Department of Health and Human Services
Office of Inspector General
Office of Audit Services

October 2024 | A-09-21-03008

Medicare Part D Paid Millions for Drugs for Which Payment Was Available Under the Medicare Part A Skilled Nursing Facility Benefit

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- An OIG evaluation in 2009 found that Part D paid for drugs for enrollees during Part A skilled nursing facility (SNF) stays, and OIG audits in 2012 and 2019 found that Part D paid for drugs for enrollees receiving Part A hospice care. Part D does not cover drugs for which payment is available under Part A.
- Because the SNF evaluation report was issued almost 15 years ago and the hospice audits showed there was a continuing problem with improper Part D payments, we reviewed Part D plan sponsors' prescription drug event (PDE) data to determine whether Part D paid for drugs for which payment was available under the Part A SNF benefit.

What OIG Found

For all 215 sample items, Part D improperly allowed PDEs for drugs that were dispensed to or on behalf of Part D enrollees during their Part A SNF stays.

- For 89 of the 215 sample items, SNFs' medical records confirmed that the drugs were administered to the Part D enrollees during their Part A SNF stays.
- For 136 of the 215 sample items, there was no documentation to determine whether drugs from the pharmacies listed on the PDEs were administered during Part D enrollees' Part A SNF stays.

On the basis of our sample results, for 2018 through 2020, we estimated that up to the entire Part D total cost of $465.1 million was improperly paid for drugs for which payment was available under the Part A SNF benefit. Of that amount, we estimated that approximately $245.4 million was for drugs that the medical records showed were administered to Part D enrollees during their Part A SNF stays.

What OIG Recommends

We made five recommendations, including that CMS work with its plan sponsors to adjust or delete PDEs, as necessary, and determine the impact to the Federal Government related to the Part D total costs of $953,370 for drugs associated with our sample items for which payment was available under the Part A SNF benefit; work with its plan sponsors to identify similar instances of noncompliance that occurred during our audit period and determine the impact to the Federal Government, which could have amounted up to an estimated $465.1 million in Part D total cost; and provide plan sponsors with timely and accurate information, such as dates of covered Part A SNF stays, to reduce instances of inappropriate Part D payment for drugs for which payment is available under the Part A SNF benefit. The full recommendations are in the report.

CMS concurred with all five recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Prior Office of Inspector General (OIG) work found that Medicare Part D (Part D) paid for drugs that most likely were paid for by Medicare Part A (Part A). Specifically, an evaluation in 2009 found that Part D paid for drugs for enrollees during Part A skilled nursing facility (SNF) stays, and audits in 2012 and 2019 found that Part D paid for drugs for enrollees receiving Part A hospice care.[1] Because the SNF evaluation report was issued almost 15 years ago and the hospice audits showed there was a continuing problem with improper Part D payments, we conducted this audit of drugs paid for by Part D for calendar years 2018 through 2020 for which payment was available under the Part A SNF benefit.[2]

OBJECTIVE

Our objective was to determine whether Medicare Part D paid for drugs for which payment was available under the Medicare Part A SNF benefit.

BACKGROUND

Medicare and the Part D Prescription Drug Program

The Medicare program provides health insurance for people aged 65 years and older, people with disabilities, and people with end-stage renal disease. Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, such as SNF services. Medicare Part B (Part B) provides insurance for preventative and medical services that are not covered under Part A. Part D provides coverage for outpatient prescription drugs. The Centers for Medicare & Medicaid Services (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 (the Act) by establishing the Part D voluntary prescription drug benefit.[3] Under Part D, which went into effect on January 1, 2006, individuals who are entitled to benefits under Part A or are enrolled in Part B may obtain voluntary coverage for outpatient prescription drugs.

CMS contracts with private insurers (also known as plan sponsors) to offer prescription drug benefits to eligible individuals who choose to enroll in Part D. Medicare enrollees have the

[1] See Appendix B for a list of related OIG reports.

[2] Data for calendar years 2018 through 2020 were the most recent available at the start of our audit.

[3] P.L. No. 108-173 (Dec. 8, 2003).

option to receive benefits from stand-alone prescription drug plans, or they may receive prescription drug coverage under managed care plans.[4]

CMS requires that plan sponsors develop a network of pharmacies to dispense drugs to Part D enrollees in their plans (42 CFR § 423.120). Pharmacies submit claims to plan sponsors (or to plan sponsors' Pharmacy Benefit Managers) for drugs they dispense to Part D enrollees.[5] Plan sponsors then must submit to CMS summary records, known as prescription drug event (PDE) records, for all covered drugs that are dispensed to enrollees throughout the year.[6, 7] (In this report, we refer to PDE records as "PDEs.")

PDEs contain cost data as well as information about each drug, including the date of service, payment fields, the pharmacy that dispensed the drug, the Part D enrollee who received the drug, and where the enrollee lived (e.g., at home or in a SNF) at the time the prescription was filled (referred to as the "patient residence code").[8, 9] The prescription drug cost and payment data contained in PDEs enable CMS to make payments to plan sponsors and administer the Part D benefit.

Medicare Payments to Plan Sponsors

CMS makes estimated monthly payments to plan sponsors for each Part D enrollee (42 CFR § 423.315). After the coverage year, CMS reconciles these estimated monthly payments with the actual costs incurred by plan sponsors to determine at the end of the year whether CMS owes money to the plan sponsors or the plan sponsors owe money to CMS (42 CFR §§ 423.315(f) and 423.343). CMS determines each plan sponsor's actual costs based on the

[4] Managed care plans (known as Medicare Advantage plans) also include medical benefits.

[5] Pharmacy Benefit Managers are organizations that help manage prescription drug benefits on behalf of health insurers, Part D drug plans, large employers, and other payers.

[6] 42 CFR § 423.322; CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data* (Apr. 26, 2006).

[7] A PDE record is not the same as an individual drug claim transaction but is a summary extract using CMS-defined standard fields.

[8] The payment fields in PDE records include the: (1) ingredient cost paid, (2) dispensing fee paid, (3) amount attributed to sales tax, and (4) vaccine administration fee. The sum of these fields, referred to as the "gross covered drug cost" (Part D total cost), is the amount that a drug plan incurs for covered Part D drugs. Another payment field is the patient payment amount, which lists the dollar amount the enrollee paid that is not reimbursed by a third party (e.g., copayments, coinsurance, deductibles, or other patient payment amounts).

[9] CMS's memo "2014 Requirements for Coding Patient Residence and Pharmacy Service Type on Claims Transactions" (June 20, 2013). Available online at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/memo2014requirementsforpatientresidencepharmacytype_06.20.13.pdf. Accessed on Feb. 28, 2024.

PDEs that the plan sponsor submits and CMS accepts (i.e., allowable PDEs) netted with direct and indirect remuneration (DIR) reported by the plan sponsor.[10]

If a plan sponsor submits PDEs for drugs that should not have been paid under Part D (e.g., drugs for which payment was available under the Part A SNF benefit), the plan sponsor may be overpaid for the drugs by the Federal Government.[11] To determine the estimated impact to the Federal Government of identified overpayments, CMS calculates the effect of the overpayment on reinsurance and low-income cost-sharing amounts.[12] CMS uses a reopening process, during which adjustments or deletions to PDEs may result in adjustments to the plan sponsor's final payment determination, to determine the impact of identified overpayments.[13] Following this process, CMS recoups the calculated amount of the impact to the Federal Government through an adjustment to the plan sponsor's estimated monthly payment.

Medicare Part D-Covered Drugs

The Act specifies that a drug prescribed to a Part D-eligible individual is not covered by Part D if payment for such drug "is available (or would be available but for the application of a deductible) under part A or B for that individual" (the Act § 1860D-2(e)(2)(B)). Federal regulations state that Part D does not cover drugs "for which payment . . . is available . . . under Part A or Part B (even though a deductible may apply . . .)" (42 CFR § 423.100(2)(i)).

Plan sponsors should rely on information, such as location of administration of a drug (e.g., to determine whether a prescription is being dispensed for an enrollee in a nursing home), when available to avoid the need for a separate coverage determination request to obtain the

[10] DIR comprises fees, payments, or payment adjustments that change the cost of Part D-covered drugs for plan sponsors or PBMs. DIR results from payment arrangements negotiated independently of CMS—between plan sponsors, PBMs, network pharmacies, drug manufacturers, and other parties involved in the administration of the Part D benefit. Manufacturer rebates make up a significant share of all DIR reported to CMS. 42 CFR § 423.308; CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data*, § 11 (Apr. 26, 2006).

[11] If a plan sponsor has identified that it has received an overpayment, the plan sponsor must report and return that overpayment no later than 60 days after the date on which it identified it received an overpayment (42 CFR § 423.360(b)–(d)). Plan sponsors must report and return any overpayment identified within the 6 most recent completed payment years (42 CFR § 423.360(f)).

[12] Reinsurance and low-income cost-sharing amounts are two mechanisms that Part D provides to pay plan sponsors for Part D basic benefits. The reinsurance subsidy is a Federal subsidy for 80 percent of allowable drug costs above an enrollee's out-of-pocket threshold. Reinsurance reduces plan sponsors' risk of participation in Part D by guaranteeing plans a certain amount of payment for Part D enrollees who have high drug costs. Low-income cost-sharing subsidies are payments on behalf of certain enrollees based on their income and asset levels (42 CFR § 423.329).

[13] CMS may reopen and revise an initial or reconsidered final payment determination: (1) for any reason within 12 months from the date of the notice of the final determination to the plan sponsor, (2) after that 12-month period but within 4 years after the date of the notice of the initial or reconsidered determination to the plan sponsor upon establishment of good cause for reopening, or (3) at any time in instances of fraud or similar fault of the Part D plan sponsor or any subcontractor of the Part D plan sponsor (42 CFR § 423.346(a)).

needed information. Assuming the available information on location is sufficient to correctly assign payment to Parts A or B or Part D, there is no need in such cases to require that additional information be obtained from the physician (CMS's *Medicare Prescription Drug Benefit Manual,* Pub. No. 100-18, chap. 6, § 20.2.2).

To the extent that a plan sponsor requires one of its contracted pharmacies to report the information provided on the prescription to assist in determining whether a drug is covered by Parts A or B vs. Part D, the plan sponsor should rely on the pharmacist's report of appropriate information to appropriately adjudicate the claim under Part D (CMS's *Medicare Prescription Drug Benefit Manual,* Pub. No. 100-18, chap. 6, § 20.2.2).

Medicare Part A Coverage of Skilled Nursing Facility Care, Including Drugs Furnished by Skilled Nursing Facilities

Part A covers posthospital skilled nursing care for enrollees who meet certain conditions. To qualify for Part A SNF coverage, an enrollee must first have a medically necessary inpatient hospital stay of at least 3 consecutive days, not counting the date of discharge (42 CFR § 409.30(a)(1)). The enrollee must be in need of SNF care, be admitted to a SNF facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital (42 CFR § 409.30(b)(1)). SNF care provided under Part A is limited to a benefit period of 100 days and requires a coinsurance payment for days 21 through 100 (42 CFR § 409.61(b)).

Medicare pays SNFs prospectively for enrollees in Part A stays. These prospective payments cover most services that SNFs provide, including nursing care and physical, occupational, and speech therapies (42 CFR §§ 413.335 and 409.20). The payments also cover such drugs and biologicals as are ordinarily furnished by SNFs for the care and treatment of inpatients (the Act §§ 1861(h)(5) and 1888(e)(2)(A)(i); 42 CFR §§ 409.20(a)(5), 409.25, and 413.335(b)).[14] In addition, these payments cover a limited supply of drugs for use outside a SNF if it is medically necessary to facilitate an enrollee's departure from the facility and is required until the enrollee can obtain a continuing supply (42 CFR § 409.25(b)). Furthermore, payments for drugs "are not limited to those routinely stocked by the facility but include those obtained for the patient from an outside source, such as a pharmacy in the community" (CMS's *Medicare Benefit Policy Manual,* Pub. No. 100-02, chap. 8, § 50.5). Part A does not cover certain drugs that may be

[14] Drugs provided in an inpatient setting to an individual who has exhausted the lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Part D coverage may be available to a Part D enrollee who has exhausted the Part A inpatient stay benefit and who remains in that inpatient setting (provided the drug would otherwise be covered under Part D) (CMS's *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, chap. 6, § 20.2.1).

billed separately to Part B (the Act § 1888(e)(2)(A)(iii)).[15] For example, Part B covers various chemotherapy drugs.

CMS's Quarterly Report Identifying Medicare Part D Enrollees Who Are Long-Term Institutionalized Residents

From 2009 through 2023, CMS provided a quarterly report that plan sponsors could use to identify Part D enrollees in a Part A-covered stay to prevent Part D payment for drugs covered by Part A. The report identified Part D enrollees who were Long-Term Institutionalized (LTI) residents and associated with the plan sponsor as of the end of a specified quarter.[16] (We refer to this report as the "LTI resident report."[17]) The report included a Prospective Payment System indicator, which showed that at least a portion of a Part D enrollee's SNF stay was covered by Part A.

In its memo issued to plan sponsors that accompanied each quarterly LTI resident report, CMS provided best practices, stating that it:

> . . . recognizes the value of this report to assist with preventing Part D payment of drugs covered by Part A. However, in addition to being used prospectively to avoid payment for drugs during Part A skilled nursing facility stays, this report data may also be used for retrospective reviews of paid claims to identify claims that should have been billed under Part A; thus, permitting [plan] sponsors to recover inappropriate Part D payments and work with long-term care (LTC) providers to ensure future compliance.[18]

HOW WE CONDUCTED THIS AUDIT

Our audit covered 2,557,806 PDEs that plan sponsors submitted for prescription drugs dispensed by pharmacies from January 1, 2018, through December 31, 2020 (audit period) to or on behalf of Part D enrollees while they were receiving Part A SNF services, for which the Part D

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[15] CMS's SNF Consolidated Billing File, updated annually, contains the complete list of Healthcare Common Procedure Coding System (HCPCS) codes that are excluded from SNF consolidated billing for claims submitted to Part A Medicare Administrative Contractors for payment. HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

[16] LTI residents are enrollees who have a reported length of stay of more than 90 days in a long-term care facility.

[17] CMS stopped providing the LTI resident report after December 2023. CMS's memo "Long-Term Institutionalized Residents Report" (Sept. 13, 2023). Available online at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-september-11-15. Accessed on Jan. 17, 2024.

[18] CMS's memo "Long-Term Institutionalized Residents Report" (Mar. 13, 2018). (This was the applicable memo for the first quarter of our audit period.) Available online at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/memoltiresidentreport_march_2018.pdf. Accessed on Feb. 28, 2024.

total cost was $465.1 million.[19] We grouped the PDE records by dispensing pharmacy type and enrollee SNF stay, which resulted in 643,480 sample units, and selected a stratified random sample of 215 sample items, for which the Part D total cost was $953,370.[20, 21] We reviewed SNFs' documentation (such as physician orders, medication administration records (MARs), and pharmacy shipping and delivery records) to determine whether the drugs were administered during the Part D enrollees' Part A SNF stays.[22]

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 describes our audit scope and methodology, Appendix C describes our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

For our audit period, Medicare Part D improperly paid for drugs for which payment was available under the Medicare Part A SNF benefit. Specifically, for all 215 sample items, Part D improperly allowed PDEs for drugs that were dispensed to or on behalf of Part D enrollees during their Part A SNF stays. For 89 of the 215 sample items, medical records from the SNFs confirmed that the drugs were administered to the Part D enrollees during their Part A SNF stays. For 136 of the 215 sample items, although the PDE records showed that the drugs were dispensed during the Part A SNF stays, there was no documentation to determine whether the drugs from the pharmacies listed on the PDEs were administered during the Part D enrollees'

[19] We limited our audit to those PDEs that were for prescription drugs that were not excluded from CMS's consolidated billing requirements for SNF stays and that occurred: (1) on or after the date of admission to a SNF for LTC pharmacies or after the date of admission for other pharmacy types, (2) at least 7 days before an enrollee discharge, and (3) before the exhaustion of an enrollee's SNF benefit, e.g., those PDEs that occurred within the first 100 days of an enrollee's Part A SNF stay.

[20] We obtained the dispensing pharmacy type from the Medicare Part D Pharmacy Characteristics file and obtained the enrollee SNF stay information from Medicare Part A SNF claims data. An enrollee's Part A SNF stay may consist of more than one Part A claim if there was not a break in service dates between the claims.

[21] For this audit, we identified the dispensing pharmacy types as "LTC," "specialty," and "retail and other."

[22] We considered a drug administered if it was available at the SNF to be: (1) administered by a health care provider or (2) self-administered.

Part A SNF stays.[23, 24] Drugs that are unaccounted for (i.e., dispensed while an enrollee is in a Part A SNF stay but not administered to the enrollee) may be at risk for waste or diversion.[25]

On the basis of our sample results, we estimated that up to the entire Part D total cost of $465.1 million was improperly paid for drugs for which payment was available under the Part A SNF benefit.[26] Of that amount, we estimated that approximately $245.4 million was for drugs that the medical records showed were administered to Part D enrollees during their Part A SNF stays.[27] According to Part D plan sponsors, they paid for these drugs because they did not have a reliable source of timely and accurate information available to identify Part D enrollees' Part A-covered SNF stays (e.g., specific admission and discharge dates for enrollees).

In addition, of the $465.1 million, we estimated that Part D enrollees paid approximately $21 million for drugs for which payment was available under the Part A SNF benefit, of which an estimated $6.4 million was for drugs that the medical records showed were administered during enrollees' Part A SNF stays.[28, 29] These payments could have caused a financial strain on Part D enrollees, especially those payments occurring on or after the 21st day of an enrollee's Part A SNF stay because the enrollee would also have been responsible for daily coinsurance.

FEDERAL REQUIREMENTS

The Act specifies that a drug prescribed to a Part D-eligible individual is not covered by Part D if payment for such drug "is available (or would be available but for the application of a deductible) under part A or B for that individual" (the Act § 1860D-2(e)(2)(B)). Federal regulations state that Part D does not cover drugs "for which payment . . . is available . . . under Part A or Part B (even though a deductible may apply. . .)" (42 CFR § 423.100(2)(i)).

[23] The combined number of deficiencies is higher than 215 because 10 sample items had some PDEs for drugs that were administered during Part D enrollees' Part A SNF stays and had other PDEs for drugs for which there was no documentation to determine whether the drugs from the pharmacies listed on the PDEs were administered during the Part D enrollees' Part A SNF stays.

[24] We did not request documentation from the SNFs for 66 PDEs associated with 4 sample items because the SNFs were part of OIG investigations. We treated the sample items as errors because the drugs were available for payment under the Part A SNF benefit.

[25] Drug diversion is the illegal distribution or abuse of prescription drugs or the use of those drugs for purposes not intended by a prescriber.

[26] The estimated amount was $465,077,908.

[27] The estimated amount was $245,365,324.

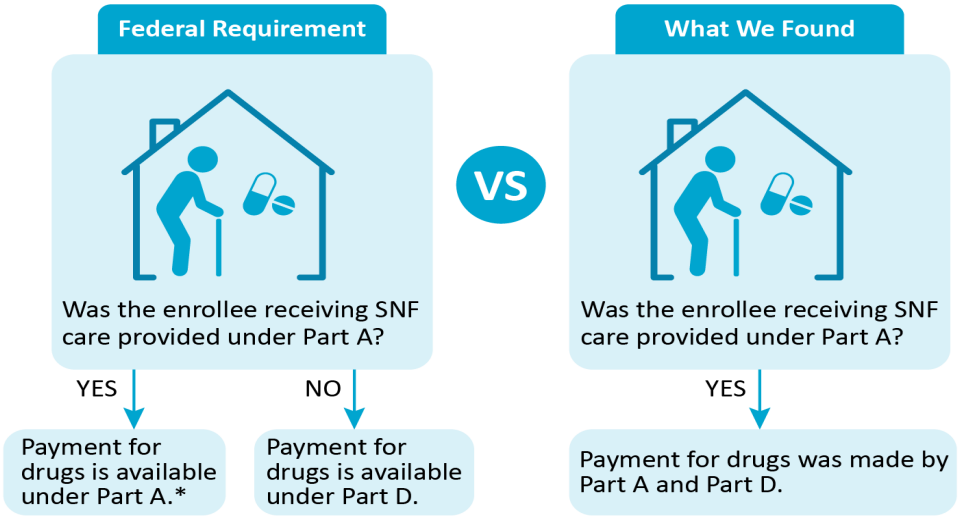
[28] The $21 million was the portion paid by enrollees that is not reimbursed by a third party (e.g., copayments, coinsurance, deductibles, or other patient payment amounts).

[29] The estimated amounts were $21,040,555 and $6,415,048, respectively.

MEDICARE PART D IMPROPERLY PAID FOR DRUGS FOR WHICH PAYMENT WAS AVAILABLE UNDER THE MEDICARE PART A SKILLED NURSING FACILITY BENEFIT

For all 215 sample items, Part D improperly allowed PDEs for drugs that were dispensed to Part D enrollees during their Part A SNF stays; there were 1,321 improperly allowed PDEs, totaling $953,370. The figure shows how payment for drugs should be made for a Part D enrollee in a SNF stay according to Federal requirements vs. what our audit found.

Figure: Payment for Drugs for a Medicare Part D Enrollee According to Federal Requirements vs. What Our Audit Found



* Part A does not cover certain drugs that may be billed separately to Part B.

For 89 of the 215 sample items, the medical records from the SNFs showed that the drugs were administered to the Part D enrollees during their Part A SNF stays. For 136 of the 215 sample items, although the PDE records showed that the drugs were dispensed during the Part A SNF stays, there was no documentation from the SNFs to determine whether the drugs dispensed by the pharmacies listed on the PDEs were administered during the Part D enrollees' Part A SNF stays.[30] Drugs that are unaccounted for (i.e., dispensed while an enrollee is in a Part A SNF stay but not administered to the enrollee) may be at risk for waste or diversion.

For Some Drugs Associated With Our Sample Items, Medical Records Showed That the Drugs Were Administered to Medicare Part D Enrollees During Their Skilled Nursing Facility Stays

For 89 of the 215 sample items, Part D allowed 510 PDEs, totaling $541,652, for drugs that medical records (e.g., MARs) from the SNFs confirmed were administered to Part D enrollees during their Part A SNF stays. Table 1 on the following page shows the breakdown by pharmacy type (i.e., LTC, specialty, and retail and other) for these PDEs.

[30] See footnote 23.

Table 1: Medicare Part D Total Costs for Drugs That Were Administered During Part D Enrollees' Medicare Part A SNF Stays by Pharmacy Type

		Drugs Administered During SNF Stay		
Pharmacy Type	Total No. of Sample Items	No. of Sample Items	No. of Part D-Allowed PDEs	Part D Total Costs
LTC	50	36	433	50,278
Specialty	65	36	48	358,932
Retail and other	100	17	29	132,442
Total	**215**	**89**	**510**	**$541,652**

Below are examples that show dispensing of drugs by the three pharmacy types (LTC, specialty, and retail and other) that were administered to Part D enrollees during their Part A SNF stays and how the SNFs obtained those drugs.

LTC Pharmacies

LTC pharmacies are typically owned by or contract with nursing homes to provide drugs to nursing home residents. Drugs dispensed by LTC pharmacies in our audit were primarily obtained by SNFs from these pharmacies. For 36 of the 50 sample items, documentation from the SNFs showed that the drugs dispensed by LTC pharmacies were administered to Part D enrollees during their Part A SNF stays.

For example, one LTC pharmacy dispensed drugs for a Part D enrollee who was admitted to a SNF under Part A on August 15, 2018, and discharged on November 19, 2018. The SNF obtained nine different types of drugs from the LTC pharmacy and administered them to the Part D enrollee during the enrollee's Part A SNF stay. Because the drugs were dispensed and administered to the Part D enrollee during the Part A SNF stay, the drugs were available for payment under the Part A SNF benefit. Part D allowed 49 PDEs, with total costs of $1,129 for the 9 drugs.

Specialty Pharmacies

Specialty pharmacies generally provide medications that are more complex than most prescription medications for people living with serious health conditions (e.g., cancer, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis). Drugs dispensed by specialty pharmacies in our audit were primarily provided to SNFs by Part D enrollees or their families. For 36 of the 65 sample items, documentation from the SNFs showed that the drugs dispensed by specialty pharmacies were administered to enrollees during their Part A SNF stays. Although the drugs from the specialty pharmacies were not excluded from Part A consolidated billing and therefore were available for payment under the Part A SNF benefit, for 34 of the 36 sample items, the drugs were provided to the SNFs by the enrollees or their families.

For example, a SNF accepted admission of a Part D enrollee from a hospital only when the family assured the SNF that it would provide to the facility the drug the enrollee was taking. The enrollee was admitted to the SNF under Part A on August 21, 2019, and discharged on September 16, 2019. The SNF obtained from the family a drug used for the treatment of lung cancer and administered 27 tablets to the Part D enrollee during the enrollee's stay.[31] Part D allowed payment for 1 PDE, with total costs of $15,494, for 30 tablets of the drug. The SNF stated that it did not know that the family was using the Part D benefit to pay for the drugs. The SNF explained that the hospital had a difficult time placing the enrollee in a SNF because of the high cost of the drug, which made it cost prohibitive for a SNF to accept the enrollee. According to the SNF, the cost of this drug was more than Medicare paid the SNF for the entire stay, plus the hours of therapy that enabled this enrollee to successfully return home.

Retail and Other Pharmacies

Retail pharmacies dispense medications to the general public.[32] Drugs dispensed by retail and other types of pharmacies in our audit were obtained either by the SNFs or by the Part D enrollees or their families.[33] For 17 of the 100 sample items, documentation from the SNFs showed that the drugs dispensed by retail and other pharmacies were administered to Part D enrollees during their Part A SNF stays.

For example, a SNF obtained directly from a Part D enrollee a drug used to treat certain types of prostate cancer, which the SNF administered to the enrollee during the enrollee's Part A SNF stay.[34] The Part D enrollee was admitted to the SNF on June 9, 2019, and discharged on July 12, 2019. Because the drug was dispensed and administered to the Part D enrollee during the Part A SNF stay, the drug was available for payment under the Part A SNF benefit. Part D allowed 1 PDE, with total costs of $11,114, for which the Part D enrollee paid $556 for the drug.

[31] Some oral cancer drugs are covered separately by Part B. These drugs are included in CMS's SNF Consolidated Billing File (see footnote 15). We limited our audit to those PDEs that were for prescription drugs that were not excluded from CMS's consolidated billing requirements for SNF stays.

[32] Retail pharmacies are independent pharmacies, chain pharmacies, supermarket pharmacies, and mass merchandiser pharmacies that dispense medications to the general public at retail prices.

[33] Other pharmacies include: (1) mail-order pharmacies, which use common carriers to deliver medications to patients or their caregivers; (2) compounding pharmacies, which use specialized equipment and specially designed facilities to prepare components that are combined into a drug; and (3) nonpharmacy dispensing sites (e.g., physician offices, emergency rooms, urgent care centers, and rural health facilities) that dispense medicinal preparations under the supervision of a physician to patients for self-administration.

[34] See footnote 31.

For Some Drugs Associated With Our Sample Items, There Was No Documentation To Determine Whether the Drugs Were Administered to Medicare Part D Enrollees

For 136 of the 215 sample items, Part D allowed 811 PDEs, totaling $411,718, for drugs for which payment was available under the Part A SNF benefit and no documentation (such as medical records) was available to determine whether the drugs from the pharmacies listed on the PDEs were administered during Part D enrollees' Part A SNF stays.

For example, a Part D enrollee was admitted to a SNF under Part A on August 14, 2020, and discharged on November 21, 2020. During the enrollee's stay, the SNF obtained from its contracted pharmacy a combination of three drugs to help control HIV infection and administered those drugs. Although the enrollee was in a Part A-covered SNF stay and received the drugs from the SNF, another pharmacy dispensed the same drugs (i.e., three 30-day supplies for two of the drugs and two 30-day supplies for another drug), resulting in Part D total costs of $12,411. There was no documentation to determine whether the drugs from the pharmacy listed on the PDEs were administered during the Part D enrollee's Part A SNF stay. However, because payment for the drugs was available under the Part A SNF benefit and the enrollee was already receiving the drugs in the covered SNF stay, Part D should not have paid for the drugs dispensed by the other pharmacy. Multiple pharmacies dispensing the same drug may lead to excess supplies of the drugs, which could result in waste.

In another example, a Part D enrollee was admitted to a SNF under Part A on October 20, 2018, and discharged on December 31, 2018. During the enrollee's stay, a retail pharmacy dispensed seven different types of drugs. There was no documentation available to determine whether the drugs from the retail pharmacy listed on the PDEs were administered during the enrollee's Part A SNF stay. In addition, the drugs were not included in the physician orders or MARs, and a different pharmacy was listed on the delivery sheets for other drugs that the SNF obtained and administered to the enrollee. Part D allowed 16 PDEs (i.e., three 30-day supplies for four drugs, two 30-day supplies for the fifth drug, one 90-day supply for the sixth drug, and one 30-day supply for the seventh drug), with total costs of $9,912 for the drugs. Because payment for the drugs was available under the Part A SNF benefit, Part D should not have paid for the drugs dispensed by the pharmacy.

A drug that continues to be dispensed by a pharmacy while a Part D enrollee is in a Part A SNF stay could cause harm to the enrollee or another person. Specifically, the filling of unnecessary or unwanted prescriptions could lead to unsafe disposal of the drugs. Unused drugs that are not safely disposed of could end up in the wrong hands (e.g., drugs thrown in the trash can be retrieved to be abused or for drug diversion). Furthermore, unwanted drugs may be held past their expiration dates, which may cause the drugs to be less effective. Certain expired medications are at risk of bacterial growth, and subpotent antibiotics may fail to treat infections, leading to more serious illnesses and antibiotic resistance.[35]

[35] Food and Drug Administration, "Don't Be Tempted to Use Expired Medicines." Available online at https://www.fda.gov/drugs/special-features/dont-be-tempted-use-expired-medicines. Accessed on Feb. 28, 2024.

PLAN SPONSORS DID NOT HAVE TIMELY AND ACCURATE INFORMATION TO IDENTIFY MEDICARE PART D ENROLLEES IN MEDICARE PART A SKILLED NURSING FACILITY STAYS

According to plan sponsors, they paid for drugs for which payment was available under the Part A SNF benefit because they did not have a reliable source of timely and accurate information available to identify Part D enrollees in Part A-covered SNF stays.

During our audit period, although CMS provided plan sponsors with the quarterly LTI resident report to identify Part D enrollees in a Part A-covered stay, the report did not contain specific admission and discharge dates for enrollees. Because there were no specific dates in this report, plan sponsors contacted SNFs to obtain accurate dates of stay to identify Part D claims potentially billed in error. According to some plan sponsors, SNFs did not always cooperate with them to provide the dates. Additionally, plan sponsors did not have access to Part A claims data; therefore, they primarily relied on the LTI resident report to determine the dates that Part D enrollees received Part A SNF benefits.

Furthermore, because CMS provided the LTI resident report quarterly, it limited plan sponsors' effectiveness in ensuring payment integrity for both prospective and retrospective payments. Providing information to plan sponsors more frequently could help reduce claim payments that later require recoupment through the retroactive recovery process. More frequent reporting of information (e.g., specific admission and discharge dates) would allow for timelier outreach to SNFs and the ability for plan sponsors to deny or to place prior authorization restrictions on pharmacy claims for Part D enrollees who are in active Part A SNF stays.

Finally, although pharmacies submit patient residence codes on all Part D claim transactions at the point of sale, some plan sponsors stated that the codes are not specific enough to determine whether an enrollee's stay in a SNF is covered by Part A. According to the plan sponsors we contacted, if CMS provided them daily with Part D enrollees' Part A SNF status, similar to how CMS provides enrollees' hospice status, it would be feasible for plan sponsors to implement a point-of-sale edit.[36, 37]

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[36] CMS provides each plan sponsor with a daily Transaction Reply Report (TRR). The TRR, which is created each evening from Monday through Saturday, is available for the plan sponsor the following business day. The TRR contains information about the Medicare enrollee, the plan contract number, and indicators such as whether the enrollee is disabled, is in hospice, or has end-stage renal disease. To ensure that a plan sponsor receives proper payment, its Medicare enrollee records must agree with those reported to and maintained by CMS. Therefore, it is important that the plan sponsor continue to reconcile its records with the TRR. The TRR does not include information related to enrollees' Part A SNF stays.

[37] There are three types of point-of-sale edits: the hard-reject and soft-reject edits and message-only alerts. The hard-reject edit stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan sponsor representative. The soft-reject edit stops the pharmacy from processing a claim unless or until a pharmacist-submitted drug utilization review is completed or a Prospective Payment System code is entered. Message-only alerts do not stop a claim from being processed but provide important clinical or coverage information, or both, to a pharmacy.

MEDICARE PART D PAID UP TO AN ESTIMATED $465 MILLION FOR DRUGS FOR WHICH PAYMENT WAS AVAILABLE UNDER MEDICARE PART A

On the basis of our sample results, we estimated that for our audit period up to the entire Part D total cost of $465,077,908 was improperly paid for drugs for which payment was available under the Part A SNF benefit. Of that amount, we estimated that $245,365,324 was for drugs that medical records showed were administered to Part D enrollees during their Part A SNF stays.

We also estimated that Part D enrollees paid $21,040,555 for drugs for which payment was available under the Part A SNF benefit.[38] Of that amount, we estimated that $6,415,048 was for drugs that medical records showed were administered during enrollees' Part A SNF stays. These payments could have caused a financial strain on Part D enrollees, especially those payments occurring on or after the 21st day of an enrollee's Part A SNF stay because the enrollee would also have been responsible for daily coinsurance.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- work with its plan sponsors to adjust or delete PDEs, as necessary, and determine the impact to the Federal Government related to the Medicare Part D total costs of $953,370 for drugs associated with our sample items for which payment was available under the Medicare Part A SNF benefit, which included $541,652 for drugs that were administered during Part D enrollees' Part A SNF stays;

- work with its plan sponsors to identify similar instances of noncompliance that occurred during our audit period and determine the impact to the Federal Government, which could have amounted up to an estimated $465,077,908 in Part D total cost, including $245,365,324 for drugs that were administered during enrollees' Part A SNF stays;

- work with its plan sponsors to identify similar instances of noncompliance that occurred before and after our audit period and determine the impact to the Federal Government related to Part D total costs for drugs for which payment was available under the Medicare Part A SNF benefit;

- provide plan sponsors with timely and accurate information, such as dates of covered Part A SNF stays, to reduce instances of inappropriate Part D payment for drugs for which payment is available under the Part A SNF benefit; and

[38] The Part D enrollee payments are part of, not in addition to, the estimated total costs associated with the drugs for which payment was available under the Part A SNF benefit.

- instruct SNFs to cooperate with plan sponsors to identify and prevent improper Part D payments for drugs for which payment was available under the Part A SNF benefit.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with all five of our recommendations and described actions that it planned to take to address them. In addition, CMS provided comments on our finding that 136 of the 215 sample items had no documentation to determine whether the drugs from the pharmacies listed on the PDEs were administered during Part D enrollees' Part A SNF stays.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included in their entirety as Appendix E.

The following sections summarize CMS's comments and our response.

CMS COMMENTS

CMS had the following comments on our five recommendations:

- For our first recommendation, CMS stated that it concurred with our recommendation within its authority. CMS stated that for PDEs for which we found documentation to support the conclusion that plan sponsors paid for drugs administered during Part D enrollees' Part A SNF stays, CMS will notify the sponsors that they should review and delete, as appropriate, the specified PDE records. CMS stated, however, that these PDE records may ultimately be adjusted or deleted by plan sponsors—for reasons unrelated to this particular audit issue—and that these records are used in complicated reconciliation calculations that do not result in dollar-for-dollar reimbursement by the Federal Government to the plan sponsor. CMS stated that, therefore, "it will not be possible to definitively determine the dollar impact of the adjustment or deletion of PDE records that are not specifically associated with Part A stays."

- For our second and third recommendations, CMS concurred and stated that it will consider the information we provided in our report when developing its strategy for future Part D audits.

- For our fourth recommendation, CMS concurred and stated that it is continuing to explore how to better provide plan sponsors with timely and accurate SNF stay information.

- For our fifth recommendation, CMS concurred and stated that it will educate SNFs to coordinate with plan sponsors to identify and help prevent improper Part D payments for drugs for which payment was available under the Part A SNF benefit.

Regarding our finding on the 136 sample items for which there was no documentation to determine whether drugs were administered during Part D enrollees' Part A SNF stays, CMS stated that while we noted only that these drugs may be at risk for waste or diversion, we still concluded that these payments were improper. CMS stated that it believes that it is not appropriate to conclude that these payments were improper without supporting documentation indicating that they were both dispensed and administered during Part D enrollees' Part A SNF stays. CMS also stated that a Part D enrollee in a Part A SNF stay could be administered drugs that were paid by Part D appropriately. CMS provided the following example: when a patient is scheduled for discharge from a SNF, and medications are dispensed to cover any gap in care immediately following discharge, the discharge plan may subsequently change, and the patient remains in the SNF. CMS stated that this enrollee may therefore have drugs administered in the SNF that were appropriately paid for by Part D at the time they were dispensed.

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding our first recommendation, we acknowledge that these PDE records may be adjusted or deleted by plan sponsors for reasons unrelated to this particular audit issue and that CMS may not be able to definitively determine the impact to the Federal Government. In addition, we maintain that CMS should work with plan sponsors to determine the impact related to drugs associated with all of our sample items, not only those for which we found documentation to support that the drugs were administered during the Part D enrollees' Part A SNF stays.

Regarding our finding on the 136 sample items, the Act specifies that a drug prescribed to a Part D-eligible individual is not covered by Part D "if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual" (the Act § 1860D-2(e)(2)(B)). Federal regulations state that Part D does not cover drugs "for which payment as so prescribed and dispensed or administered . . . is available . . . under Part A or Part B (even though a deductible may apply . . .)" (42 CFR § 423.100(2)(i)). Under the statute and regulations, Part D does not cover drugs prescribed and dispensed to an individual for which payment is available for the individual under Part A or Part B, irrespective of whether the individual was administered the drug.

Furthermore, Part A prospective payments cover such drugs and biologicals as are ordinarily furnished by SNFs for the care and treatment of inpatients (the Act §§ 1861(h)(5) and 1888(e)(2)(A)(i); 42 CFR §§ 409.20(a)(5), 409.25, and 413.335(b)). In addition, these payments cover a limited supply of drugs for use outside a SNF if it is medically necessary to facilitate an enrollee's departure from the facility and is required until the enrollee can obtain a continuing supply (42 CFR § 409.25(b)). As part of our methodology, to account for drugs that may have been appropriately paid for by Part D, we limited our audit to those PDEs that were for prescription drugs that were not excluded from CMS's consolidated billing requirements for SNF stays and that occurred: (1) on or after the date of admission to a SNF for LTC pharmacies or after the date of admission for other pharmacy types, (2) at least 7 days before an enrollee

discharge, and (3) before the exhaustion of an enrollee's SNF benefit, e.g., those PDEs that occurred within the first 100 days of an enrollee's Part A SNF stay.

For the 136 sample items, although there was no documentation to determine whether the drugs from the pharmacies listed on the PDEs were administered during the Part D enrollees' Part A SNF stays, payment for these drugs was made available under Part A. Therefore, we maintain that Medicare Part D improperly paid for these drugs because payment was available under the Part A SNF benefit.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 2,557,806 PDEs that plan sponsors submitted for prescription drugs that pharmacies dispensed from January 1, 2018, through December 31, 2020 (audit period) to Medicare Part D enrollees while they were receiving Medicare Part A SNF services, for which the Part D total cost was $465,077,908.[39] We grouped the PDE records by dispensing pharmacy type and enrollee SNF stay, which resulted in 643,480 sample units, and selected a stratified random sample of 215 sample items, for which the Part D total cost was $953,370.

We obtained an understanding of CMS's oversight activities related to PDE data, including any specific controls or monitoring related to drugs dispensed to enrollees during a Part A SNF stay and any guidance provided to Part D plan sponsors. We also obtained an understanding of plan sponsors' internal controls and monitoring activities related to drugs dispensed to enrollees during a Part A SNF stay.

We conducted our audit from August 2021 to July 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations and CMS guidance;
- obtained from CMS's Integrated Data Repository:
    - paid SNF claims with dates of service during our audit period and
    - PDE records with prescription fill dates that occurred during the claim dates for SNF stays for those Part D enrollees who received posthospital SNF services during our audit period;
- created a sampling frame of 643,480 sample units, consisting of 2,557,806 PDEs with dates of service during our audit period, grouped by dispensing pharmacy type and enrollee SNF stay, for which the Part D total cost was $465,077,908;
- selected for review a stratified random sample of 215 sample items (Appendix C);

[39] We limited our audit to those PDEs that were for prescription drugs that were not excluded from CMS's consolidated billing requirements for SNF stays and that occurred: (1) on or after the date of admission to the SNF for LTC pharmacies or after the date of admission for other pharmacy types, (2) at least 7 days before an enrollee discharge, and (3) before the exhaustion of an enrollee's SNF benefit, e.g., those that occurred within the first 100 days of an enrollee's Part A SNF stay.

- reviewed medical records (e.g., MARs) from the SNFs that provided care to the Part D enrollees associated with the 215 sample items to determine whether the Part D prescription drugs were administered during the enrollees' Part A SNF stays;

- nonstatistically selected 10 plan sponsors with Part D plans that had at least $1.5 million in total costs during our audit period for drugs dispensed during Part D enrollees' Part A SNF stays;

- obtained and reviewed information from the 10 selected plan sponsors to gain an understanding of their procedures for and challenges with identifying inappropriate Part D payments for drugs dispensed to Part D enrollees during Part A SNF stays;

- estimated the Part D total costs and enrollee payment amounts for PDEs for drugs that were dispensed during enrollees' Part A SNF stays and for which payment was available under the Part A SNF benefit (Appendix D);

- estimated the Part D total costs and enrollee payment amount for PDEs for drugs administered to Part D enrollees during their Part A SNF stays (Appendix D); 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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D	OEI-02-15-00440	3/5/2020
Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit	A-06-17-08004	8/22/2019
Vulnerabilities in the Medicare Hospice Program Affect Quality of Care and Program Integrity: An OIG Portfolio	OEI-02-16-00570	7/30/2018
Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D	OEI-02-15-00190	6/22/2015
Ensuring the Integrity of Medicare Part D	OEI-03-15-00180	6/18/2015
Medicare Part D Made Some Incorrect Payments to Community Insurance Inc. for Institutional Beneficiaries in 2008	A-05-11-00042	8/6/2012
Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice	A-06-10-00059	6/28/2012
Medicare Part D Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006	OEI-02-07-00230	6/2/2009

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame contained 2,557,806 PDE records with dates of service during our audit period that occurred during Medicare Part D enrollees' Medicare Part A SNF stays and were for prescription drugs that were not excluded from CMS's consolidated billing requirements for SNF stays.[40] These PDE records were limited to those that occurred:

- on or after the day of admission to the SNF for LTC pharmacies or after the date of admission for other pharmacy types,
- at least 7 days before the enrollee's discharge, and
- before the exhaustion of the enrollee's SNF benefit.[41]

We grouped the PDE records by dispensing pharmacy type and enrollee SNF stay, which resulted in 643,480 sample units.[42] These PDE records had a Part D total cost of $465,077,908.

SAMPLE UNIT

The sample unit was an enrollee–SNF stay–PDE group for a dispensing pharmacy type.

SAMPLE DESIGN AND SAMPLE SIZE

We selected a stratified random sample of 215 sample items. (See Table 2 on the following page.)

[40] An enrollee's Part A SNF stay may consist of more than one Part A claim if there was not a break in service dates between the claims.

[41] SNF care provided under Part A is limited to a benefit period of 100 days in each benefit period and requires coinsurance for days 21 through 100. We limited PDEs to those that occurred within the first 100 days of an enrollee's Part A SNF stay.

[42] According to the CMS Chronic Conditions Data Warehouse's *Medicare Part D Pharmacy Characteristics Codebook* (version 1, May 2017), the National Council for Prescription Drug Programs instructs all providers to specify a primary dispenser type and may optionally specify a secondary and tertiary dispenser type. For purposes of our audit, we considered a provider an LTC pharmacy if it had a primary, secondary, or tertiary dispenser type code of "04" (long-term care pharmacy) or if it did not have a preceding dispenser type code of "15" (specialty pharmacy). We considered a provider a specialty pharmacy if it had a primary dispenser type code of "15" or a secondary or tertiary dispenser type code of "15" with an overall average PDE total cost of at least $500 and without a preceding dispenser type code of "04." All pharmacies not meeting the criteria for an LTC or a specialty pharmacy were considered retail or other pharmacies.

Table 2: Sample Strata

Stratum	Description	Strata Bounds (Combined Total Costs of PDEs)	No. of Frame Units	No. of PDEs	Frame Dollar Value	Sample Size
1	LTC pharmacies	<=$1,250	216,936	1,131,914	$45,104,258	25
2	LTC pharmacies	>$1,250	16,669	330,246	50,390,092	25
3	Retail or other pharmacies	<=$2,175	375,017	957,730	85,731,746	50
4	Retail or other pharmacies	>$2,175	17,703	107,936	119,102,873	50
5	Specialty pharmacies		17,155	29,980	164,748,939	65
Total			**643,480**	**2,557,806**	**$465,077,908**	**215**

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the sample units in each stratum by enrollee ID number and the "from" date of the enrollee SNF stay and then consecutively numbered the items in each stratum. After generating the random numbers for each stratum, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate: (1) the Part D total costs and enrollee payment amount for PDEs for drugs that were dispensed during enrollees' Part A SNF stays and for which payment was available under the Part A SNF benefit and (2) the Part D total costs and enrollee payment amount for PDEs for drugs that medical records showed were administered to Part D enrollees during their Part A SNF stays. We used this software to calculate the point estimate and the corresponding lower and upper limits of the two-sided 90-percent confidence interval.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Details and Results (Part D Total Cost)

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	No. of Sample Items for Which Payment Was Available for Drugs Dispensed During SNF Stays	Value of Sample Items for Which Payment Was Available for Drugs Dispensed During SNF Stays	No. of Sample Items for Which Drugs Were Administered During SNF Stays	Value of Sample Items for Which Drugs Were Administered During SNF Stays
1	216,936	$45,104,258	25	$7,944	25	$7,944	18	$7,415
2	16,669	50,390,092	25	60,804	25	60,804	18	42,862
3	375,017	85,731,746	50	12,775	50	12,775	3	1,514
4	17,703	119,102,873	50	338,159	50	338,159	14	130,928
5	17,155	164,748,939	65	533,688	65	533,688	36	358,933
Total	**643,480**	**$465,077,908**	**215**	**$953,370**	**215**	**$953,370**	**89**	**$541,652**

Table 4: Sample Details and Results (Enrollee Payment)

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	No. of Sample Items for Which Payment Was Available for Drugs Dispensed During SNF Stays	Value of Sample Items for Which Payment Was Available for Drugs Dispensed During SNF Stays	No. of Sample Items for Which Drugs Were Administered During SNF Stays	Value of Sample Items for Which Drugs Were Administered During SNF Stays
1	216,936	$4,033,960	25	$176	25	$176	18	$157
2	16,669	1,184,370	25	1,799	25	1,799	18	1,559
3	375,017	8,526,338	50	1,694	50	1,694	3	42
4	17,703	2,898,087	50	5,279	50	5,279	14	2,146
5	17,155	5,028,995	65	14,170	65	14,170	36	11,127
Total	**643,480**	**$21,671,750**	**215**	**$23,118**	**215**	**$23,118**	**89**	**$15,031**

Table 5: Statistical Estimates
(Limits Calculated at the 90-Percent Confidence Level) [*]

Estimate Description	Point Estimate	Lower Limit	Upper Limit
Part D total costs for prescription drugs for which payment was available under the Part A SNF benefit	$465,077,908	$411,266,163	$465,077,908
Part D total costs for prescription drugs that the medical records showed were administered to Part D enrollees during their Part A SNF stays	245,365,324	198,762,550	301,752,677
Enrollee payment amount for prescription drugs for which payment was available under the Part A SNF benefit	21,040,555	14,878,611	21,671,751
Enrollee payment amount for prescription drugs that the medical records showed were administered to Part D enrollees during their Part A SNF stays	6,415,048	4,202,957	9,505,654

[*] The point estimate and upper limit, calculated using the OIG-OAS statistical software, for the Part D total cost for drugs for which payment was available under the Part A SNF benefit were $465,874,906 and 530,570,597, respectively. The upper limit, calculated using the OIG-OAS statistical software, for the enrollee payment amount for drugs for which payment was available under the Part A SNF benefit was $30,956,867. We adjusted these amounts downward to reflect the known value of the sampling frame.

APPENDIX E: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 6th, 2024

TO: Amy J. Frontz
Deputy Inspector General for Audit Services

FROM: Chiquita Brooks-LaSure
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicare Part D Paid Millions for Drugs for Which Payment Was Available Under the Medicare Part A Skilled Nursing Facility Benefit*, A-09-21-03008

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS recognizes the importance of continuing to provide Medicare beneficiaries with access to high quality skilled nursing facility (SNF) care while protecting taxpayer and beneficiary dollars by preventing improper payments.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires Part D sponsors to exclude from payment an otherwise covered Part D drug if payment is available under Part A or Part B. Every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called a prescription drug event (PDE) to CMS. The PDE data are not the same as individual drug claim transactions but are summary extracts using CMS-defined standard fields.[1] The PDE record contains prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. Plan sponsors may adjust or delete PDE records as necessary.[2] An adjustment or deletion is any change reported after the original PDE record was submitted. For example, if a prescription is billed to Part D but is covered under Part A, and a PDE has already been submitted, the plan is required to submit a deletion record.[3]

The Balanced Budget Act of 1997 mandates the implementation of a per diem prospective payment system (PPS) for skilled nursing facilities (SNFs) covering almost all costs (routine, ancillary and capital) related to the services furnished to beneficiaries under Part A of the Medicare program (certain items are separately payable outside the per-diem amount). Typically, the payment for Medicare-covered drugs is bundled into the Medicare Part A payments made to these types of facilities under the SNF PPS for patients in a Medicare Part A covered SNF stay. Since the SNF PPS per diem payments are intended to reimburse the facility for all medication costs for those medications covered under Medicare Part A (and not excluded from the per-diem amount under section 1888(e)(2)(A)(ii) of the Act), Part D should only be billed for covered Part D drugs (referred to as "drugs") intended to be utilized by the beneficiary post discharge from their Part A-covered stay.

CMS previously provided a quarterly Long-Term Institutionalized Resident Report (LTI Report) to assist Part D sponsors in identifying Part D enrollees in a Part A-covered stay. The LTI report was used by

[1] See, Questions and Answers on Obtaining Prescription Drug Event (PDE) Data, available here: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/partdclaimsdataqa.pdf
[2] See, Requirements for Submitting Prescription Drug Event (PDE) Data, available here: https://www.cms.gov/medicare/prescription-drug-coverage/drugcoverageclaimsdata/downloads/pdeguidance.pdf
[3] See HPMS memorandum, PDE Guidance for Post Point-of-Sale Claim Adjustments, July 3, 2013, available here: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/post%20pos%20adjustments_247.pdf

sponsors for retrospective reviews of paid claims to identify claims that should have been billed under Part A, thus permitting sponsors to attempt to recover inappropriate Part D payments and work with LTC providers to ensure future compliance. CMS discontinued providing this report after 2023 because of data accuracy and timeliness issues and is testing a new reporting scheme that, if found to provide more accurate and timely information, would be implemented program-wide to all plan sponsors in 2025.[4]

OIG notes in its report that for 136 of the 215 sample items, OIG found no documentation to determine whether drugs from the pharmacies listed on the PDEs were actually administered, as opposed to just dispensed, or not later deleted by the plan sponsor during Part D enrollees' Part A SNF stays. While OIG noted only that these drugs may be at risk for waste or diversion, OIG still concluded these payments were improper. First, CMS believes that it is not appropriate to conclude that these payments were improper without supporting documentation indicating that they were both dispensed and administered during a Part D enrollee's Part A SNF stay. Second, a Part D enrollee in a Part A SNF stay could be administered drugs paid by Part D appropriately. For example, when a patient is scheduled for discharge from a SNF, and medications are dispensed to cover any gap in care immediately following discharge, the discharge plan may subsequently change, and the patient remains in the SNF. This beneficiary may therefore have drugs administered in the SNF that were appropriately paid for by Part D at the time they were dispensed.

CMS remains committed to continuing to improve payment accuracy by providing timely and accurate information to Part D sponsors and will continue to ensure the strength and stability of Part D programs.

OIG's recommendations and CMS's responses are below.

OIG Recommendation

CMS should work with its plan sponsors to adjust or delete PDEs, as necessary, and determine the impact to the Federal Government related to the Medicare Part D total costs of $953,370 for drugs associated with our sample items for which payment was available under the Medicare Part A SNF benefit, which included $541,652 for drugs that were administered during Part D enrollees' Part A SNF stays.

CMS Response

Within our authority, CMS concurs with OIG's recommendation. Part D sponsors that are not terminated and have not received final settlement described at 42 CFR 423.521 may adjust or delete PDE records. For PDEs where OIG found documentation to support the conclusion that the Part D sponsor paid for drugs administered during Part D enrollees' Part A SNF stays, CMS will notify the Part D sponsors that they should review and delete, as appropriate, the specified PDE records. However, these PDE records may ultimately be adjusted or deleted by the Part D sponsors for multiple reasons, unrelated to this particular audit issue. In addition, the PDE records are used in complicated reconciliation calculations that do not result in a dollar-for-dollar reimbursement by the Federal Government to the Part D sponsor. Therefore, it will not be possible to definitively determine the dollar impact of the adjustment or deletion of PDE records that are specifically associated with Part A stays.

OIG Recommendation

CMS should work with its plan sponsors to identify similar instances of noncompliance that occurred during our audit period and determine the impact to the Federal Government, which could have amounted up to an estimated $465,077,908 in Part D total cost, including
$245,365,324 for drugs that were administered during enrollees' Part A SNF stays.

[4] See HPMS memorandum, Long-Term Institutionalized Resident Report, September 13, 2023 available here: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-september-11-15

CMS Response
CMS concurs with this recommendation and when developing our strategy for future Part D audits we will consider the information OIG has provided in this report.

OIG Recommendation
CMS should work with its plan sponsors to identify similar instances of noncompliance that occurred before and after our audit period and determine the impact to the Federal Government related to Part D total costs for drugs for which payment was available under the Medicare Part A SNF benefit.

CMS Response
CMS concurs with this recommendation and when developing our strategy for future Part D audits we will consider the information OIG has provided in this report.

OIG Recommendation
CMS should provide plan sponsors with timely and accurate information, such as dates of covered Part A SNF stays, to reduce instances of inappropriate Part D payment for drugs for which payment is available under the Part A SNF benefit.

CMS Response
CMS concurs with OIG's recommendation. CMS is continuing to explore how to better provide plan sponsors with timely and accurate SNF stay information.

OIG Recommendation
CMS should instruct SNFs to cooperate with plan sponsors to identify and prevent improper Part D payments for drugs for which payment was available under the Part A SNF benefit.

CMS Response
CMS concurs with OIG's recommendation and will educate SNFs to coordinate with Part D sponsors to identify and help prevent improper Part D payments for drugs for which payment was available under the Part A SNF benefit.

CMS thanks OIG for its efforts on this issue and looks forward to working with OIG on this and other issues in the future.

Report Fraud, Waste, and Abuse

OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS programs. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.

TIPS.HHS.GOV

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Who Can Report?

Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

How Does it Help?

Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

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Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

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