Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE IMPROPERLY PAID MILLIONS OF DOLLARS FOR PRESCRIPTION DRUGS PROVIDED TO INCARCERATED BENEFICIARIES DURING 2006 THROUGH 2010

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.



Gloria L. Jarmon Deputy Inspector General

> January 2014 A-07-12-06035

Office of Inspector General

https://oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at https://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

Medicare Part D accepted prescription drug event records totaling almost \$12 million in unallowable gross drug costs on behalf of incarcerated beneficiaries during calendar years 2006 through 2010.

WHY WE DID THIS REVIEW

Individuals who are incarcerated in correctional facilities (incarcerated beneficiaries) are generally not eligible for Federal health care benefits. We are conducting a series of reviews of Medicare payments for services provided to incarcerated beneficiaries. We previously reported that Medicare made improper Part A and Part B payments totaling \$33.6 million to health care providers for services provided to incarcerated beneficiaries. This is a review of payments made on behalf of incarcerated beneficiaries in Medicare Part D.

The objective of this review was to determine the extent to which the Centers for Medicare & Medicaid Services (CMS) accepted prescription drug event (PDE) records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries during calendar years (CYs) 2006 through 2010.

BACKGROUND

Medicare Part D offers prescription drug benefits to individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B. CMS, which administers Medicare, contracts with private prescription drug plans to offer prescription drug benefits to eligible individuals under Medicare Part D. Two types of private prescription drug plans provide Part D coverage: Medicare Advantage prescription drug plans and stand-alone prescription drug plans. In this report, we refer to entities that administer stand-alone prescription drug plans as "sponsors." Sponsors are paid prospectively, and CMS makes final payment determinations each year by adjusting the sponsors' payments using information from the PDE records.

An individual is eligible for Part D benefits if he or she is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the service area of a Part D plan. Federal regulations specify that facilities in which individuals are incarcerated are not to be regarded as being within service areas for purposes of Part D coverage.

For CYs 2006 through 2010, sponsors submitted final PDE records to CMS with gross drug costs totaling approximately \$256 billion.

WHAT WE FOUND

CMS inappropriately accepted PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries and used those records to make its final payment determinations. Specifically, for 49 of the 100 beneficiaries that we sampled, CMS accepted 1,298 PDE records submitted by sponsors for prescription drugs provided to incarcerated

beneficiaries. The gross drug costs associated with these 1,298 accepted PDE records totaled \$325,903. On the basis of our sample results, we estimated that CMS accepted PDE records with gross drug costs totaling an additional \$11,656,314 for incarcerated beneficiaries.

We were not able to verify that the remaining 51 sampled beneficiaries were incarcerated in correctional facilities on the dates listed in CMS's database. Therefore, we did not question the gross drug costs associated with these beneficiaries' PDE records.

CMS inappropriately accepted PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries because it had inadequate internal controls during our review. When Part D began on January 1, 2006, Federal regulations were the principal source of guidance to sponsors, although CMS later issued additional guidance. Additionally, CMS did not provide sufficient and timely information to sponsors that would have allowed them to readily and accurately verify a beneficiary's incarceration status and dates of incarceration.

WHAT WE RECOMMEND

We recommend that CMS:

- resolve improper Part D payments for prescription drugs provided to incarcerated beneficiaries by reopening and revising CYs 2006 through 2010 final payment determinations to remove gross drug costs of \$325,903 for the sampled incarcerated beneficiaries:
- strengthen internal controls to ensure that Medicare does not pay for prescription drugs
 for incarcerated beneficiaries, specifically by developing and implementing policies and
 procedures that provide sponsors on a timely basis with all of the incarceration
 information that is necessary for them to verify beneficiaries' dates and status of
 incarceration, including the names and contact information of correctional facilities; and
- work with the sponsors to identify and resolve improper Part D payments made for
 prescription drugs provided to incarcerated beneficiaries, which would include the
 estimated \$11,656,314 in additional gross drug costs identified in this report, by
 reopening and revising final payment determinations for all periods before
 implementation of the enhanced policies and procedures described above.

CMS COMMENTS AND OUR RESPONSE

In written comments on our draft report, CMS concurred with our first two recommendations and described corrective actions that it planned to take. Specifically, CMS stated that it would first address policy and system changes and would then reopen each contract year that has not been closed to recover improper payments. CMS did not concur with our third recommendation because, it said, there was no effective way to fully recover the improper payments in question without first implementing the appropriate policies and procedures, including the relevant systems changes. However, CMS also stated that once it implements regulations clarifying its policy, it will update the applicable eligibility and enrollment systems, which will facilitate the

appropriate changes in the PDE data. CMS added that it would then reopen each year that had not already been closed to resolve these improper payments.

We acknowledge that CMS is developing and implementing policies and procedures that would address enrollment of incarcerated beneficiaries and agree with its approach as long as CMS resolves, to the maximum extent possible, the improper payments that occurred for all applicable periods.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective	1
Background	1
Medicare Prescription Drug Coverage	
Sources and Flow of Incarceration Information	
Sponsor Verification of Incarcerated Beneficiaries	
How We Conducted This Review	3
FINDINGS	4
Medicare Paid for Prescription Drugs for Incarcerated Beneficiaries	
Federal Requirements	4
Medicare Accepted Prescription Drug Event Records With Gross Drug Costs	
Totaling Almost \$12 Million for Incarcerated Beneficiaries	5
Internal Controls Did Not Prevent Improper Payments for Prescription Drugs	
for Incarcerated Beneficiaries	5
RECOMMENDATIONS	6
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	7
APPENDIXES	
A: Audit Scope and Methodology	8
B: Statistical Sampling Methodology	10
C: Sample Results and Estimates	11
D: CMS Comments	12

INTRODUCTION

WHY WE DID THIS REVIEW

Individuals who are incarcerated in correctional facilities (incarcerated beneficiaries) are generally not eligible for Federal health care benefits. We are conducting a series of reviews of Medicare payments for services provided to incarcerated beneficiaries. We previously reported that Medicare made improper Part A and Part B payments totaling \$33.6 million to health care providers for services provided to incarcerated beneficiaries. This is a review of payments made on behalf of incarcerated beneficiaries in Medicare Part D.

OBJECTIVE

Our objective was to determine the extent to which the Centers for Medicare & Medicaid Services (CMS) accepted prescription drug event (PDE) records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries during calendar years (CYs) 2006 through 2010.

BACKGROUND

Medicare Prescription Drug Coverage

Medicare provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease (Title XVIII of the Social Security Act (the Act)). Under Medicare Part D, which began January 1, 2006, ² individuals entitled to Medicare benefits under Part A or enrolled in Part B and who live in the service area of a Part D plan may obtain prescription drug coverage. CMS, which administers Medicare, contracts with private prescription drug plans to offer prescription drug benefits to eligible individuals. Two types of private prescription drug plans provide Part D coverage. Medicare Advantage prescription drug plans cover a variety of medical services, including prescription drugs, while stand-alone prescription drug plans cover only prescription drugs. We limited our review to stand-alone prescription drug plans and, in this report, we refer to entities that administer these plans as "sponsors."

As a condition of payment, every time a Medicare beneficiary fills a prescription covered under Part D, the sponsor must submit a PDE record to CMS.³ PDE records (which are collectively referred to as "PDE data") include drug cost and payment information that enables CMS to

¹ Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011 (A-07-12-01113, January 23, 2013).

² Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. No. 108-173 § 101) amended Title XVIII of the Act (§ 1860D-1(a); 42 U.S.C. § 1395w-101(a)) to establish the Voluntary Prescription Drug Benefit Program, known as Medicare Part D.

³ The Act, §§ 1860D-15(c)(1)(C) and (d)(2); 42 CFR § 423.322.

administer the Part D benefit. Sponsors must submit final PDE data to CMS within 6 months after the end of the coverage year (42 CFR § 423.343(c)(1)).

For CYs 2006 through 2010, sponsors submitted final PDE data to CMS with gross drug costs totaling approximately \$256 billion.⁴

CMS pays sponsors for Part D benefits prospectively.⁵ These prospective payments are based on information in the sponsors' approved annual bids. After the close of the coverage year, CMS reconciles the prospective payments with the actual costs incurred by sponsors and determines the amount that each sponsor will owe to or receive from Medicare for the plan year. CMS's reconciliations are based on sponsors' final PDE data. CMS uses these data to make payments to drug sponsors and administer the Part D benefit.⁶

Incarcerated beneficiaries are not eligible to receive prescription drug benefits under Part D.

Sources and Flow of Incarceration Information

Chapter 3 of CMS's *Medicare Prescription Drug Benefit Manual—Eligibility, Enrollment and Disenrollment* (the Manual) uses the term "incarceration" to refer to the status of an individual who is confined to a correctional facility, such as a jail or a prison. According to the Manual, an individual who is incarcerated is considered to be living outside of any Part D plan's service area for the purposes of eligibility, even if the correctional facility is located within a plan's service area.

The Social Security Administration (SSA) is CMS's primary source of information about incarcerated beneficiaries. Generally, SSA collects information, such as the names of Medicare beneficiaries and the dates on which beneficiaries begin periods of incarceration, directly from penal authorities. SSA also collects incarceration end dates from beneficiaries' requests for reinstatement of Social Security benefits.

To identify the incarcerated beneficiaries, CMS's Enrollment Database interfaces with SSA's systems. Each month CMS receives a file, known as the Prison Reply Data file, from SSA. This file includes information about each incarcerated beneficiary, the incarceration start date and end date (if applicable), and the name and contact information of the correctional facility. CMS then records the dates of incarceration onto the Common Medicare Eligibility tables, which ultimately update the Medicare Advantage Prescription Drug (MARx) system.

Medicare Part D Payments for Incarcerated Beneficiaries (A-07-12-06035)

⁴ CMS defines "gross drug costs" as the sum of the following 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 as a result of another payer amount (*Instructions: Requirements for Submitting Prescription Drug Event Data*, § 7.2.3).

⁵ The Act, §§ 1860D-14 and 15; 42 CFR §§ 423.315 and 423.329.

⁶ 42 CFR §§ 423.329 and 423.343.

CMS uses the information from the MARx system to notify sponsors of incarceration information using monthly Transaction Reply Reports (TRRs). The TRR includes the beneficiary's name, Health Insurance Claim Number (HICN), and the beginning date of incarceration.⁷

Sponsor Verification of Incarcerated Beneficiaries

The Manual instructs sponsors to disenroll beneficiaries who are currently incarcerated and to disregard past periods of incarceration when the beneficiary is not incarcerated at the time that the sponsor verifies the incarceration status. The Manual also instructs sponsors to verify a beneficiary's incarceration status either by contacting the beneficiary or by using public resources, such as public Web sites.

If the sponsor is able to verify the beneficiary's incarceration status and start date, the sponsor retroactively disenrolls the beneficiary beginning the first day of the month following the beginning month of incarceration, and sponsors retroactively adjust the PDE records associated with that beneficiary. The Manual specifies that in any instances when the sponsor can verify only that the beneficiary is incarcerated but cannot verify the start date, the sponsor disenrolls the beneficiary on the first of the month following the month that the sponsor verified the incarceration. When a sponsor is unable to verify a beneficiary's incarceration status or current location, the sponsor disenrolls the beneficiary after 6 months.

HOW WE CONDUCTED THIS REVIEW

We reviewed a stratified random sample of 100 beneficiaries. We selected this sample from 23,049 beneficiaries who were listed as being incarcerated in CMS's Enrollment Database and whose incarceration periods began and ended during CYs 2006 through 2010 (unless they were still incarcerated on the as-of date (November 1, 2011) of the CMS Prison Reply Data file that we used; see Appendix A). Sponsors submitted 301,398 PDE records with gross drug costs totaling \$33,736,925 on behalf of these 23,049 beneficiaries. For each sampled beneficiary, we obtained information on periods of incarceration from CMS's Prison Reply Data file, verified the incarceration periods by contacting each correctional facility, and then reviewed the PDE records associated with these sampled beneficiaries.

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 details of our audit scope and methodology, Appendix B contains the details of our sample design and methodology, and Appendix C contains our sample results and estimates.

⁷ CMS does not give sponsors TRRs that include incarceration end dates.

FINDINGS

CMS inappropriately accepted PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries and used those records to make its final payment determinations. Specifically, for 49 of 100 sampled beneficiaries, CMS accepted 1,298 PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries. The gross drug costs associated with these 1,298 accepted PDE records totaled \$325,903. On the basis of our sample results, we estimated that CMS accepted PDE records with gross drug costs totaling an additional \$11,656,314 for incarcerated beneficiaries. ⁸

We were not able to verify that the remaining 51 sampled beneficiaries were incarcerated in correctional facilities on the dates listed in CMS's database. Therefore, we did not question the gross drug costs associated with these beneficiaries' PDE records.

CMS inappropriately accepted PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries because it had inadequate internal controls during our review. When Part D began on January 1, 2006, Federal regulations were the principal source of guidance to sponsors, although CMS later issued additional guidance. Additionally, CMS did not provide sufficient and timely information to sponsors that would have allowed them to readily and accurately verify a beneficiary's incarceration status and dates of incarceration.

MEDICARE PAID FOR PRESCRIPTION DRUGS FOR INCARCERATED BENEFICIARIES

Federal Requirements

An individual is eligible for Part D benefits if he or she is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the service area of a Part D plan (42 CFR § 423.30(a)(1)(i-ii)). Facilities in which individuals are incarcerated are not to be regarded as being within service areas for purposes of Part D coverage (42 CFR § 423.4).

The Manual instructs sponsors to disenroll beneficiaries who are currently incarcerated and to disregard past periods of incarceration when the beneficiary is not incarcerated at the time that the sponsor verifies the incarceration status (§ 50.2). The Manual also instructs sponsors to use public resources, such as Web sites, to verify a beneficiary's incarceration status (§ 50.2.1.3).

⁸ We estimated that CMS accepted PDE records with gross drug costs totaling \$11,982,217 by using the point estimate (Appendix C). This amount included the \$325,903 in gross drug costs that we identified in our sample and that we are already questioning. We therefore report \$11,656,314 (\$11,982,217 - \$325,903) as the estimated amount of additional gross drug costs associated with prescription drugs provided to incarcerated beneficiaries.

⁹ References in this report to the Manual are made to the current version of the Manual when the provisions are the same as those in the Manual in effect during the period of the audit or the same as CMS practice at that time. To the extent that the provisions differ, reference is made to the July 16, 2008, Manual version.

If the sponsor verifies the beneficiary's incarceration status and start date, the sponsor then retroactively disenrolls the beneficiary beginning the first day of the month following the beginning month of incarceration (the Manual, § 50.2.1.3). Sponsors retroactively adjust the PDE records associated with that beneficiary. The Manual also specifies that in any instances in which the sponsor can verify only that the beneficiary is incarcerated but cannot verify the start date, the sponsor will disenroll the beneficiary on the first of the month following the month that the sponsor verified the incarceration (§ 50.2.1.3).

Furthermore, when a sponsor is unable to verify a beneficiary's incarceration status or current location, the beneficiary is disenrolled after 6 months (the Manual, § 40.2.1.2).

Medicare Accepted Prescription Drug Event Records With Gross Drug Costs Totaling Almost \$12 Million for Incarcerated Beneficiaries

Contrary to Federal requirements, for 49 of the 100 sampled beneficiaries, CMS accepted 1,298 PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries. The gross drug costs associated with these 1,298 accepted PDE records totaled \$325,903. On the basis of our sample results, we estimated that CMS accepted PDE records with gross drug costs totaling an additional \$11,656,314 for incarcerated beneficiaries. CMS used these PDE records to adjust annual Part D payments to sponsors. ¹¹

We were not able to verify that the remaining 51 sampled beneficiaries were incarcerated in correctional facilities on the dates listed on CMS's Prison Reply Data file. The Manual states that for a beneficiary to be disenrolled, the sponsor must verify the beneficiary's incarceration status, either by contacting the beneficiary or by using public resources such as Web sites. We attempted to verify the incarceration status of these 51 beneficiaries but because we were unable to do so, we did not question the gross drug costs associated with these beneficiaries' PDE records.

Internal Controls Did Not Prevent Improper Payments for Prescription Drugs for Incarcerated Beneficiaries

CMS improperly accepted PDE records submitted by sponsors for prescription drugs provided to incarcerated beneficiaries because it had inadequate internal controls during the period of our

¹⁰ The Manual is updated yearly with changes. Editions of the Manual from the first 3 years of our audit period (i.e., CYs 2006, 2007, and 2008) informed sponsors (in Chapter 3) that incarcerated individuals were not eligible for Part D and directed the sponsors to disenroll those individuals. CMS officials told us that although the Manual did not specifically address the required effective dates of disenrollment, CMS had always required the sponsors to disenroll their incarcerated beneficiaries beginning the first day of the month following the beginning month of incarceration.

¹¹ As stated in "Background," CMS is responsible, after the close of a coverage year, for reconciling the prospective payments with the actual costs incurred by sponsors and for determining the amount that each sponsor will owe to or receive from Medicare for the plan year. According to the Congressional Budget Office, beneficiaries' premium payments cover about one-quarter of the overall costs of the basic Part D benefit, and Federal payments to sponsors cover the other three-quarters of these costs. Because Part D is funded in this way, the estimated \$11,982,217 in inappropriately accepted PDE records that this report has identified was not funded in its entirety by the Federal Government.

review. When Part D began on January 1, 2006, Federal regulations served as the principal source of guidance to sponsors. Although CMS later issued additional guidance, two of the three sponsors with which we discussed these issues did not have policies and procedures in place regarding prescription drugs provided to incarcerated beneficiaries until at least 4 years after the start of the Part D program. Other inadequate controls involved the completeness and timeliness of information provided to sponsors:

- Despite having received incarceration information (the Prison Reply Data file) from SSA, CMS did not provide sponsors with the names or contact information of correctional facilities, which sponsors needed to readily verify beneficiaries' dates and status of incarceration. Sponsors told us that, without this information, they relied on public Web sites. Sponsors said that it was difficult to locate the correct Web site to find the incarceration information and added that, even when they accessed the correct Web site, the incarceration information was not always available.
- Further, sponsors did not always receive incarceration information from CMS in a timely manner. Incarceration information received by the sponsors was often outdated—by the time the sponsors were notified of a beneficiary's incarceration, the beneficiary may no longer have been incarcerated. For the period of our review, there was an average of 10 months between the date on which a beneficiary became incarcerated and the date that the sponsor received the incarceration information for that beneficiary.

RECOMMENDATIONS

We recommend that CMS:

- resolve improper Part D payments for prescription drugs provided to incarcerated beneficiaries by reopening and revising CYs 2006 through 2010 final payment determinations to remove gross drug costs of \$325,903 for the sampled incarcerated beneficiaries;
- strengthen internal controls to ensure that Medicare does not pay for prescription drugs
 for incarcerated beneficiaries, specifically by developing and implementing policies and
 procedures that provide sponsors on a timely basis with all of the incarceration
 information that is necessary for them to verify beneficiaries' dates and status of
 incarceration, including the names and contact information of correctional facilities; and
- work with the sponsors to identify and resolve improper Part D payments made for
 prescription drugs provided to incarcerated beneficiaries, which would include the
 estimated \$11,656,314 in additional gross drug costs identified in this report, by
 reopening and revising final payment determinations for all periods before
 implementation of the enhanced policies and procedures described above.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first two recommendations and described corrective actions that it planned to take. Specifically, CMS stated that it would first address policy and system changes and would then reopen each contract year that has not been closed to recover improper payments. CMS did not concur with our third recommendation because, it said, there was no effective way to fully recover the improper payments in question without first implementing the appropriate policies and procedures, including the relevant systems changes. However, CMS also stated that once it implements regulations clarifying its policy, it will update the applicable eligibility and enrollment systems, which will facilitate the appropriate changes in the PDE data. CMS added that it would then reopen each year that had not already been closed to resolve these improper payments.

CMS also provided technical comments regarding two of the legal criteria pertaining to disensollment timeframes.

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

We acknowledge that CMS is developing and implementing policies and procedures that would address enrollment of incarcerated beneficiaries and agree with its approach as long as CMS resolves, to the maximum extent possible, the improper payments that occurred for all applicable periods.

With respect to CMS's technical comments involving the 6-month disenrollment timeframe mentioned several times in this report, we note that the regulation and Manual provision specifying disenrollment after 12 months did not become effective until after our audit period. For our response to CMS's comment regarding one of the Manual citations, see the explanation in footnote 9.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered approximately \$256 billion in gross drug costs reflected in sponsors' final PDE records for CYs 2006 through 2010. We did not review CMS's overall internal control structure because our objective did not require us to do so. We reviewed only the internal controls directly related to our objective.

We performed fieldwork from November 2011 through July 2012.

METHODOLOGY

To accomplish our objective, we

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials and officials from selected sponsors to gain an understanding of their internal controls related to incarcerated beneficiaries;
- interviewed SSA officials to gain an understanding of SSA's systems and processes for obtaining data on incarcerated individuals;
- obtained CMS's Prison Reply Data file (received monthly from SSA) to identify (as of November 1, 2011) the correctional facility where each beneficiary was housed;
- obtained CMS's Enrollment Database as of June 25, 2011, to identify incarcerated beneficiaries who were associated with 455,758 PDE records (with gross drug costs totaling \$50,319,074), and limited those claims we reviewed by examining only those whose incarceration periods began and ended during CYs 2006 through 2010 (unless they were still incarcerated according to the CMS Prison Reply Data file as of November 1, 2011);
- modified our population by:
 - o removing all duplicate PDE records,
 - o removing all PDE records for "non-covered" drugs (e.g., over-the-counter drugs),
 - removing all PDE records that were submitted by Medicare Advantage prescription drug plans, and
 - removing all PDE records that did not have sufficient facility information in CMS's Prison Reply Data file to allow us to verify the incarceration status of the beneficiary;

- selected a stratified random sample of 100 beneficiaries (Appendix B);
- contacted each correctional facility to verify the incarceration dates of each sampled beneficiary to determine the allowability of the PDE records;
- identified the unallowable PDE records as of the first day of the month following the initial month of incarceration through the end of the confirmed incarceration period;
- projected the total gross drug costs associated with the unallowable PDE records (Appendix C); and
- discussed the results of our review with CMS officials on November 20, 2012.

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

POPULATION

The population consisted of PDE records associated with incarcerated beneficiaries whose incarceration periods began and ended during CYs 2006 through 2010 (unless they were still incarcerated on the as-of date (November 1, 2011) of the CMS Prison Reply Data file that we used).

SAMPLING FRAME

The sampling frame consists of 301,398 PDE records with gross drug costs totaling \$33,736,925 that were paid for prescription drugs provided to 23,049 incarcerated beneficiaries under Part D during CYs 2006 through 2010. In the data, each beneficiary was identified by an HICN.

SAMPLE UNIT

The sampling unit is one HICN.

SAMPLE DESIGN

We used a stratified random sample:

<u>Stratum</u>	Gross Drug Cost per HICN	Number of HICNs	Gross Drug Cost
1	\$10,000 or more	630	\$13,133,366
2	\$.01 - \$9,999.99	<u>22,419</u>	\$20,603,559
Total		23,049	\$33,736,925

SAMPLE SIZE

The sample size consisted of 100 HICNs; we selected 50 HICNs from each stratum.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General, Office of Audit Services, statistical software (RATS-STATS).

ESTIMATION METHODOLOGY

We used RAT-STATS to estimate the gross drug costs that were inappropriately paid for prescription drugs that were provided to incarcerated beneficiaries during our audit period.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Results

Stratum (Number of HICNs)	Stratum Range (Gross Drug Cost per HICN)	Frame Size (Number of HICNs)	Frame Value (Gross Drug Cost)	Sample Size (Number of	Value of Sample (Gross Drug	Sample Errors
				HICNs)	Cost)	
1	\$10,000 or more	630	\$13,133,366	50	\$307,830	23
2	Less than \$10,000	22,419	20,603,559	50	18,073	26
Totals		23,049	\$33,736,925	100	\$325,903	49

Table 2: Estimates of Inappropriate Part D Payments

(Limits Calculated for a 90-Percent Confidence Interval)

	Total Gross Drug Cost
Point estimate	\$11,982,217
Lower limit	\$8,386,717
Upper limit	\$15,577,718

APPENDIX D: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator Washington, DC 20201

DATE:

OCT 3 0 2013

TO:

Daniel R. Levinson Inspector General

FROM:

Marilyn Tavenner

SUBJECT:

Office of Inspector General (OIG) Draft Report: Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Incarcerated Beneficiaries

During 2006 Through 2010 (A-07-12-06035)

Thank you for the opportunity to review and comment on this OIG draft report aimed at determining the extent to which the Centers for Medicare & Medicaid Services (CMS) accepted prescription drug event (PDE) records submitted by sponsors on behalf of individuals who are incarcerated. Individuals may enroll in Part D plans if they meet the eligibility requirements, which include residing within the plan's service area. Consistent with this policy, an individual who is incarcerated does not reside in a plan service area.

The CMS supports some of the report's recommendations to strengthen internal controls to help ensure that payments for Medicare Part D services comply with federal requirements to the extent that information is available to do so. Accordingly, we agree that in cases where the information indicates an individual is incarcerated, that individual is determined to no longer reside in the plan's service area and should be disenrolled.

The lack of a more robust set of CMS internal processes regarding access to services under the Medicare Part D program has been a concern to CMS. CMS is taking steps to address this issue and ensure that this requirement is executed in accordance with the information we receive from the correctional facilities and the Social Security Administration.

Below is the CMS response to the OIG recommendations in the final report.

OIG Recommendation

The OIG recommends CMS resolve improper Part D payments for prescription drugs provided to incarcerated beneficiaries by reopening and revising CYs 2006 through 2010 final payment determinations to remove gross drug costs of \$325,903 for the sampled incarcerated beneficiaries.

Page 2- Daniel R. Levinson

CMS Response

The CMS concurs with this recommendation. After implementing regulations clarifying the relevant policy, CMS will update the applicable eligibility and enrollment systems. This, in turn, will facilitate the appropriate changes to the PDE data. CMS will conduct a reopening on each year that has not already been closed to resolve improper payments. When CMS conducts a reopening on a contract year, the improper payment issues will be resolved for that contract year.

OIG Recommendation

The OIG recommends CMS strengthen internal controls to ensure that Medicare does not pay for prescription drugs for incarcerated beneficiaries, specifically by developing and implementing policies and procedures that provide sponsors on a timely basis with all of the incarceration information that is necessary for them to verify beneficiaries' dates and status of incarceration, including the names and contact information of correctional facilities.

CMS Response

The CMS concurs with this recommendation to prevent improper payments of Part D services to incarcerated individuals. CMS will seek to codify the eligibility requirements in regulations and establish an operational mechanism to relay confirmed incarceration status to plans for their use in determining eligibility for new and/or continued enrollment and receipt of Medicare covered services. Upon disenrollment from a Medicare prescription drug plan sponsor, CMS will no longer pay for services rendered to the individual.

The CMS will continue to investigate means to provide the correctional facility contact information to the plan; however, receipt of such information in a timely manner is dependent upon the federal, state and local penal facilities reporting the data. Thus, CMS is not able to guarantee that all the information regarding the correctional facility will be available for the sponsor to verify beneficiaries' dates and status of incarceration. In cases where incomplete data are received, CMS will continue sharing this information with sponsors as an indicator of possible ineligibility for the sponsor to investigate further.

OIG Recommendation

The OIG recommends CMS work with the sponsors to identify and resolve improper Part D payments made for prescription drugs provided to incarcerated beneficiaries, which would include the estimated \$11,656,314 in additional gross drug costs identified in this report, by reopening and revising final payment determinations for all periods before implementation of the enhanced policies and procedures described above.

CMS Response

The CMS non-concurs with this recommendation. There is no effective way of fully recovering these payments without first implementing the appropriate policies and procedures, including the

Page 3- Daniel R. Levinson

relevant systems changes. After implementing regulations clarifying the relevant policy, CMS will update the applicable eligibility and enrollment systems. This, in turn, will facilitate the appropriate changes to the PDE data. When CMS conducts a reopening on a contract year, the improper payment issues will be resolved for that contract year. CMS will conduct a reopening on each year that has not already been closed to resolve improper payments.

Other Comments

The CMS would also like to provide the following comments on the report: On pages 3 and 5, the beneficiary is disenrolled after 12 months, not 6 months per 42 CFR 423.44(d)(5)(ii). In addition, on page 5, the manual citation in the second paragraph should read section 50.2.1.2.

Thank you again, for the opportunity to review and comment on this report. We appreciate the time and effort that went into developing it, and look forward to continuing to work with the OIG on this important issue.