidance to submitters of E1 transactions to help ensure awareness of: (1) Department of Health and Human Services prohibitions on sharing log-in information and (2) limits on the ways E1 transaction data may be used.

We conducted the current audit to determine whether the steps CMS took to address the prior findings were effective and whether the impermissible use of E1 transactions that we previously identified among a non-statistically selected set of providers in CYs 2013 through 2015 was widespread among the providers that submitted E1 transactions in CY 2019.[3]

OBJECTIVE

Our objective was to determine whether providers used E1 transactions for the permissible purposes of billing for a prescription or determining drug coverage billing order.

[1] *The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes* (A-05-17-00020) Feb. 11, 2020. We selected the 30 providers covered by this audit based on the results of a risk analysis.

[2] A taxonomy code is a unique 10-character code that designates a Medicare provider or supplier's classification and specialization.

[3] This was the most current data available when we initiated our audit.

BACKGROUND

Medicare Part D Prescription Drug Program

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program.

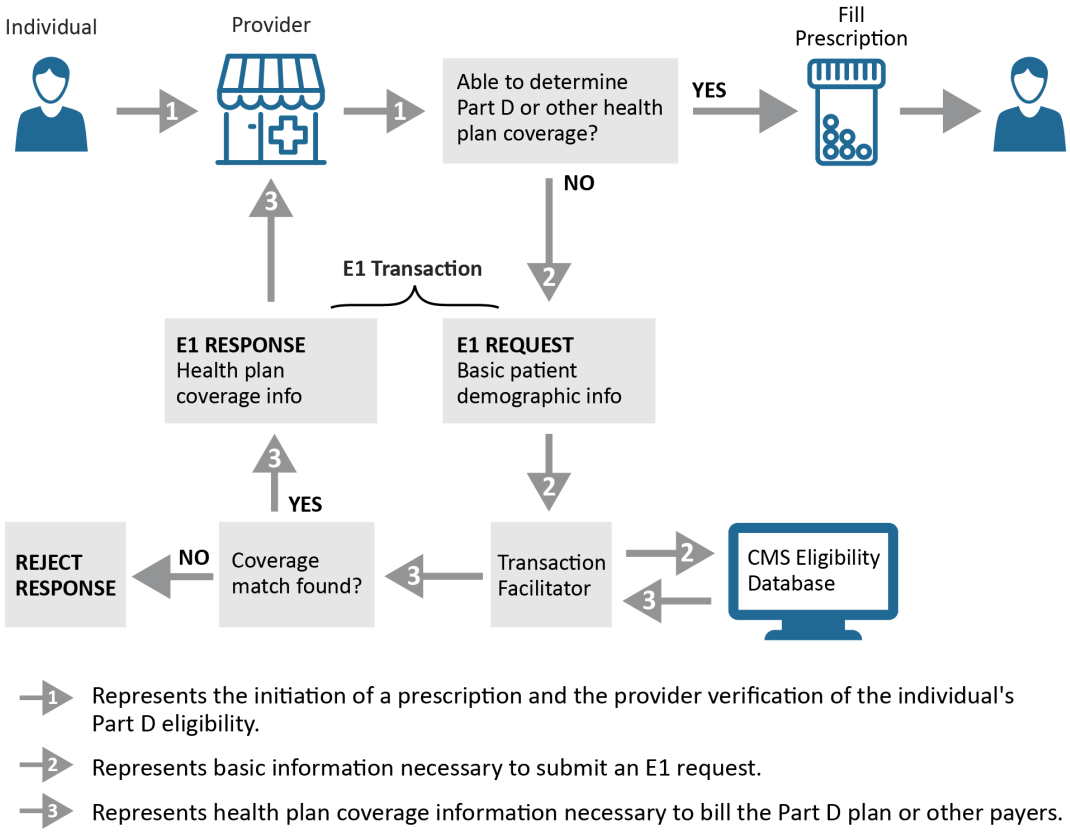
Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing a voluntary prescription drug benefit referred to as Medicare Part D. Under Part D, individuals entitled to benefits under Medicare Part A (Hospital Insurance) or enrolled in Part B (Medical Insurance) may obtain prescription drug coverage. CMS contracts with prescription drug plan sponsors to provide prescription drug coverage for Part D eligible individuals.

Medicare Part D E1 Transaction Process

An E1 transaction is an electronic transaction consisting of both a request and a response. Approved providers may submit E1 transaction requests to the Facilitator. These requests may be used for the purposes of determining: (1) individuals' Part D eligibility and other drug coverage information and (2) billing order when more than one source of insurance coverage exists. If a Medicare Part D coverage match is found in the CMS Eligibility Database, the Facilitator sends a response to the requestor that includes the individual's Medicare Part D plan information along with information about any other health insurance coverage. However, if no coverage match is found in the CMS Eligibility Database, the Facilitator sends a "reject" response to the requestor.[4] The figure on the following page illustrates the E1 transaction process.

[4] The CMS Eligibility Database contains eligibility information for every person enrolled in Medicare Part A, B, or D. The Eligibility Database also contains information on other health insurance that the individual may have supplemental to Medicare. CMS updates the Eligibility Database daily.

Figure: E1 Transaction Process



E1 transaction responses contain individuals' protected health information. To limit exposure of this sensitive information, it is important that providers use E1 transactions only for permissible purposes.

Federal Requirements

Federal regulations at 42 CFR section 423.464 require Part D sponsors to coordinate with other entities providing prescription drug coverage to determine whether costs for Part D eligible individuals are being reimbursed by another entity and whether such costs may be treated as incurred costs. Part of this coordination of benefits includes confirming coverage under Part D in preparation for filling a prescription initiated by a prescriber (which as we noted above is the intended purpose of the E1 transaction).

The Medicare Prescription Drug Benefit Manual states that pharmacies use an E1 transaction to determine an individual's Part D coverage information in real time. When an individual does not have their Part D plan card, pharmacies may submit an E1 transaction to retrieve the information needed to bill a prescription to an individual's Part D insurance plan or to determine the billing order when the individual has additional drug coverage (Pub. No. 100-18, chapter 14, § 30.4.1). In December 2015, CMS issued a memo clarifying what constitutes an

appropriate use of E1 transactions.[5] In the memo, CMS stated that the E1 transaction should be submitted "for Medicare purposes" and "that the data are used to support the coordination of benefits."

For our audit period, Federal regulations at 42 CFR section 423.160(b)(3) (2019 version), required providers that transmit prescriptions and prescription-related information using electronic media to adhere to guidance including Version D.0 of the National Council for Prescription Drug Programs' guide *Telecommunication Standard Implementation Guide Version D.0* (NCPDP guide).[6] Section 6.1.1 of the NCPDP guide states that, for Medicare Part D, the E1 transaction is used to determine patient eligibility. If a patient enrolled in Medicare Part D does not present a Medicare Part D identification card to the pharmacy provider, or the pharmacy provider wants to verify coverage, this transaction may be used to determine which plan(s) to bill and, if known, in what order. The Facilitator provides this information on the E1 response to the pharmacy provider. Section 3.2.1 of the NCPDP guide defines a "provider" as a retail pharmacy, mail-order pharmacy, doctor's office, clinic, hospital, long-term-care facility, or any other entity that dispenses prescription drugs and submits those prescriptions to a payer for reimbursement.

HOW WE CONDUCTED THIS AUDIT

Our audit covered the 18.8 million CY 2019 E1 transactions that resulted in a response from the Facilitator that included individual coverage information (i.e., these transactions did not result in a "reject" response). As discussed in the Results of Audit section below, we accepted as having been submitted for a permissible purpose the 13.5 million E1 transactions that corresponded with a prescription drug event (PDE) record. For the remaining 5.3 million E1 transactions (that did not correspond with a PDE record and which we refer to here as "unmatched" E1 transactions), we reviewed a statistical sample of 543 E1 transactions submitted by 24 randomly selected providers. We contacted the 24 providers and requested that they complete a survey and provide supporting documentation for the unmatched E1 transactions. We used the information we obtained from these providers to determine whether the sampled E1 transactions were requested for the permissible purposes of billing a prescription or determining billing order.

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 objectives.

[5] CMS, "Appropriate Access and Use of the Part D Eligibility Query," issued December 3, 2015.

[6] For the current related regulations, see 42 CFR § 423.160(b) (2024).

Appendix A contains the details of our audit scope and methodology, and Appendix B describes our statistical sampling methodology.

RESULTS OF AUDIT

Providers used E1 transactions for the permissible purposes of billing for a claim or determining drug coverage billing order during our CY 2019 audit period.

Of the 18.8 million E1 transactions covered by our audit, almost 13.5 million matched a PDE record. The fact that these 13.5 million E1 transactions corresponded with PDEs gave us reasonable assurance that the providers submitted the transactions for the permissible purpose of obtaining drug coverage information.

We were not able to match the remaining 5.3 million E1 transactions that providers submitted during our audit period to PDE records. The lack of a match to a PDE record indicated a risk that the E1 transactions were submitted for some purpose other than to bill for a claim or determine drug coverage billing order. As described in Appendix B, we reviewed a statistical sample of these unmatched E1 transactions to determine whether they were submitted for permissible purposes. Our sample consisted of as many as 30 unmatched E1 transactions submitted by 24 randomly selected providers for a total of 543 unmatched E1 transactions.[7] Although these 543 sampled transactions did not directly correspond with PDE records, we determined that the providers submitted them for permissible purposes. For example:

- Several sampled providers gave us information demonstrating that they submitted the sampled E1 transactions to prospectively verify coverage information for individuals who were residing in long-term care facilities.

- Some sampled providers (specifically, sampled hospitals) gave us information demonstrating that they submitted sampled E1 transactions to prospectively verify drug and other insurance coverage information in advance of possible hospital admissions.

One sampled provider was affiliated with a larger group of providers that each had its own National Provider Identifier (NPI) – a unique identifier that CMS assigns to covered health care providers in the United States. It was this group's practice to submit all E1 transactions using the NPI of a single provider within the group.[8] When we informed this sampled provider that

[7] Some of the randomly selected providers submitted fewer than 30 unmatched E1 transactions. In those instances, we reviewed each of the unmatched E1 transactions the provider submitted. Two of the twenty-four randomly selected providers closed after the audit period and before our fieldwork began. These 2 providers submitted 15 unmatched E1 transactions during our audit period. Because we could not obtain information from the closed providers, and to be conservative, we considered the 15 unmatched E1 transactions to have been submitted for permissible purposes.

[8] During our fieldwork, we alerted CMS to this issue and asked whether the practice was permissible. CMS officials told us that it is. The sampled provider told us that it was no longer submitting E1 transactions using the NPI of a related provider.

we were not able to match its E1 transactions to PDE records, the provider worked with us to match the E1 transaction with PDE records that had been submitted under that other NPI.

In addition, for a small number of E1 transactions in our sample, providers were not able to provide documentation supporting the permissible use of the transactions. However, these providers offered reasonable explanations as to why provider personnel believed coverage data was needed at the time the E1 request was made. For example, according to the sampled providers, E1 transactions are sometimes submitted for prescriptions that individuals choose not to fill or elect to have filled elsewhere. Providers also told us that responses from E1 requests are sometimes used to help resolve billing disputes. In cases such as these, the E1 transactions would not be expected to correspond with PDE records.

CONCLUSION

Since our initial audit, CMS and the Facilitator have taken steps to help ensure provider compliance with Federal requirements related to E1 transactions. Among other things, CMS and the Facilitator: (1) actively monitor the ratio of E1 transactions submitted to PDEs processed and follow up with providers that are identified as outliers, (2) exclude from submitting E1 transactions those providers that have been identified as using E1 transactions for impermissible purposes, and (3) enacted E1 transaction processing edits to ensure that coverage information is provided only to providers with NPIs associated with approved taxonomy codes.

Based on the results of this audit of E1 transactions processed during CY 2019 and the effectiveness of the steps CMS and the Facilitator have taken to improve compliance, we determined that any impermissible use of E1 transactions is not widespread. As a result, this audit report does not include any recommendations.

We shared our draft report with CMS, and it informed us that it did not have comments other than technical comments, which we addressed as appropriate.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered the 18.8 million CY 2019 E1 transactions that resulted in a response from the Facilitator that included coverage information (i.e., these transactions did not result in a "reject" response). As discussed in the Results section, we accepted as having been submitted for a permissible purpose all E1 transactions that corresponded with a PDE record. For the remaining

5.3 million "unmatched" E1 transactions, we reviewed a statistical sample of 543 transactions submitted by 24 randomly selected providers.

We reviewed CMS and Facilitator internal controls for limiting exposure of protected health information obtainable through the processing of E1 transactions.

We conducted audit work from August 2023 through November 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed information from CMS and the Facilitator related to actions taken based on the previous audit and current monitoring of providers submitting E1 transactions;
- obtained a database of CY 2019 E1 transactions from the Facilitator;
- matched E1 transactions to PDE records using Medicare enrollee identification numbers and dates of service (identified 13,492,033 E1 transaction that matched PDE records and 5,297,376 E1 transactions that did not match PDE records);[9]
- selected a stratified multistage random sample of 24 providers and 543 E1 transactions for review;
- requested that the sampled providers submit documentation supporting the purpose of sampled E1 transactions and complete a survey asking for information about:
    - any policies or procedures related to: (1) submitting E1 transactions; (2) using information obtained through E1 transaction responses; and (3) processing prescriptions for Part D enrollees;

[9] In performing this match, we identified PDE records dated within 90 days of the associated E1 transactions.

- any peculiarities or trends we identified in their submission of E1 transactions;
- why they submitted a large number of E1 transactions without processing prescriptions for beneficiaries with Part D coverage and documentation to support the explanation;

- reviewed supporting documentation and survey responses to determine whether providers used E1 transactions for permissible purposes; and
- discussed the results of our audit with CMS officials.

We shared our draft report with CMS, and it informed us that it did not have comments other than technical comments, which we addressed as appropriate.

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 objectives.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame of primary sample units was a list of the 56,272 unique providers[10] that submitted unmatched E1 transactions.[11]

Our sampling frame of secondary sample units consisted of 5,297,376 unmatched E1 transactions submitted by one of the unique providers (primary sample units). The sampling frame included only those E1 transactions submitted by providers who were not: (1) under OIG investigation, (2) excluded by CMS from submitting E1 transactions, or (3) on CMS's deactivated NPI list.

SAMPLE UNIT

The primary sample unit was a provider. The secondary sample unit was an unmatched E1 transaction.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified multistage sample design. First, we stratified the sampling frame of providers (primary sample units) into three strata according to the stratum bounds detailed in the table below.

Table 1: Division of Strata for Sample Design

Stratum	Stratum Bounds	Number of Providers	Number of Unmatched E1 Transactions
1	Providers with more than 10,000 unmatched E1 transactions	78	2,589,765
2	Providers with more than 1,000, but less than or equal to 10,000 unmatched E1 transactions	432	1,292,140
3	Providers with more than 0, but less than or equal to 1,000 unmatched E1 transactions	55,762	1,415,471
Total		**56,272**	**5,297,376**

[10] We aggregated E1 transactions that contained the same enrollee identifier, provider identifier, and date processed, and made an audit decision to accept as valid all unmatched E1 transactions in an aggregated row if any one of the transactions that comprise the row could be shown to have been submitted to bill for a prescription or to determine drug coverage billing order.

[11] In determining whether an E1 transaction was "unmatched," we compared the transaction to PDEs that occurred within 90 days before or after the E1 transaction.

Next, for each stratum, we randomly selected 8 providers and then a simple random sample of as many as 30 unmatched E1 transactions (secondary samples units) for each of those providers:

- for Stratum 1, we selected 8 providers with 240 E1 transactions;
- for Stratum 2, we selected 8 providers with 240 E1 transactions; and
- for Stratum 3, we selected 8 providers with 63 E1 transactions.[12]

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services, statistical software.

METHOD FOR SELECTING SAMPLED PROVIDERS AND UNMATCHED E1 TRANSACTIONS

We sorted the primary units in each stratum by a unique field, NPI number. We then consecutively numbered the items in each stratum. After generating random numbers for each of these strata, we selected the corresponding primary frame items for review.

We sorted the secondary units associated with each sampled primary unit by two fields that, taken together, form a unique identifier (Medicare Health Insurance Claim Number and Date Processed). We then consecutively numbered the sorted lists of secondary units. After generating random numbers for each of these strata, we selected the corresponding secondary frame items for review.

ESTIMATION METHODOLOGY

We have chosen not to report any estimates of unmatched E1 transactions in the sampling frame that were not used to bill for a prescription or to determine drug coverage billing order due to the low impermissible rate found in the sample.

[12] Some providers in stratum 3 had fewer unmatched E1 transactions than our maximum sample size. When that occurred, we reviewed all the provider's unmatched E1 transactions.

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