

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**COMPOUNDED DRUGS UNDER
MEDICARE PART B:
PAYMENT AND OVERSIGHT**



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Inspector General

April 2014
OEI-03-13-00270

EXECUTIVE SUMMARY: COMPOUNDED DRUGS UNDER MEDICARE PART B: PAYMENT AND OVERSIGHT OEI-03-13-00270

WHY WE DID THIS STUDY

Compounded drugs are customized medications that meet specific needs of individual patients and are produced in response to a licensed practitioner's prescription. Compounded drugs that are contaminated pose a severe threat to public health and safety. An outbreak of fungal meningitis and other fungal infections in late 2012 was linked to contaminated injectable compounded drugs. As of October 2013, the Centers for Disease Control and Prevention had reported over 700 cases linked to this outbreak. Although certain compounded drugs can be eligible for coverage under Medicare Part B, Medicare does not pay for compounded drugs when the Food and Drug Administration determines that an entity is producing compounded drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act). In light of the 2012 outbreak and increased scrutiny of compounded drugs, we sought to determine the extent to which Part B paid for compounded drugs and to examine Medicare Administrative Contractors' (MAC) policies and procedures for reviewing and processing claims for compounded drugs.

HOW WE DID THIS STUDY

We surveyed Centers for Medicare & Medicaid Services (CMS) staff and Part B MACs to assess their oversight of Medicare claims for compounded drugs. We asked CMS and MACs whether they track the number of claims and the amount paid for compounded drugs and to describe their policies and procedures for reviewing and processing claims for compounded drugs.

WHAT WE FOUND

We found that neither CMS nor MACs tracked the number of claims for compounded drugs under Part B or the corresponding amounts paid, and that Part B claims do not contain information that can be used to systematically identify claims for compounded drugs. We also found that claims for compounded drugs do not identify the compounding pharmacy; however, this information may be included in documentation kept by the provider. Finally, we found that most MACs manually reviewed Part B claims containing "not otherwise classified" codes, which can represent compounded drugs, to determine payment amounts.

WHAT WE RECOMMEND

The inability to track claims for compounded drugs and identify the compounding pharmacies that produce these drugs prevents CMS and MACs from taking steps to stop payments for compounded drugs that are produced in violation of the Act. Therefore, we recommend that CMS (1) establish a method to identify Part B claims for compounded drugs, (2) explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug, and (3) explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs. CMS concurred with the first recommendation, did not concur with the second, and conditionally concurred with the third.

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OBJECTIVES

1. To determine the extent to which Medicare Part B paid providers for compounded drugs in 2012.
2. To determine Medicare Administrative Contractors' (MAC) policies and procedures for reviewing and processing Part B claims for compounded drugs.

BACKGROUND

An outbreak of fungal meningitis and other fungal infections in late 2012 was linked to contaminated injectable compounded drugs. As of October 2013, the Centers for Disease Control and Prevention (CDC) had reported over 700 cases linked to this outbreak. Compounded drugs that are contaminated pose a severe threat to public health and safety. Therefore, we determined the extent to which Part B paid for compounded drugs, and we examined MACs' policies and procedures for reviewing and processing claims for compounded drugs.

Compounded Drugs

Pharmacy compounding is a practice in which pharmacists combine, mix, or alter ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. Compounding does not generally include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling.¹ Providers prescribe compounded drugs for various reasons, including:

- a noncompounded version of the medicine is discontinued or generally unavailable,
- the patient is allergic to certain dyes or preservatives in the noncompounded version,
- the patient has unique needs and requires tailored dosage strength (e.g., an infant), or
- the pharmacist can combine several medications to increase compliance in taking the medications.²

¹ Food and Drug Administration (FDA), *Limited FDA Survey of Compounded Drug Products*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm> on November 14, 2012.

² The International Academy of Compounding Pharmacists, *What Is Compounding?* Accessed at <http://www.iacprx.org/displaycommon.cfm?an=1&subarticlenbr=1> on October 3, 2013.

The quality of a finished compounded-drug product can be affected by numerous factors, including (but not limited to) the quality of the active pharmaceutical ingredient used and the quality of the compounding practices of the pharmacy in which the product is created.³

Pharmacy compounding is a vital service that helps many people, including those who are allergic to inactive ingredients in FDA-approved medicines and others who need medications that are not available commercially.⁴ However, poor compounding practices can result in contamination or medications that do not possess the strength, quality, and purity required, which may pose risks to patients.⁵

Medicare Coverage of Compounded Drugs Under Part B and Part D

Medicare Part B. Medicare Part B continues to cover a limited number of outpatient prescription drugs and biologicals (hereinafter referred to collectively as drugs). Part B-covered drugs generally fall into the following categories: drugs furnished incident to a physician's services (e.g., injectable drugs used in connection with the treatment of cancer); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with durable medical equipment (DME) (e.g., inhalation drugs).⁶

MACs. The Centers for Medicare & Medicaid Services (CMS) contracts with MACs, which are private companies, to process and pay Medicare Part B claims, including those for prescription drugs. As of December 2012, 9 MACs covering 13 Medicare Parts A and B jurisdictions were operational.⁷ Through Statements of Work, CMS assigns specific functions to MACs and also outlines performance standards for those functions. The functions performed by MACs include, but are not limited to, claims processing, provider enrollment, customer service for providers, medical review, and appeals.⁸

³ FDA, *Report: Limited FDA Survey of Compounded Drug Products*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm> on November 14, 2012.

⁴ FDA, *The Special Risks of Pharmacy Compounding*. Accessed at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm> on November 20, 2013.

⁵ *Ibid.*

⁶ 68 Fed. Reg. 50428, 50428–50429 (August 20, 2003).

⁷ CMS originally proposed 15 A/B MAC jurisdictions, but as of December 2013 the agency was consolidating these jurisdictions to form 10 A/B MAC jurisdictions.

⁸ The A/B MACs handle provider enrollment functions for their providers; however, DME MACs do not because the National Supplier Clearinghouse handles enrollment for DME suppliers.

To obtain Part B reimbursement for covered outpatient prescription drugs, health care providers submit claims to MACs using Healthcare Common Procedure Coding System (HCPCS) codes.⁹ In the case of prescription drugs, each HCPCS code defines the drug name and the amount of the drug represented by the HCPCS code, but does not specify the manufacturer or package size.

Part B Coverage of Compounded Drugs. Generally, compounded drugs are eligible for coverage under Medicare Part B.¹⁰ However, when FDA determines that an entity is producing compounded drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act), Medicare does not pay for these drugs.¹¹ For example, by compounding drugs on a large scale, an entity may be operating as a manufacturer without complying with the manufacturing requirements under the Act.¹² Such companies may be manufacturing drugs that are subject to the “new drug application” (NDA) requirements of the Act, but for which FDA has not approved an NDA, or drugs that are misbranded or adulterated.¹³ If FDA has not approved the manufacturing and processing procedures used by these facilities, it has no assurance that the drugs these companies are producing are safe and effective.¹⁴

In its *Medicare Benefit Policy Manual*, CMS stated that it will notify MACs when FDA has determined that compounded drugs are being produced in violation of the Act. After the MAC receives subsequent instruction from CMS, it stops Medicare payment for compounded drugs produced in violation of the Act.¹⁵ However, there is no code or modifier on Part B claims that can be used to systematically identify compounded drugs.

Medicare Part D. The Medicare prescription drug program, known as Medicare Part D, provides an optional prescription drug benefit to all Medicare beneficiaries entitled to Medicare Part A or enrolled in Medicare

⁹ CMS uses HCPCS codes to provide a standardized coding system for describing the specific items and services provided in the delivery of health care.

¹⁰ This refers only to Part B-covered drugs described in the previous section. Section 1862(a)(1)(A) of the Social Security Act (SSA) requires that drugs must be “reasonable and necessary” to be covered under Medicare Parts A and B. Drugs and biologicals are defined in section 1861(t) of the SSA. Pricing for compounded drugs is described in CMS’s *Medicare Claims Processing Manual*, Rev. 2554, September 28, 2012, ch. 17 § 20.1.2.

¹¹ CMS, *Medicare Benefit Policy Manual*, Rev. 170, May 10, 2013, ch. 15 § 50.4.7.

¹² *Ibid.*

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ *Ibid.*

Part B.¹⁶ Part D plans are administered by private companies, known as plan sponsors, that contract with CMS to offer prescription drug coverage. For compounded drugs under Part D, only the components that satisfy the definition of a Part D drug are allowable costs under Part D.^{17, 18} Every time a beneficiary has a prescription filled under Part D, the plan sponsor must submit a prescription drug event (PDE) record.¹⁹ The PDE record contains drug cost, payment, prescribing, dispensing, and utilization data, as well as a code that indicates whether a prescription is for a compounded drug. To conduct oversight, in February 2013 CMS used this “compound code” to perform a number of descriptive analyses.²⁰

Concern About Compounded Drugs

A late 2012 outbreak of fungal meningitis and other fungal infections was linked to contaminated injectable products compounded by the New England Compounding Center (NECC). As of October 23, 2013, CDC had reported 751 cases and 64 deaths linked to this outbreak.²¹ In October 2012, FDA investigators found substantial problems with NECC’s facilities, including mold and bacterial contamination and failure to maintain a sterile environment.²² Between the time of the NECC outbreak and a May 16, 2013, congressional hearing, 10 additional firms had conducted voluntary FDA-overseen recalls of sterile compounded or repackaged drug products.²³

FDA Authority. At the time of the NECC meningitis outbreak, FDA had limited authority to regulate compounding pharmacies and enforce

¹⁶ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

¹⁷ CMS, *Medicare Prescription Drug Benefit Manual*, Rev. 10, February 19, 2010, ch. 6 § 10.4.

¹⁸ In general, 42 CFR § 423.100 defines a Part D drug as a drug used for a medically accepted indication, dispensed upon a prescription, and approved under the Act. It also includes certain biological products, insulin, medical supplies, and vaccines.

¹⁹ SSA §§ 1860D-15(c)(1)(C) and (d)(2), 42 CFR § 423.322.

²⁰ For all Part D PDE claims for compounded drugs dispensed in 2012, CMS determined (among other things): the percentage of all covered Part D claims reported as being compounded; the average drug cost for covered compounded drugs per beneficiary; the top-billing pharmacies; and the top drugs.

²¹ CDC, *Multi-State Meningitis Outbreak—Current Case Count*. Accessed at <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html> on December 31, 2013.

²² FDA, *FDA Form 483 for New England Compounding Center* (Oct. 26, 2012). Accessed at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM325980.pdf> on October 7, 2013.

²³ Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, *Statement Before the Subcommittee on Health, Committee on Energy and Commerce May 23, 2013*. Accessed at <http://www.fda.gov/NewsEvents/Testimony/ucm353654.htm> on October 7, 2013.

compliance with safety standards.²⁴ The agency normally asserted jurisdiction in situations in which pharmacies had moved from pharmacy compounding to pharmacy manufacturing.²⁵ In November 2013, Congress clarified FDA’s oversight authority of compounding pharmacies in the Drug Quality and Security Act.²⁶

METHODOLOGY

Data Sources and Collection

MAC Surveys. In June 2013, we surveyed the 9 Part B MACs that represented the 13 jurisdictions in effect as of December 2012. The surveys asked about MACs’ policies and procedures regarding Medicare claims for compounded drugs, including the HCPCS code(s) that providers use for compounded drugs, the payment policies for compounded drugs, and any additional information that MACs require providers to include on Medicare claims for compounded drugs.

Further, we asked MACs how they identify and review Part B claims for compounded drugs and whether they track the number of such claims or perform any oversight for such claims. We also asked MACs whether they received instructions from CMS to stop payment for certain compounded drugs and, if so, whether they did. We asked MACs whether they were able to determine their Part B payments to providers for compounded drugs and, if so, to provide the total amount paid for these drugs in 2012. All MACs responded to our request.

CMS Data. We obtained from CMS all relevant policies and procedures on the coverage of and payment for compounded drugs. We surveyed CMS staff in the Hospital and Ambulatory Policy Group, within the Division of Ambulatory Services, about the agency’s oversight of Part B claims for compounded drugs. Specifically, we asked these staff what instructions CMS provides MACs regarding Part B claims for compounded drugs, whether CMS notified MACs to stop payment for drugs produced in violation of the Act, and whether CMS received information from FDA on entities producing drugs in violation of the Act.

²⁴ Congressional Research Service, *Federal Authority to Regulate the Compounding of Human Drugs* (April 12, 2013). Accessed at <https://www.fas.org/sgp/crs/misc/R43038.pdf> on December 31, 2013.

²⁵ FDA, *Compliance Policy Guidance for FDA Staff and Industry*, Section 460.200, May 29, 2002. Accessed at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm> on October 3, 2013. On November 27, 2013, FDA withdrew this guidance because it was no longer consistent with the agency’s current thinking on the issues it addressed. 78 Fed Reg. 72901–72902 (December 4, 2013).

²⁶ P.L. 113-54.

We also reviewed Part D policies related to compounded drugs and obtained CMS's report analyzing Part D claims for compounded drugs.

Data Analysis

MACs. We reviewed MACs' survey responses to determine their policies and procedures for reviewing and processing claims for compounded drugs, including the procedure codes, payment policies, and other information required on Part B claims for compounded drugs. From those responses, we determined whether MACs tracked (1) the number of claims for compounded drugs and (2) the amount that Part B paid providers for compounded drugs in 2012.

CMS and MAC Oversight. We reviewed CMS's and MACs' policies and procedures as well as CMS's report on its analysis of Part D claims data for compounded drugs. We then analyzed responses from CMS and MACs to determine the extent of each entity's oversight.

Limitations

We did not verify the accuracy or completeness of the data provided by CMS or the MACs, or the MACs' responses to our survey. The scope of this review was limited to CMS's and MACs' policies and procedures; we did not collect or analyze information from FDA.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

CMS and MACs did not track the number of claims or the amount paid for compounded drugs under Medicare Part B

Part B claims do not contain information that can be used to systematically identify all claims for compounded drugs. HCPCS codes for drugs represent specific drugs and dosage amounts; because compounded-drug products are unique combinations of pharmaceutical ingredients, they are not assigned unique HCPCS codes. When billing for compounded drugs, or other drugs that are not associated with specific HCPCS codes, providers use “not otherwise classified” (NOC) codes.

CMS reported that it did not track Part B claims for compounded drugs paid under NOC codes in 2012. Although some MACs reported that there are certain criteria specific to compounded drugs (e.g., providers are instructed to enter 1 billing unit, list the drug names, bill at the invoice price, etc.), they also do not track claims for these drugs, and therefore could not determine the total number of claims or amount paid for compounded drugs in 2012.

Unlike claims submitted under Part B, those submitted under Part D contain a code—the “compound code”—that indicates whether a prescription is for a compounded drug. Because this information is available on Part D claims, CMS recently conducted oversight by performing a number of descriptive analyses of Part D claims for compounded drugs.

Claims for compounded drugs do not identify the compounding pharmacy; however, it may be included in documentation kept by the provider

Part B claims for compounded drugs do not include the name or identification code of the compounding pharmacy from which the provider purchased the drugs. There is no requirement for providers to identify the compounding pharmacy on a Part B claim. However, MACs representing eight jurisdictions indicated that the invoice or medical records generally include this information, meaning that the pharmacy name is included in the documentation kept by the provider, and could be obtained upon request.²⁷ MACs representing the remaining five jurisdictions do not require providers to include the information identifying the pharmacies. Without the pharmacy name or a code that identifies the pharmacy, neither

²⁷ One of these MACs reported that it does not require the invoice, but that it could request the pharmacy information.

CMS nor MACs would be able to determine from the claim alone where the provider purchased the compounded drug.

Most MACs manually reviewed Part B claims containing NOC codes, which can represent compounded drugs, to determine payment amounts

MACs have the general authority for reviewing, pricing, and paying claims.²⁸ MACs representing 10 jurisdictions reported that they manually review claims containing NOC codes, which can represent compounded drugs.²⁹ For example, MACs that conduct manual reviews reported that claims with NOC codes are separated from the other claims and undergo an enhanced review. Because these MACs review all claims with NOC codes and compounded drugs are billed for under NOC codes, these MACs thereby review all claims for compounded drugs.

MACs that manually review claims for compounded drugs generally do so to determine the payment amount. Unlike HCPCS codes for specific drugs, NOC codes—including those for compounded drugs—do not have nationally established payment amounts.³⁰ MACs representing several jurisdictions reported that when they manually review claims for compounded drugs, they assign payment amounts on the basis of the description of the drugs that the provider enters on the claim.

MACs have similar coding requirements but vary slightly in their payment and reporting processes for compounded drugs

All MACs permitted providers to use the NOC code J3490 when billing for compounded drugs. MACs representing 7 of the 13 jurisdictions reported that providers could also use other NOC codes, including J3590, J7799, and J9999. Medicare and its beneficiaries spent \$345 million on claims with these four NOC codes in 2012.³¹ Although MACs require providers to include specific billing codes, most MACs (those for 9 of

²⁸ For example, according to CMS's *Medicare Benefit Policy Manual*, MACs are to stop Medicare payment for compounded drugs produced in violation of the Act only after MACs receive the appropriate instructions from CMS. CMS reported that during 2012, it did not instruct the MACs to stop payment for compounded drugs because it did not receive any communication from FDA regarding pharmacies that FDA determined to have been producing drugs in violation of the Act. As we previously stated, we did not collect any information from FDA.

²⁹ The manual review is in addition to the automated review and payment process for claims with HCPCS codes for specific drugs.

³⁰ Although each NOC code does not have an established payment amount, MACs may use fee schedules that establish payment amounts for individual drugs that are submitted under each NOC code.

³¹ This total includes *all* claims containing one of these four NOC codes, which includes claims both for compounded and noncompounded drugs. Therefore, total expenditures for only compounded drugs would likely be lower.

13 jurisdictions) do not require providers to include specific diagnostic codes when submitting claims for compounded drugs. MACs representing all but one jurisdiction require providers to include the names of each drug and the dosage amount on claims for compounded drugs. For all of these 12 jurisdictions, MACs require the drug name and dosage amount to be included in a general text field that allows providers to describe the compounded drug. Although MACs representing most jurisdictions require drug names and dosage amounts, none of these MACs require providers to include the component drugs' National Drug Codes, an 11-digit code that identifies the manufacturer, drug product, and the package size.

As for payment policies, MACs for 10 of the 13 jurisdictions paid providers in 2012 the invoice price for compounded drugs, i.e., the purchase price from the compounding pharmacy. MACs covering the remaining three jurisdictions paid for compounded drugs using a specific fee schedule, i.e., they had developed payment amounts for the drugs commonly used in compounded products. In addition to paying providers for the drug cost, MACs representing nine jurisdictions also paid providers for additional related costs including shipping, handling, a compounding fee, and tax.

CONCLUSION AND RECOMMENDATIONS

Our findings indicate that neither CMS nor MACs track the number of claims or the amount paid for compounded drugs under Medicare Part B. Unlike Part D claims, which include a code that identifies claims for compounded drugs, Part B claims do not contain an indicator to identify these drugs. The inability to track claims for compounded drugs and identify the compounding pharmacies limits the ability of CMS and MACs to take steps that could stop payments for compounded drugs produced in violation of the Act.

CMS grants MACs the authority to oversee, review, and pay claims for compounded drugs. We found that most MACs manually review claims for compounded drugs to determine payment amounts because compounded drugs are billed under NOC codes that do not have nationally established payment amounts. In other words, these claims undergo a manual review not because they are for compounded drugs, but because they are submitted using NOC codes.

Therefore, we recommend that CMS:

Establish a method to identify Part B claims for compounded drugs

Unlike Part D, Part B does not offer a means of systematically identifying all claims for compounded drugs. If CMS were to establish a method that specifically identifies compounded drug claims (e.g., a modifier) and were to require providers to include this information on all claims for compounded drugs, CMS and MACs could identify and track all Part B claims for compounded drugs.

Explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug

Claims for compounded drugs under Part B do not identify the pharmacy that produced the drug. As a result, CMS and MACs are unable to determine where these drugs are being produced. If providers were required to include this information, it would enable CMS to work with MACs to stop payment for drugs produced in violation of the Act.

Explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs

If claims data were to include information that identified compounded drugs and the pharmacies that produce them, CMS and/or MACs would be able to conduct descriptive analyses of claims for compounded drugs under Part B, similar to the analysis that CMS conducted for such claims under Part D. These analyses could include calculating how much Part B

is paying for compounded drugs; determining where compounded drugs are being produced; determining which compounded drugs are being billed for; and, if there are future outbreaks, identifying the claims for drugs produced by the pharmacies linked to these outbreaks.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to establish a method to identify Part B claims for compounded drugs and noted that it may be possible to create a modifier or specific code that physicians would be required to use when billing for compounded drugs. CMS stated that this approach may allow compounded drugs to be distinguished from other drugs that are billed under NOC codes, but that any issues related to public safety of compounded drugs should be addressed before the drugs are administered.

CMS did not concur with our recommendation to explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug. CMS stated that it does not need to identify the dispensing compounding pharmacy to pay the physician who is billing for the drugs. CMS noted that it is not clear that authority exists under the statute to collect the suggested information as that information is not necessary to determine the payment amount. CMS also stated that changes to Medicare claims processing systems to accommodate the inclusion of dispensing pharmacy information would be significant and would compete for administrative resources with statutorily required payment methodology changes that necessitate system changes. Further, CMS does not believe that stopping Medicare payment for compounded drugs produced in violation of the Act will be a reliable tool for addressing public safety issues regarding compounded drugs.

CMS concurred with our third recommendation to explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs. CMS stated that concurrence was conditional upon successful implementation of the first recommendation and it would undertake such analyses only if it were for a program-related purpose.

We recommend that CMS explore the possibility of identifying the pharmacy that produced the compounded drug. We acknowledge that claims analysis is retrospective and identifying the pharmacy on the claim would not by itself address public safety issues. We also recognize the challenges of including additional information on Part B claims. However, this additional information could supplement any descriptive, proactive analyses of Part B claims for compounded drugs, identify

pharmacies that may be producing compounded drugs in violation of the Act, and alert providers about pharmacies associated with those violations, which, in turn, could prevent future payments.

We did not make any changes to the report on the basis of CMS's comments. For the full text of CMS's comments, see the Appendix.

APPENDIX

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 11 2014
TO: Daniel R. Levinson
Inspector General
FROM: Marilyn Tavenner /S/
Administrator
SUBJECT: Office of Inspector General (OIG) Draft Report: Compounded Drugs Under Medicare Part B: Payment and Oversight (OEI-03-13-00270)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject OIG draft report. OIG's objectives were to determine--(1) The extent to which Medicare Part B paid providers for compounded drugs in 2012; and (2) Medicare Administrative Contractors' (MAC) policies and procedures for reviewing and processing Part B claims for compounded drugs.

The OIG surveyed MAC policies and procedures for identifying, reviewing and processing Part B claims for compounded drugs. OIG also collected information about Part B policies for compounded drugs and oversight of payment for these drugs. Finally, OIG reviewed Part D policies related to compounded drugs.

The OIG found that neither CMS nor the MACs track the number of claims for compounded drugs or the amount paid for such claims. OIG pointed out that Part B claims do not contain information that would easily identify all claims for compounded drug, and also noted that Part B claims for compounded drugs do not identify the compounding pharmacy from which the provider purchased the drugs. OIG believes that information that identifies the source of the compounded drug is available from the provider. The report also described claims processing and claims submission requirements at the MACs, finding that most MACs conducted enhanced manual reviews of compounded drug claims and that payments were usually based on the invoice. OIG also compared claims information in Part B to Part D, noting that information on Part D claims identifies claims for compounded drugs.

OIG Recommendation

The OIG recommends that CMS establish a method to identify Part B claims for compounded drugs.

CMS Response

The CMS concurs with this recommendation. Currently, compounded drugs generally are paid under "not otherwise classified (NOC)" codes. These codes are used for all drugs that are not specifically described by other codes. We believe that it may be possible to create a modifier or specific code that physicians would be required to use when billing for compounded drugs. While this approach may allow compounded drugs to be distinguished from other drugs that are

Agency Comments (continued)

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billed under NOC codes, we believe any issues related to public safety of compounded drugs should be addressed before compounded drugs are administered. The information that we would receive from billing and coding reflect Medicare payment after the drugs are administered.

OIG Recommendation

The OIG recommends that CMS explore the possibility of requiring providers to include the pharmacy that produced the compounded drug on the Part B claim.

CMS Response

The CMS does not concur with this recommendation. Generally, Medicare only collects information on a claim that is needed for payment. CMS does not need to identify the dispensing compounding pharmacy in order to pay the physician that is billing for the drugs. It is not clear that authority exists under the statute to collect the suggested information as that information is not necessary to determine the amount of payment. Changes to Medicare claims processing systems to accommodate the inclusion of dispensing pharmacy information would be significant and would compete for administrative resources with statutorily required payment methodology changes that necessitate system changes. Claims payment systems changes needed to implement statutorily required policy changes are the priority for the Agency.

The OIG's recommendation is motivated by a 2012 outbreak of fungal meningitis linked to contaminated injectable compounded drugs. OIG's recommendation is intended to assist CMS and the MAC in stopping payment for drugs manufactured in violation of the Federal Food, Drug and Cosmetic Act (FFDCA). We do not believe that stopping Medicare payment for compounded drugs produced in violation of the FFDCA will be a reliable tool for addressing public safety issues that motivated the OIG's report. By the time the MAC receives the claim, it will be too late to do anything to prevent the patient from receiving a tainted drug. Moreover, we believe information needed for public safety purposes (e.g., to track patients that received a tainted drug) could be obtained from the pharmacy and the administering physician once a public safety problem has been identified without requiring it on the Medicare claim.

OIG Recommendation

The OIG recommends that CMS explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs.

CMS Response

The CMS concurs with this recommendation. Concurrence is conditioned upon the successful implementation of the first recommendation. Further, we would only undertake such analyses if it were for a program-related purpose such as Medicare program integrity, analysis of spending trends, or new coverage, or payment policy.

The CMS thanks OIG for the work done on this issue and looks forward to working with OIG in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office.

Edward K. Burley served as team leader for this study. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Kevin McAloon. Central office staff who provided support include Meghan Kearns and Christine Moritz.

Office of Inspector General

<http://oig.hhs.gov>

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