

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MAJORITY OF PROVIDERS
REVIEWED USED MEDICARE
PART D ELIGIBILITY
VERIFICATION TRANSACTIONS
FOR POTENTIALLY
INAPPROPRIATE PURPOSES**

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**February 2020
A-05-17-00020**

Office of Inspector General

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Report in Brief

Date: February 2020
Report No. A-05-17-00020

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

The Centers for Medicare & Medicaid Services (CMS) requested that OIG audit a mail-order pharmacy's Medicare Part D Eligibility Verification Transactions (E1 transactions). To address CMS's request, we conducted this audit of E1 transactions, which included the requested provider's transactions. During our audit, we discovered that providers were taking advantage of gaps in CMS's program integrity in E1 transactions. Because E1 transactions contain beneficiary protected health information (PHI), we wanted to verify that the providers were appropriately using E1 transactions for their intended purposes.

Our objective was to determine whether providers used E1 transactions to bill for a prescription or determine drug coverage billing order.

How OIG Did This Audit

We judgmentally selected 30 providers that submitted 3.9 million E1 transactions. We selected these 30 providers because they submitted a large volume of E1 transactions relative to the number of prescriptions processed. We matched E1 transactions to prescriptions within 90 days of an E1 transaction. The result was 2.6 million E1 transactions not matched to a prescription. We reviewed supporting documentation to determine whether providers used E1 transactions for appropriate purposes.

The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes

What OIG Found

The majority of providers (25 of 30) used E1 transactions for some purpose other than to bill for a prescription or determine drug coverage billing order. On average, 98 percent of these 25 providers' E1 transactions were not associated with a prescription. We did not contact 10 providers because they were closed, under investigation, or both. Fifteen providers submitted or hired other entities to submit E1 transactions for inappropriate purposes, which involved using a beneficiary's PHI.

After our audit period, CMS took additional steps to monitor use of the eligibility verification system and take appropriate enforcement action when abuse is identified.

The deficiencies we identified occurred because CMS had not yet (1) fully implemented controls to monitor providers submitting a high number of E1 transactions relative to prescriptions processed until after our audit period, (2) published clear guidance that E1 transactions are not to be used for marketing purposes, and (3) limited non-pharmacy access.

What OIG Recommends

We recommend that CMS (1) continue to monitor providers submitting a high number of E1 transactions relative to prescriptions processed, (2) issue guidance that clearly states that E1 transactions should not be used for marketing purposes, (3) ensure that only pharmacies and other authorized entities submit E1 transactions, and (4) take appropriate enforcement action when abuse is identified.

CMS concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Centers for Medicare & Medicaid Services (CMS) requested that the Office of Inspector General (OIG) audit a mail-order pharmacy's Medicare Part D Eligibility Verification Transactions (E1 transactions). To address CMS's request, we conducted this audit of E1 transactions by the requested provider and 29 additional providers.¹ A "provider" is defined 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. Providers must use E1 transactions for their intended purposes, which include determining a beneficiary's Medicare Part D coverage information to bill for a prescription or determining drug coverage billing order when the beneficiary is covered by more than one insurance plan. Because E1 transactions contain beneficiary protected health information (PHI),² we wanted to verify that the providers were using these E1 transactions for intended purposes.

OBJECTIVE

Our objective was to determine whether providers used E1 transactions to bill for a prescription or determine drug coverage billing order.

BACKGROUND

Administration of the Medicare 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 Medicare.

Medicare Part D Prescription Drug Program

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. CMS contracts with sponsors to provide prescription drug coverage for eligible individuals.

¹ For coordination purposes, OIG provided a copy of the report to HHS Office for Civil Rights.

² PHI includes demographic data, the individual's physical or mental health or condition, the provision of healthcare to the individual, the payment for the provision of healthcare to the individual, and information that identifies the individual or for which there is a reasonable basis to believe that it can be used to identify the individual (45 CFR § 160.103).

Medicare Part D E1 Transaction Process

In the early stages of development of the Part D program, CMS realized that pharmacies would need a mechanism to determine eligibility for Part D enrollees in real time at the point of sale. As a result, CMS and the pharmacy industry collaborated with the National Council for Prescription Drug Programs (NCPDP) to develop the E1 transaction. Currently, the E1 transaction is one of two methods available that allows pharmacies to determine Part D enrollment. The other method is seeing a beneficiary's Medicare Part D plan card. CMS contracts with a transaction facilitator to house Part D coverage information and respond to E1 transaction requests.

An E1 transaction is an electronic transaction consisting of both an E1 request and an E1 response. The provider submits an E1 request containing either (1) its NCPDP provider identification (ID) number³ or its National Provider Identifier (NPI) and (2) basic patient demographic information⁴ to the applicable switch,⁵ which forwards the E1 request to the transaction facilitator.⁶ The transaction facilitator matches the data contained in the E1 request to the CMS Eligibility file and returns an E1 response to the pharmacy through the applicable switch. An E1 response contains the beneficiary's Part D coverage information, which allows the pharmacy to bill the beneficiary's Part D plan and other payer(s), as applicable, after filling the beneficiary's prescription. (See Appendix B.)

Intended Purposes of E1 Transactions

Providers must use E1 transactions for their intended purposes, which are determining a beneficiary's Part D coverage information to bill for a prescription or determining the billing order when the beneficiary has additional drug coverage. The NCPDP *Telecommunication Standard Implementation Guide Version D.0* (NCPDP guide), section 6.1.1, states that for Part D, the pharmacy provider uses the E1 transaction to determine patient eligibility for billing purposes. The NCPDP guide, section 3.2.1, 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.

³ The NCPDP Provider ID was developed to provide pharmacies with a unique national identifier that would assist pharmacies in their interactions with pharmacy payers and claims processors.

⁴ Basic patient demographic information or PHI is the cardholder's ID, last name, first character of the first name, date of birth, and ZIP Code. The cardholder's ID can be the beneficiary's health insurance claim number, Social Security number (SSN), last four digits of the SSN, or Railroad Retirement Board number.

⁵ Pharmacies contract with switches, which request and receive Part D coverage information from the transaction facilitator.

⁶ The transaction facilitator is also a switch.

The *Medicare Prescription Drug Benefit Manual* (the Manual), states that pharmacies use an E1 transaction to determine a beneficiary's Part D coverage information in real time (Pub. No. 100-18, chapter 14, § 30.4.1). When a beneficiary does not have his or her Part D plan card, pharmacies may submit an E1 transaction to retrieve the information needed to bill for a prescription to a beneficiary's Part D insurance plan or to determine the billing order when the beneficiary has additional drug coverage. In December 2015, CMS issued a memo clarifying what constitutes an appropriate use of the E1 transaction.⁷ In the memo, CMS states that the E1 transaction should be submitted "for Medicare purposes" and "that the data are used to support the coordination of benefits."

Provider Monitoring and Access Controls

Before our audit began, CMS identified some providers that were not using E1 transactions for their intended purposes and worked with the transaction facilitator to deny those providers access to E1 transactions. The transaction facilitator implemented an access control for those E1 transactions where the transaction facilitator also served as the switch. The control verified that the provider number used to submit E1 transactions belonged to a legitimate contracted pharmacy provider. However, this control was not applied across all E1 transactions. One switch (which was not the transaction facilitator), allowed non-pharmacy entities to use their NPIs to submit E1 transactions and obtain beneficiary coverage information. After our audit period, CMS began monitoring providers submitting high numbers of E1 transactions and denying them access to E1 transactions, as necessary. CMS's monitoring included reviewing providers that submitted a large volume of E1 transactions relative to the number of prescriptions processed. CMS denied access to additional providers based on information we provided during our audit. CMS officials implemented controls, effective January 1, 2019, to limit non-pharmacy access to E1 transactions.

Electronic Protected Health Information

E1 transactions require PHI to determine the beneficiary's eligibility coverage, which is protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁸ Sections 261 and 262 of HIPAA established national standards that protect the confidentiality and integrity of electronic PHI while it is being electronically stored or transmitted between entities.

The HIPAA Administrative Simplification provisions were codified in sections 1171 through 1179 of the Act. The HIPAA Security Rule is a component of the HIPAA Administrative Simplification security standards incorporated into 45 CFR parts 160, 162, and 164.

Covered transactions include transactions with respect to eligibility for a health plan (HIPAA § 1173(a)). A covered entity is defined as a (1) health plan, (2) healthcare clearinghouse, or

⁷ CMS, "Appropriate Access and Use of the Part D Eligibility Query," issued December 3, 2015.

⁸ HIPAA, P.L. No. 104-191, enacted on August 21, 1996.

(3) healthcare provider that transmits any health information in electronic form (45 CFR § 160.103). A covered entity must reasonably safeguard PHI from any unauthorized use or disclosure and protect the privacy of the PHI (45 CFR § 164.530(c)) and obtain a beneficiary's authorization for the use of PHI for marketing purposes or for the sale of the PHI (45 CFR §§ 164.508(a)(3) and (4)).

On October 7, 2003, HHS delegated to CMS the authority to enforce compliance with the Security Rule and to impose civil monetary penalties on covered entities that violate it. The Final Rule for enforcement of the Security Rule became effective on March 16, 2006.

HOW WE CONDUCTED THIS AUDIT

We judgmentally selected 30 providers that submitted 3,940,390 E1 transactions in calendar years 2013 through 2015. We selected providers that submitted at least 5,000 E1 transactions and collectively processed less than 12 percent of Part D prescriptions. We used beneficiary ID numbers and dates of service to match E1 transactions to prescriptions filled within 90 days of the E1 transaction. We were unable to match 2,649,704 E1 transactions to prescriptions. We contacted providers directly and requested supporting documentation to determine whether pharmacies submitted E1 transactions to bill for a prescription or determine drug coverage 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.

Appendix A contains the details of our audit scope and methodology, Appendix B contains an E1 transaction flowchart showing how E1 transactions are processed, Appendix C contains the findings in our sampled population, and Appendix D contains the Federal requirements for PHI and E1 transactions.

FINDINGS

The majority of providers (25 of 30) used E1 transactions for some purpose other than to bill for a prescription or determine drug coverage billing order. On average, 98 percent of these 25 providers' E1 transactions were not associated with a prescription. We did not contact 10 providers because they were closed, under investigation, or both. Fifteen providers submitted or hired other entities to submit E1 transactions for the following purposes, which involved using the beneficiary's PHI:⁹

⁹ The total number exceeds 15 because some providers had multiple unallowable E1 transactions.

- 9 providers obtained coverage information for beneficiaries without prescriptions;
- 6 providers evaluated marketing leads;
- 4 providers allowed marketing companies to submit E1 transactions under the providers' NPI for marketing purposes;
- 2 providers not associated with long-term-care facilities obtained Part D coverage using batch transactions;
- 2 providers obtained information about private insurance coverage to bill for items not covered under Part D; and
- 2 non-pharmacy providers submitted E1 transactions.

After our audit period, CMS took additional steps to monitor use of the eligibility verification system and take appropriate enforcement action when abuse is identified.

The deficiencies we identified occurred because CMS had not yet (1) fully implemented controls to monitor providers submitting a high number of E1 transactions relative to prescriptions processed until after our audit period, (2) published clear guidance that E1 transactions are not to be used for marketing purposes, and (3) limited non-pharmacy access.

PROVIDERS OBTAINED COVERAGE INFORMATION FOR BENEFICIARIES WITHOUT PRESCRIPTIONS

Pharmacies use an E1 transaction to determine a Medicare beneficiary's Part D coverage information in real time and to retrieve information needed to bill a prescription or to determine billing order.¹⁰ A covered entity or business associate must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.¹¹

Nine providers obtained coverage information for beneficiaries without prescriptions, which resulted in the providers' unnecessary access to beneficiaries' PHI. After obtaining the coverage information, the providers then contacted the beneficiary's doctor and tried to obtain an initial prescription. One of the nine providers, with 605,146 E1 transactions, stated that when it contacted the beneficiary's doctor, the doctor often informed the provider that the beneficiary did not need the medication.

¹⁰ The Manual, chapter 14, § 30.4.1, effective June 7, 2010.

¹¹ 45 CFR § 164.502(b), effective March 26, 2013.

PROVIDERS EVALUATED MARKETING LEADS

Agreements between pharmacies and switches specify that PHI is not to be used for marketing purposes. A covered entity must reasonably safeguard PHI from any unauthorized use or disclosure and protect the privacy of the PHI.¹² And a covered entity must obtain a beneficiary's authorization for the use of PHI for marketing purposes or for the sale of the PHI.¹³

Six providers evaluated potential new customers using leads bought from telemarketing companies. These providers submitted E1 transactions and test claims to determine whether prospective patients' insurance covered products such as durable medical equipment and diabetic supplies.

PROVIDERS ALLOWED MARKETING COMPANIES TO SUBMIT E1 TRANSACTIONS UNDER THE PROVIDERS' NATIONAL PROVIDER IDENTIFIER

Agreements between pharmacies and switches specify that PHI is not to be used for marketing purposes, and the end user of the information obtained in the E1 transaction must be a business licensed to dispense medication. A covered entity must reasonably safeguard PHI from any unauthorized use or disclosure and protect the privacy of the PHI (45 CFR § 164.530(c)). A covered entity must obtain a beneficiary's authorization for the use of PHI for marketing purposes or for the sale of the PHI (45 CFR §§ 164.508(a)(3) and (4)).

Four providers allowed marketing companies to submit E1 transactions under the providers' NPIs for marketing purposes. Two providers gave E1 transaction access to marketing companies affiliated with the providers, and two providers gave E1 transaction access to outside marketing companies for contracted telemarketing services and to generate leads. Beginning on October 25, 2014, one provider had agreements with six different marketing companies. This provider informed us that these marketing companies submitted well over 100,000 E1 transactions without the provider's authorization. This practice of granting telemarketers' access to E1 transactions or using E1 transactions for marketing purposes puts the privacy of the beneficiaries' PHI at risk.

PROVIDERS NOT ASSOCIATED WITH LONG-TERM-CARE FACILITIES OBTAINED PART D COVERAGE USING BATCH TRANSACTIONS

The Manual permits pharmacies to submit real-time E1 transactions. Long-term-care facilities are directed to batch their end-of-year E1 transactions (chapter 14 § 30.4.1). Two providers, which were not associated with long-term-care facilities, submitted batch E1 transactions throughout the year.

¹² 45 CFR § 164.530(c), effective October 1, 2012.

¹³ 45 CFR § 164.508(a)(3), effective October 1, 2012; 45 CFR § 164.508(a)(4), effective March 26, 2013.

PROVIDERS OBTAINED PRIVATE INSURANCE COVERAGE INFORMATION TO BILL FOR ITEMS NOT COVERED UNDER MEDICARE

The Manual states that pharmacies use E1 transactions to determine a Medicare beneficiary's Part D coverage information (chapter 14 § 30.4.1). The December 2015 CMS memorandum states that the E1 transaction should be submitted "for Medicare purposes."

Two providers submitted E1 transactions strictly to obtain commercial insurance coverage information for items not generally covered by Medicare. One provider was a pharmacy that specialized in non-Part D-covered drugs. The other provider was a pharmacy that used E1 transactions to determine whom it would bill for diabetic supplies and over-the-counter medications not covered by Medicare.

NON-PHARMACY PROVIDERS SUBMITTED E1 TRANSACTIONS

Covered healthcare providers must use their NPIs to identify themselves on all standard transactions.¹⁴ The NCPDP guide, section 6.1.1, states that the pharmacy provider submits the E1 transaction to determine patient eligibility for Part D. The NCPDP guide, section 3.2.1, defines a "provider" as a retail pharmacy, mail-order pharmacy, or any other entity that dispenses prescription drugs and submits those prescriptions to a payer for reimbursement.¹⁵

Two entities that were not Part D providers used their NPIs and submitted E1 transactions without CMS approval. One entity was a pharmacy management software company that had its own NPI and submitted E1 transactions as part of a prescription generation service.¹⁶ During our audit (on June 14, 2017), CMS blocked the software company's ability to submit E1 transactions based on the company's response to a CMS questionnaire. The other non-pharmacy entity was a compounding drug service company that did not have its own NPI. Instead, it used a doctor's NPI. This doctor did not submit E1 transactions or dispense prescriptions and was not aware that his NPI was being used by the compounding drug service company to submit E1 transactions. CMS implemented controls to limit non-pharmacy access to E1 transactions on January 1, 2019.¹⁷

¹⁴ 45 CFR § 162.410(a)(2), effective October 1, 2012.

¹⁵ Effective August 7, 2007.

¹⁶ This is a service the software company offers to prescribers to generate electronic prescriptions for specialty medications.

¹⁷ CMS officials told us that the controls include rejection of OIG sanctioned providers, providers without an approved National Plan and Provider Enumeration System taxonomy code, and CMS Precluded providers.

CAUSES OF UNALLOWABLE E1 TRANSACTION USE

The deficiencies we identified occurred because CMS had not yet (1) fully implemented controls to monitor providers submitting a high number of E1 transactions relative to prescriptions processed until after our audit period, (2) published clear guidance that E1 transactions are not to be used for marketing purposes, and (3) limited non-pharmacy access.

ACTIONS ALREADY TAKEN BY THE CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS has taken some corrective actions since our audit period to reduce the use of E1 transactions for unauthorized purposes. Specifically, CMS began monitoring providers that submitted a high number of E1 transactions relative to prescriptions processed. CMS worked with the transaction facilitator to deny E1 transaction access for 20 of the 30 providers in our sample based on both its own review and the information we provided during our audit. CMS also deactivated NPIs for 3 of the 30 providers.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- continue to monitor providers submitting a high number of E1 transactions relative to prescriptions processed,
- issue guidance that clearly states that E1 transactions should not be used for marketing purposes,
- ensure that only pharmacies and other authorized entities submit E1 transactions, and
- take appropriate enforcement action when abuse is identified.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described the actions it has taken or plans to take to address them. CMS also requested that we remove from our report our recommendation for CMS to “ensure that only pharmacies and other authorized entities submit E1 transactions,” which it believes has been implemented. CMS explained that it has taken action to reduce the number of inappropriate E1 transactions by restricting E1 transactions to pharmacies or other specifically approved entities. CMS stated that since January 2019, it has rejected more than 250,000 E1 transactions from unauthorized entities.

CMS’s comments in their entirety are included as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

We commend CMS for the actions it has already taken and acknowledge the additional steps that CMS is in the process of taking to implement our recommendations. With respect to CMS's request that we remove our recommendation that CMS ensure that only pharmacies and other authorized entities submit E1 transactions, the recommendation is based on evidence obtained before January 2019. In addition, our audit work did not include determining whether the January 2019 corrective action was effective. For these reasons, we have kept the recommendation in the final report.

OTHER MATTERS

We determined that one provider included in our sample submitted E1 transactions while listed in OIG's exclusions database.¹⁸ Although there may be legitimate reasons for an excluded provider to submit an E1 transaction, such a submission may also indicate that the provider sought payment for items or services from a Federal health care program. Additionally, two providers included in our sample submitted E1 transactions to determine insurance coverage before applying pharmaceutical manufacturer copayment coupons.¹⁹ We did not determine as part of this audit whether the providers applied any manufacturer coupons to any items reimbursable by a Federal health care program. CMS should consider additional safeguards and controls to monitor for these circumstances.

¹⁸ Federal health care programs are prohibited from paying for any items or services furnished, ordered, or prescribed by an excluded provider (42 CFR § 1001.1901). This prohibition applies to payments to the excluded provider and anyone who contracts with the excluded provider.

¹⁹ CMS's December 2015 memo states that E1 transactions "cannot be used for the purpose [of] ruling out Medicare coverage in order to ensure that coupon use would not violate the anti-kickback statute"

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We judgmentally selected 30 providers that submitted 3,940,390 E1 transactions for Medicare-eligible enrollees in calendar years 2013 through 2015. We selected providers that submitted at least 5,000 E1 transactions and collectively processed less than 12 percent of Part D prescriptions. We used Medicare beneficiary ID numbers and dates of service to match E1 transactions to prescriptions filled within 90 days of the E1 transaction. We were unable to match 2,649,704 E1 transactions to prescriptions. We contacted providers directly and requested supporting documentation to determine whether E1 transactions were requested by pharmacies for their intended purposes of billing a prescription or determining billing order.

We did not review the overall internal control structure of CMS as it relates to the eligibility verification system. Rather, we limited our internal control review to controls over entity access.

We conducted fieldwork from May 2017 through April 2018.

METHODOLOGY

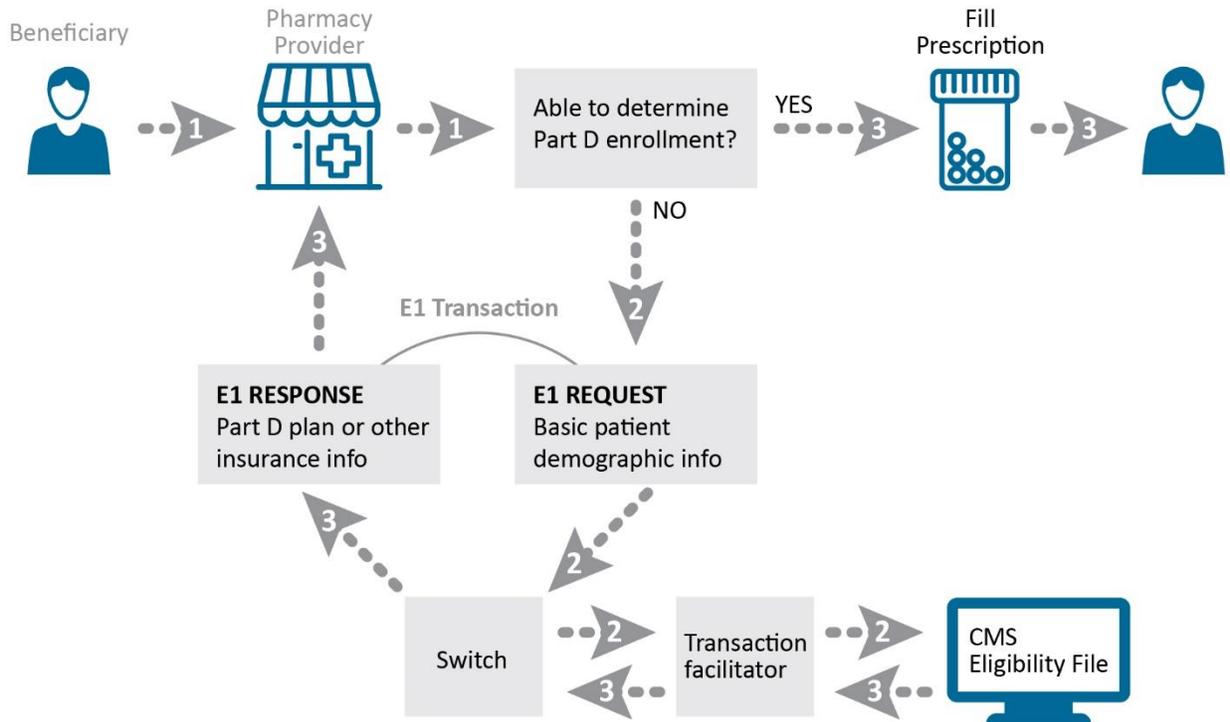
To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- compared 2013 through 2015 summary Part D prescription claims data to summary E1 data by provider;
- selected 30 providers that submitted at least 5,000 E1 transactions and collectively processed less than 12 percent of Part D prescriptions;
- obtained a database of 2013 through 2015 E1 transactions for the 30 selected providers;
- matched E1 transactions to Part D prescriptions by Medicare beneficiary ID number and date of service within 90 days, which resulted in 2,649,704 unmatched E1 transactions;
- sent 26 providers a letter that requested information related to their unmatched E1 transactions and included:
 - any policies or procedures related to (1) submitting and using E1 transactions and (2) processing prescriptions for Part D enrollees;
 - written agreements with the switch(es) providing the E1 transaction services;

- explanation of why they submitted so many E1 transactions in certain months, as applicable; and
- explanation of why they submitted so many E1 transactions without processing prescriptions for beneficiaries with Part D coverage and documentation to support the explanation;
- reviewed supporting documentation to determine whether providers used E1 transactions for their intended purposes; and
- discussed the results of our audit with CMS officials.

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: E1 TRANSACTION FLOWCHART



1. Represents the beneficiary initiating his or her prescription purchase and the pharmacy initiating the verification of the beneficiary's Part D eligibility.
2. Represents basic information necessary to submit an E1 request.
3. Represents detailed information necessary to bill the Part D plan or other payers.

APPENDIX C: FINDINGS IN OUR SAMPLED POPULATION

Provider	Unable To Contact	25 Providers	Total E1s	Unmatched E1s ²⁰	Unmatched Percentage ²¹	Findings					
						1	2	3	4	5	6
1			1,436,153	376,771	26%						
2		X	605,146	597,371	99%	X	X	X			
3	X	X	511,355	501,783	98%						
4			307,072	146,950	48%						
5		X	181,963	181,922	100%	X		X			
6		X	177,966	177,702	100%	X					
7	X	X	109,052	108,581	100%						
8		X	89,142	87,319	98%	X	X				
9	X	X	81,042	79,817	99%						
10	X	X	51,560	51,165	99%						
11		X	49,097	49,085	100%	X					
12	X	X	48,202	48,085	100%						
13		X	36,072	20,070	56%		X				
14		X	31,354	31,345	100%				X		
15		X	27,138	27,091	100%	X					
16	X	X	24,697	24,240	98%						
17			23,708	2,747	12%						
18		X	22,422	22,422	100%						X
19		X	21,782	21,782	100%	X	X				
20	X	X	16,313	16,313	100%						
21		X	10,796	10,796	100%	X	X	X			
22	X	X	10,706	10,706	100%						
23			9,811	4,939	50%						
24	X	X	9,659	9,651	100%						
25		X	9,257	9,159	99%		X	X			
26		X	8,918	8,629	97%					X	
27		X	7,833	7,719	99%	X				X	
28			7,566	1,036	14%						
29	X	X	7,400	7,300	99%						
30		X	7,208	7,208	100%				X		X
	10²²	25	3,940,390	2,649,704	67%	9	6	4	2	2	2

25 Providers' Totals:

2,156,080	2,117,261	98%
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²⁰ E1 transactions.

²¹ Percentages have been rounded.

²² We were unable to contact 10 providers that were closed, under investigation, or both.

Numbers of Findings and Findings Legend

Finding 1 (9)	Providers Obtained Coverage Information for Beneficiaries Without Prescriptions
Finding 2 (6)	Providers Evaluated Marketing Leads
Finding 3 (4)	Providers Allowed Marketing Companies To Submit E1 Transactions Under the Providers' NPI
Finding 4 (2)	Providers Not Associated With a Long-Term-Care Facility Obtained Part D Coverage Using Batch Transactions
Finding 5 (2)	Providers Obtained Private Insurance Coverage Information To Bill for Items Not Covered Under Medicare
Finding 6 (2)	Non-Pharmacy Providers Submitted E1 Transactions

APPENDIX D: FEDERAL REQUIREMENTS FOR PROTECTED HEALTH INFORMATION AND E1 TRANSACTIONS

FEDERAL REQUIREMENTS FOR PROTECTED HEALTH INFORMATION

A covered entity must reasonably safeguard PHI from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications, or other requirements of this subpart (45 CFR § 164.530(c)). Federal regulations state that a covered entity or business associate must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request (45 CFR § 64.502(b)). Federal regulations state that a covered entity must obtain a beneficiary's authorization for the use of PHI for marketing purposes or for the sale of the PHI (45 CFR §§ 164.508(a)(3) and (4)). In addition, Federal regulations state that a covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information (45 CFR § 164.530(c)).

FEDERAL REQUIREMENTS FOR E1 TRANSACTIONS

The Manual states that pharmacies use E1 transactions to determine a Medicare beneficiary's Part D coverage information. Pharmacies use this service when beneficiaries do not have their Medicare Part D plan card information to retrieve information needed to bill a claim to a patient's insurance plan or to determine billing order if the beneficiary has multiple insurance coverage (chapter 14 § 30.4.1)). Federal regulations state that a covered healthcare provider must use the NPI that it obtained from the National Provider System to identify itself on all standard transactions that it conducts where its healthcare provider identifier is required (45 CFR § 162.410(a)(2)).

The NCPDP guide section 6.1.1 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 ID 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 transaction facilitator provides this information on the E1 response to the pharmacy provider. Section 3.2.1 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.

CMS's December 3, 2015, memo "Appropriate Access and Use of the Part D Eligibility Query" states that transactions are requested by a pharmacy for Medicare purposes, and the data are used to support coordination of benefits, which would include permitting States to coordinate benefits payable under Medicaid through E1 requests. However, the memo further states that E1 information cannot be used for the purpose of ruling out Medicare coverage to ensure that coupon use would not violate the anti-kickback statute (the Act § 1128B(b)).

APPENDIX E: CMS COMMENTS



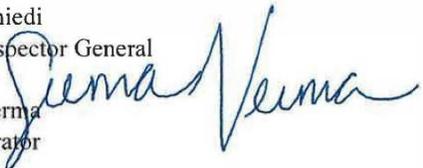
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: October 31, 2019

TO: Joanne Chiedi
Acting Inspector General

FROM: Seema Verma 
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Providers Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes (A-05-17-00020)

The Centers for Medicare & Medicaid Services (CMS) appreciates OIG's audit on appropriate use of Medicare Part D Eligibility Verification Transactions (E1 transactions). OIG initiated this audit based on a CMS request and CMS appreciates OIG's work to ensure E1 transactions are used for their intended purpose.

The E1 transaction was implemented as part of the Medicare Part D program as a mechanism to determine eligibility for Part D enrollees on a real-time basis at the point of sale. This function allows a Part D pharmacy provider to submit its National Provider Identifier and patient demographic information to the CMS contractor, which forwards the E1 request to the transaction facilitator. The transaction facilitator matches the data contained in the E1 request to CMS data and returns an E1 response to the pharmacy through the contractor. An E1 response contains the beneficiary's Part D coverage information, which allows the pharmacy to bill the beneficiary's Part D plan and other payer(s), as applicable, after filling the beneficiary's prescription.

CMS is committed to ensuring Part D covered providers use E1 transactions in the appropriate manner and has already initiated several actions to help ensure compliance. Since 2016, CMS has monitored E1 transactions to identify outliers, for example, pharmacies that submitted a high number of E1 transactions relative to prescriptions processed. After review, if appropriate, CMS will deny the provider E1 transaction access. In addition, in January 2019, CMS revised the system to reject E1 transactions generated by most non-pharmacies. Since this revision, a total of 255,053 E1 transactions have been rejected.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

Continue to monitor providers submitting a large number of E1 transactions relative to prescriptions processed.

CMS Response

CMS concurs with this recommendation. As noted above, CMS uses reports to monitor activity and directs the contractor managing E1 transactions to deny E1 access when appropriate. CMS has identified pharmacies that submitted a high number of E1 transaction relative to prescriptions processed and has revoked their E1 access accordingly. Going forward, CMS will review our monitoring processes to ensure continued effectiveness.

OIG Recommendation

Issue guidance that clearly states that E1 transactions should not be used for marketing purposes.

CMS Response

CMS concurs with this recommendation. Information on appropriate use of E1 transactions can be found on the Department of Health and Human Services website.¹ In addition, CMS is working to develop additional guidance relating to the use of E1 transactions.

OIG Recommendation

Ensure that only pharmacies and other authorized entities submit E1 transactions.

CMS Response

CMS concurs with this recommendation. CMS has taken action to reduce the number of inappropriate E1 transactions by restricting E1 transactions to pharmacies or other specifically approved entities beginning in January 2019. Since then, CMS rejected over 250,000 E1 transactions from unauthorized entities. Therefore, we believe that this recommendation has been implemented and request that it be removed from OIG's report.

OIG Recommendation

Take appropriate enforcement action when abuse is identified.

CMS Response

CMS concurs with this recommendation. CMS has already taken steps to discourage misuse of E1 transactions. For pharmacies that submitted a high number of E1 transactions relative to prescriptions processed, CMS has the ability to survey these pharmacies and currently revokes E1 access if misuse is detected. Going forward, CMS will look into additional ways in which to take enforcement action against providers who may be inappropriately using E1 access.

¹ <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/marketing/index.html>