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

April 2026 | A-05-21-00008

CMS Has Limited Oversight of Selected Compounded Drugs Prescribed to Medicare Part D Enrollees

REPORT HIGHLIGHTS

April 2026 | A-05-21-00008

CMS Has Limited Oversight of Selected Compounded Drugs Prescribed to Medicare Part D Enrollees

Why OIG Did This Audit

- Qualified health care professionals create compounded drugs by combining, mixing, or altering ingredients to create a prescription drug for patients whose medical needs cannot be met by an available U.S. Food and Drug Administration (FDA)-approved drug. FDA does not approve compounded drugs and does not verify the safety, effectiveness, or quality of these drugs before they are marketed.
- Over the past several years, OIG has participated in an increasing number of fraud investigations related to compounded drugs.
- To gain an understanding of Medicare Part D program integrity as it relates to compounded drugs, we conducted an audit of CMS's oversight of compounded drugs covered by Part D.

What OIG Found

CMS's oversight of selected compounded drugs prescribed to Part D enrollees is limited because the data CMS routinely obtains from sponsors (private companies that contract with CMS to provide the prescription drug benefit) does not provide a complete picture of a compounded drug's ingredients. As a result, enrollees we selected for review were given:

- An FDA-approved reconstituted injectable drug that may have been incorrectly identified on Prescription Drug Event (PDE) records as a compounded drug. Further, we found the days' supply dispensed by pharmacies exceeded the amount of time, indicated on the prescribing information label, that may pass between when a drug is reconstituted and when it is administered.
- Compounded drugs that included a drug (gabapentin) that CMS has identified as subject to misuse and that is known to increase the effects of opioids at the same time the enrollees had a separate prescription for that same drug. Additionally, some enrollees also received an opioid in a separate prescription during the same period.
- Compounded drugs that included a controlled substance (ketamine) that was not listed on the PDE record. Some of these enrollees also received an opioid in a separate prescription during the same period.

Since CMS does not routinely review the ingredients included in compounded drugs, it is limited in its ability to oversee sponsor efforts to ensure that quality assurance programs identify potential medication errors and potential overutilization of certain drugs.

What OIG Recommends

We made three recommendations to CMS, including that it work with sponsors, as appropriate, to ensure sponsors' claims for Part D compounded drugs are accurately reported on PDE records consistent with CMS guidance. The full recommendations are in the report. CMS concurred with all three recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Qualified health care professionals create compounded drugs by combining, mixing, or altering ingredients to create a prescription drug for patients whose medical needs cannot be met by an available U.S. Food and Drug Administration (FDA)-approved drug. FDA does not approve compounded drugs. This means that FDA does not verify the safety, effectiveness, or quality of these drugs before they are marketed. Over the past several years, the Office of Inspector General has participated in an increasing number of fraud investigations related to compounded drugs. These investigations have uncovered many instances of illegal kickbacks and false billings. To gain an understanding of Medicare Part D (Part D) program integrity as it relates to compounded drugs, we conducted an audit of the Centers for Medicare & Medicaid Services' (CMS) oversight of compounded drugs covered by Part D.

OBJECTIVE

Our objective was to assess CMS's oversight of compounded drugs prescribed to Part D enrollees.

BACKGROUND

Medicare Part D Prescription Drug Program

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program. Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing a voluntary prescription drug benefit to Medicare enrollees, referred to as Part D. Under Part D, individuals entitled to benefits under Medicare Part A (Hospital Insurance) or enrolled in Part B (Medical Insurance) may obtain prescription drug coverage.

Private companies, known as Part D sponsors, contract with CMS to provide the prescription drug benefit. In turn, sponsors contract with pharmacies that dispense prescription drugs to individuals enrolled in sponsors' plans. Under the Social Security Act § 1860D-2(e), covered Part D drugs are available only by prescription, approved by FDA, used and sold in the United States, and used for a medically accepted indication.[1]

[1] Social Security Act § 1860D-2(e); 42 CFR § 423.100.

Compounded Drugs

Qualified health care professionals create compounded drugs by combining, mixing, or altering ingredients to create a prescription drug for patients whose medical needs cannot be met by an available FDA-approved drug.[2] For example, a patient who is allergic to an inactive ingredient, such as a dye, may require a compounding pharmacy to prepare a special formulation that avoids that ingredient. FDA-approved drugs that are reconstituted in accordance with the products' approved labeling are not considered compounded drugs.[3]

Unlike drugs made by conventional manufacturers that require FDA approval, compounded drugs are not approved by FDA for safety, effectiveness, or quality before they are marketed. FDA has noted that, as a result, compounded drugs may pose a higher risk to patients than FDA-approved drugs.[4]

A compounded drug is covered under Part D only if it:

- Contains at least one ingredient that meets the definition of a Part D drug—meaning that Part D would cover the drug if it were dispensed separately

- Does not contain any ingredients that would be covered under Part B[5]

CMS officials told us that CMS does not routinely monitor the ingredients included in a compounded drug, and it has not instructed or provided guidance to sponsors related to monitoring compounded drugs. However, CMS occasionally requests that sponsors provide

[2] 83 Fed. Reg. 63648, 63649 (Dec. 11, 2018).

[3] Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling (21 U.S.C. § 353a(e)). Reconstitution is the process of adding a liquid to a powdered medication and then dissolving the medication to form a solution, as outlined in each drug's prescribing information label.

[4] 83 Fed. Reg. 63648, 63649 (Dec. 11, 2018).

[5] Part B covers certain outpatient prescription drugs and biologicals; for example, drugs provided incident to a physician's service and drugs furnished for use with Medicare-covered durable medical equipment. Part B-covered drugs are not usually self-administered (section 1861(s)(2) of the Social Security Act and 42 CFR § 414.900(b)).

ingredient lists to assist CMS during an investigation.[6] CMS officials told us that CMS does not have ready access to the ingredient lists that sponsors obtain from pharmacies.

In addition, sponsors must follow certain guidelines for determining the amount they will pay for a compounded drug. Specifically, CMS requires sponsors to pay for all ingredients that independently meet the definition of a Part D drug and allows sponsors to pay for non-Part D ingredients (e.g., bulk powders that are active pharmaceutical ingredients).[7, 8, 9]

Medicare Part D Prescription Drug Events

Part D sponsors submit a Prescription Drug Event (PDE) record to CMS each time a drug is dispensed to an enrollee in one of their plans. Data included in PDE records are used for payment purposes, as well as for program integrity and oversight. Each PDE record contains information about the drug and enrollee, as well as identification numbers for both the pharmacy and the prescriber. Although compounded drugs often contain multiple drug ingredients, PDE records list only the single National Drug Code (NDC) for the most expensive Part D-covered drug ingredient.[10] PDE records also indicate whether the drug was compounded. However, when a drug is reconstituted, there is no option on PDE records to label it as such.[11]

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[6] Federal regulations at 42 CFR § 423.120(c) incorporate the Telecommunications Standard Implementation Guide version D.0, which requires pharmacy claims sent to sponsors to list all ingredients in a compounded drug. These standards require pharmacies to submit the NDC for and quantity of each ingredient used to make a compounded drug on the pharmacy claim, herein referred to as ingredient lists. (See also 76 Fed. Reg. 21432, 21521 (Apr. 15, 2011)). The Telecommunications Standard Implementation Guide is published by The National Council for Prescription Drug Programs, which develops standards for electronic pharmacy prescribing and billing transactions.

[7] 42 CFR § 423.120(d) and 76 Fed. Reg. 21432, 21523 (Apr. 15, 2011). Sponsors may directly pay for non-Part D ingredients that are included on the pharmacy claim (without charging the enrollee or reporting these costs on the Prescription Drug Event record they submit to CMS). Alternatively, sponsors may reimburse pharmacies for non-Part D ingredients as part of the dispensing fee.

[8] An active pharmaceutical ingredient refers to any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body (21 CFR § 207.1).

[9] Medicare Prescription Drug Benefit Manual, chapter 6, section 10.4.

[10] Drug products are identified and reported using a unique three-segment number called the NDC, which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory at https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (accessed on Mar. 20, 2026).

[11] Prescription drug event data guidance is published on the CMS website at https://www.cms.gov/medicare/prescription-drug-coverage/drugcoverageclaimsdata/index (accessed on Oct. 27, 2025).

Role of Part D Sponsors in Quality Assurance

Part D sponsors are a central data collection point for enrollee PDEs. These PDEs often involve multiple prescribers and pharmacies that, alone, may be unaware of an enrollee's complete prescription drug regimen. To reduce the potential for medication errors and adverse interactions, CMS requires that Part D sponsors have quality assurance programs to monitor Part D-covered drugs.[12] Sponsors' quality assurance programs must meet several standards.

For example:

- They must ensure that a review of the prescribed drug therapy is performed before prescriptions are dispensed to an enrollee, typically at point of sale. These reviews must be designed to identify overutilization.[13]

- They must identify potentially reportable medication errors.[14]

- They must provide CMS with information covering their quality assurance measures and systems that CMS deems necessary, in accordance with CMS guidance.[15]

Medicare Part D Program Integrity

CMS's Center for Program Integrity is tasked with preventing, detecting, and combating fraud, waste, and abuse in Federal health care programs such as Medicare. This includes responsibility for Part D program integrity. In addition to the activities of the Center for Program Integrity, CMS relies on sponsors' quality assurance programs to monitor Part D-covered drugs.

CMS implemented the Overutilization Monitoring System (OMS). The OMS analyzes PDE records to help ensure that sponsors prevent overutilization of prescribed medications.[16] In January 2019, the OMS was enhanced to provide information to sponsors about enrollees who take opioids and gabapentin (a prescription medication primarily used to prevent or control

[12] 42 CFR § 423.153(c); Medicare Prescription Drug Benefit Manual, chapter 7, section 20.1.

[13] Overutilization is the use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the enrollee at risk of a clinically significant undesirable effect, or both (42 CFR § 456.702).

[14] 42 CFR § 423.153(c)(4); Medicare Prescription Drug Benefit Manual, chapter 7, section 20.5.

[15] 42 CFR § 423.153(c)(5); Medicare Prescription Drug Benefit Manual, chapter 7, section 20.1.

[16] CMS's "Medicare Part D Overutilization Monitoring System Memo" (July 5, 2013).

seizures and for treating nerve pain). CMS identified gabapentin as a drug potentiator misused to achieve euphoric highs.[17]

HOW WE CONDUCTED THIS AUDIT

Our audit covered 45,812 ingredient lists and the associated PDE records that sponsors submitted to CMS for compounded drugs on behalf of 25 selected pharmacies from July 1 through December 31, 2019.[18] We selected an initial nonstatistical sample of 529 ingredient lists and the associated PDE records (initial sample items) for detailed review.

Based on the results of our review of the 529 initial sample items, we expanded our analysis to all Part D enrollees who received prescriptions from the 25 nonstatistically selected pharmacies and who were associated with PDEs for compounded drugs that included certain drug ingredients that the enrollee had received in a separate prescription during the same period. We selected (1) a nonstatistical sample of 400 ingredient lists (of 12,659) (100 for each of the relevant 4 pharmacies) that included gabapentin and (2) all 49 ingredient lists that included a controlled substance.[19]

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

CMS's oversight of selected compounded drugs prescribed to Part D enrollees is limited because the data CMS routinely obtains from sponsors does not provide a complete picture of a compounded drug's ingredients. Specifically, we found reconstituted injectable drugs were incorrectly identified on PDE records as compounded drugs; enrollees were given compounded drugs that included gabapentin, a separate prescription for gabapentin, and in some cases, an

[17] A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance's and the potentiator's abuse potential. See CMS, Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, April 2, 2018.

[18] Data for the 6-month period ended Dec. 31, 2019, was the most current data available to us at the time we began our audit.

[19] Under the Controlled Substances Act of 1970, controlled substances are drugs or other substances that are classified among five schedules based on their medical use and potential for abuse and dependence (21 U.S.C. §§ 802(6) and 812).

opioid during the same period; and enrollees were given a compounded drug that included a controlled substance not listed on the PDE record. Additionally, the PDE record layout limits Part D sponsors to reporting only the single NDC for the most expensive Part D-covered drug ingredient; therefore, CMS is not routinely aware of all ingredients in the compound drugs prescribed to the Part D enrollees. Since CMS does not routinely review the ingredients included in compounded drugs, it is limited in its ability to oversee sponsor efforts to ensure that quality assurance programs identify potential medication errors and potential overutilization of certain drugs.

CMS HAS LIMITED OVERSIGHT OF SELECTED COMPOUNDED DRUGS PRESCRIBED TO MEDICARE PART D ENROLLEES

Reconstituted Injectable Drugs May Have Been Incorrectly Identified on PDE Records as Compounded Drugs

Part D enrollees associated with 244 of the 379 injectable drugs that were part of our initial sample items were given an FDA-approved reconstituted injectable drug that may have been incorrectly identified on PDE records as a compounded drug.[20] Further, we found that the days' supply dispensed by pharmacies exceeded the amount of time, indicated on the prescribing information label, that may pass between when a drug is reconstituted and when it is administered.[21]

When sponsors misidentify FDA-approved drugs (which should be subject to point-of-sale safety edits that are consistent with the prescribing information label) as compounded drugs (which are not FDA-approved and therefore have no prescribing information label), enrollees are at an increased risk of a preventable medication error that may lead to inappropriate use and harm.[22] Enrollees are at an increased risk because compounded drugs do not have prescribing information labels that indicate the amount of time that may pass between when a drug is compounded and when it is administered.

[20] The value "2" in the "Compound Code" field on the PDE record indicates that a drug is compounded.

[21] Labeling for prescription drugs is FDA's primary tool for communicating drug information to health care professionals and to patients and their caregivers. To ensure quality and patient safety, a drug's prescribing information label includes specific storage requirements and, if applicable, limits on the amount of time that may elapse between when a drug is reconstituted and when it is administered to a patient (21 CFR §§ 211.137(c)-(d)). Frequently Asked Questions about Labeling for Prescription Medicines is published on the FDA website at https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines (accessed on Oct. 27, 2025).

[22] CMS points to the National Coordinating Council for Medication Error Reporting and Prevention's (NCCMERP) definition of medication error as a guide for internal medication errors identification and reduction systems. NCCMERP defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Plans may exercise the discretion to define medication errors either more narrowly or more broadly. See CMS, Medicare Prescription Drug Benefit Manual, chapter 7, section 20.5.

Enrollees Given Compounded Drugs That Included Gabapentin, a Separate Prescription for Gabapentin, and in Some Cases, an Opioid During the Same Period

Part D enrollees associated with 14 of the 529 initial sample items we selected for review and 86 of the 400 additional gabapentin sample items were given a compounded drug that included gabapentin, which the enrollee had also received in a separate prescription during the same period.[23] Specifically, gabapentin (a drug potentiator) was included in at least two prescriptions for the same enrollee during the same period. For these enrollees, we identified (1) a PDE record associated with a prescription for a compounded drug that included bulk powder gabapentin in addition to another drug ingredient that sponsors identified as the most expensive Part D-covered drug ingredient and, as a result, was the only NDC listed on the PDE record and (2) at least one non-compounded drug PDE record associated with a prescription for gabapentin. For 9 of the 86 gabapentin sample items, the enrollees also received an opioid in a separate prescription during the same period.[24]

Because the PDE record layout limits Part D sponsors' to reporting only the single NDC for the most expensive Part D-covered drug ingredient, and because CMS does not routinely review the ingredients included in compounded drugs, CMS is limited in its ability to oversee sponsor efforts to ensure that quality assurance programs identify drugs that may be subject to misuse, such as when drug potentiators like gabapentin are taken in combination with opioids, that may lead to an increased risk of a preventable medication error.

Enrollees Given a Compounded Drug That Included a Controlled Substance Not Listed on the PDE Record

Part D enrollees associated with 19 of the 49 additional controlled substance sample items were given a compounded drug that included a controlled substance that was not listed on the PDE record. Specifically, for these 19 sample items, both ketamine—a Schedule III controlled substance with known safety concerns associated with abuse and misuse, psychiatric events, and increases in blood pressure—and the drug potentiator gabapentin were bulk powder ingredients of the compounded drugs.[25] Neither of these drugs were listed on the 19 PDE records because bulk powders do not meet the definition of a Part D-covered drug ingredient, and CMS does not require a controlled substance within a compounded drug to be listed on a

[23] We considered a drug to be included in a separate prescription "during the same period" when PDE records showed that one or more prescriptions overlapped a compounded drug's days' supply by at least 50 percent of the days.

[24] None of the enrollees associated with the 14 initial sample items received an opioid in a separate prescription during the same period.

[25] Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical dependence or high psychological dependence. Schedule III drugs' abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Drug scheduling information is published on the Drug Enforcement Administration website at https://www.dea.gov/drug-information/drug-scheduling (accessed on Oct. 27, 2025).

PDE record. For 2 of the 19 sample items, the enrollees also received an opioid in a separate prescription during the same period.

Because the PDE record layout limits Part D sponsors to reporting only the single NDC for the most expensive Part D-covered drug ingredient, and because CMS does not routinely review the ingredients included in compounded drugs, CMS is limited in its ability to oversee sponsor efforts to ensure that quality assurance programs identify drugs that may be subject to misuse, such as when drug potentiators like gabapentin are taken in combination with opioids, that may lead to an increased risk of a preventable medication error.

RECOMMENDATIONS

- We recommend that CMS work with sponsors, as appropriate, to ensure sponsors' claims for Part D compounded drugs are accurately reported on PDE records consistent with CMS guidance.

- We recommend that CMS provide guidance to sponsors on enhancing their oversight of compounded drugs containing controlled substances and gabapentin, such as ensuring their quality assurance programs monitor full ingredient lists for compounded drugs.

- We recommend that CMS provide guidance to sponsors regarding monitoring active pharmaceutical ingredients in bulk powder form used in compound drugs.

CMS COMMENTS

In written comments on our draft report, CMS concurred with all three OIG recommendations and committed to issuing guidance to Part D sponsors to strengthen oversight of compounded drugs, reinforcing its ongoing commitment to program integrity and enrollee safety. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, are included as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 45,812 ingredient lists and the associated PDE records that sponsors submitted to CMS for compounded drugs on behalf of 25 selected pharmacies from July 1 through December 31, 2019. We selected an initial nonstatistical sample of 529 ingredient lists and the associated PDE records (initial sample items) for detailed review.[26] The 529 PDE records indicated that the prescriptions were for compounded drugs: 379 were injectable drugs, and 150 were non-injectable drugs.

We took the following steps to identify the initial sample items: (1) selected a nonstatistical sample of 25 (of 63) pharmacies that received Part D payments for compounded drug claims exceeding $200,000 and that we identified as having 1 or more risk indicators such as pharmacy complaints submitted by enrollees to 1-800-MEDICARE or pharmacies appearing on a CMS high-risk report;[27] (2) from each selected pharmacy, selected the prescriber whose prescriptions resulted in the largest total payment for Part D-covered compounded drugs; (3) from each selected prescriber, selected at least 1 Part D enrollee whose prescriptions resulted in the largest total payments to the selected pharmacy (a total of 45 enrollees); and (4) selected all relevant PDEs from the 45 selected enrollees, which resulted in the 529 initial sample items.[28] The 529 PDE records indicated that the prescriptions were for compounded drugs: 379 were injectable drugs, and 150 were non-injectable drugs.

Based on the results of our review of the 529 initial sample items, we expanded our analysis to all Part D enrollees who received prescriptions from the 25 nonstatistically selected pharmacies and who were associated with PDEs for compounded drugs that included certain drug ingredients that the enrollee had received in a separate prescription during the same period. We selected (1) a nonstatistical sample of 400 ingredient lists (of 12,659) that included gabapentin (100 for each of the relevant 4 pharmacies) (gabapentin sample items)[29, 30, 31] and

[26] There were 6 sponsors associated with the 529 initial sample items.

[27] We initially selected 30 pharmacies but excluded 5 from review because of ongoing investigative work.

[28] There were 6 sponsors associated with the 529 initial sample items.

[29] These 4 pharmacies were the only pharmacies associated with enrollees given compounded drugs that included gabapentin and a separate prescription for gabapentin during the same period for the 529 initial sample items.

[30] We selected ingredient lists with gabapentin listed as ingredient #1 before ingredient lists with gabapentin listed as ingredient #2.

[31] Gabapentin was not listed on the compounded drug PDE record because it was not the single NDC for the most expensive Part D-covered drug ingredient of the compounded drug.

(2) all 49 ingredient lists[32] that included a controlled substance (controlled substance sample items).

We limited our review of internal controls to those related to CMS's and sponsors' oversight of compounded drugs claimed under Medicare Part D.

METHODOLOGY

We took the following steps to accomplish our objective:

- Reviewed applicable Federal and State laws, regulations, and guidance
- Reviewed written responses from CMS related to questions regarding its oversight of compounded drugs
- Selected an initial nonstatistical sample of 529 ingredient lists and the associated PDE records for detailed review. We took the following steps to identify these sample items:
    - Selected a nonstatistical sample of 25 (of 63) pharmacies that received Part D payments for compounded drug claims exceeding $200,000 and that we identified as having 1 or more risk indicators
    - From each selected pharmacy, selected the prescriber whose prescriptions resulted in the largest total payment for Part D-covered compounded drugs
    - From each selected prescriber, selected at least 1 Part D enrollee whose prescriptions resulted in the largest total payments to the selected pharmacy (selected a total of 45 enrollees)
    - Selected all relevant PDEs from the 45 selected enrollees, which resulted in the 529 initial sample items
- Expanded our analysis to all Part D enrollees who received prescriptions from the 25 nonstatistically selected pharmacies and who were associated with PDEs for compounded drugs that included certain drug ingredients that the enrollee had received in a separate prescription during the same period. We selected:
    - a nonstatistical sample of 400 ingredient lists (of 12,659) (100 for each of the relevant 4 pharmacies) that included gabapentin
    - all 49 ingredient lists that included a controlled substance

[32] The 49 ingredient lists were associated with 3 pharmacies.

- Obtained an understanding of CMS's oversight by contacting:
    - sponsors to obtain ingredients lists, requirements placed on pharmacies to receive payment, and pharmacy contact information
    - prescribers to obtain medical records and verification that the compounded drug an enrollee received matched their prescription
    - pharmacies to obtain procedures for providing compounded drugs to enrollees, compounding records, and the results of past State inspections
- 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: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: February 9, 2026

TO: John D. Hagg
Acting Deputy Inspector General for Audit Services

FROM: Dr. Mehmet Oz DR
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Has Limited Oversight of Selected Compounded Drugs Prescribed to Medicare Part D Enrollees (A-05-21-00008)

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 is committed to program integrity and beneficiary safety in Medicare Part D.

CMS sets regulatory requirements and guidance for Medicare Part D sponsors' quality assurance and compliance programs, including safeguards to prevent fraud, waste, abuse, and risks to beneficiary safety. CMS oversees sponsors' implementation of these programs through required reporting, ongoing monitoring, and routine Part D program audits to assess whether the controls are effective and compliant with Medicare rules. When deficiencies are identified, CMS enforces accountability through corrective action plans, sanctions, or civil money penalties to protect program integrity and beneficiaries.

Compounded drugs are customized to meet the needs of patients who cannot use commercially available drugs, for example, due to an allergy to an inactive ingredient. Medicare Part D covers compounded drugs if they contain at least one ingredient that would be covered by Part D if dispensed separately.[1] Access to compounded drugs is essential for patients with allergies and other unique healthcare needs.

Although compounded drugs make up a very small percentage of overall prescriptions, CMS consistently monitors Part D sponsor submitted data on pharmacy billing and usage for these drugs. Sponsors must adhere to applicable Part D regulations and the guidelines specified in the Medicare Prescription Drug Benefit Manual to determine the appropriate billing amount for compounded drugs. CMS requires that sponsors ensure all ingredients in compounded drugs are covered if they would individually qualify as Part D drugs. Part D sponsors are also required to establish quality assurance measures and systems that ensure network pharmacies comply with minimum standards for pharmacy practice as established by the states. Additionally, Part D sponsors are required to establish drug utilization review systems to screen each prescription dispensed to an enrollee.

[1] Please see 42 C.F.R. § 423.120(d) and the Medicare Prescription Drug Benefit Manual available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf

CMS takes seriously its responsibility to oversee beneficiary safety and Part D sponsor compliance and appreciates OIG's additional review into this area. OIG's recommendations and CMS's responses are below.

OIG Recommendation
CMS should work with sponsors, as appropriate, to ensure sponsors and other entities, including pharmacies, correctly identify compounded drugs on PDE records.

CMS Response
CMS concurs with this recommendation and will work to provide guidance to sponsors.

OIG Recommendation
CMS should enhance its oversight of compounded drugs containing controlled substances and gabapentin, such as reviewing sponsors' quality assurance programs monitoring of ingredient lists for compounded drugs.

CMS Response
CMS concurs with this recommendation and will work to provide guidance to sponsors.

OIG Recommendation
CMS should provide guidance to sponsors regarding monitoring active pharmaceutical ingredients in bulk powder form used in compound drugs.

CMS Response
CMS concurs with this recommendation and will work to provide guidance to sponsors.

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

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