Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PART B OVERPAID MILLIONS FOR SELECTED OUTPATIENT DRUGS

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



Daniel R. Levinson Inspector General

> July 2015 A-09-14-02024

Office of Inspector General

http://oig.hhs.gov

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at http://oig.hhs.gov

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

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

Medicare contractors nationwide overpaid providers by approximately \$35.8 million for selected outpatient drugs over 3 years. CMS took actions during and after our audit period to prevent overpayments for outpatient drugs, including educating providers and establishing prepayment edits. Medicare contractors could recover as much as \$11.5 million in additional overpayments if they were to review payments to providers for outpatient drugs billed after our audit period.

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary in each Medicare jurisdiction. (We refer to both as the "Medicare contractor.") From July 1, 2009, through June 30, 2012 (audit period), Medicare contractors nationwide paid providers \$11.5 billion for 26 million claim line items for outpatient drugs. Previous Office of Inspector General reviews of outpatient services found that Medicare contractors overpaid providers by more than \$122.4 million for selected outpatient drugs. Because of the significant overpayments identified in those reviews, we performed 13 individual reviews of payments for selected outpatient drugs at the Medicare contractors.

The objectives of this review were to (1) summarize the results of our individual reviews, which determined whether payments that the Medicare contractors made to providers for selected outpatient drugs were correct; (2) identify actions that CMS has taken to prevent overpayments for selected outpatient drugs; and (3) identify potential overpayments for outpatient drugs billed from July 2012 through June 2014 (after our audit period).

BACKGROUND

Medicare Part B covers the cost of outpatient drugs for beneficiaries. CMS administers Part B and contracts with Medicare contractors to, among other things, determine reimbursement amounts and pay claims, conduct audits, and safeguard against fraud and abuse. Each Medicare contractor is responsible for processing claims submitted by providers within designated regions, or jurisdictions, of the United States and its territories.

Providers report the outpatient drugs administered to Medicare beneficiaries using standardized codes called Healthcare Common Procedure Coding System (HCPCS) codes and report units of service in multiples of the units shown in the HCPCS narrative description. Correct payments depend on providers' accurate reporting of the HCPCS codes and units of service for each line item billed.

To reduce payment errors, CMS introduced a number of claim-review initiatives to identify and address incorrect billing caused by coverage or coding errors made by providers. One of these review initiatives was the implementation of Medically Unlikely Edits (MUEs). MUEs are automatic prepayment edits within the Medicare claims processing systems that compare the billed units with the maximum units of service for a given HCPCS code (MUE value). The

MUE value is the maximum number of units that a provider would reasonably administer to a beneficiary for that service on a single date of service. An MUE denies payment for an entire line item when the units of service exceed the MUE value for the HCPCS code billed. Line item MUEs, which are updated each quarter, do not exist for all HCPCS codes.

Of the 26 million line items for outpatient drugs processed by Medicare contractors during our audit period, we reviewed 15,912 totaling approximately \$131.2 million paid by Medicare contractors in 13 jurisdictions, and we issued 13 separate audit reports. We reviewed a variety of outpatient drugs, including injectable drugs used for cancer treatment and pain management.

HOW WE CONDUCTED THIS REVIEW

We analyzed and summarized the results of our 13 individual reviews and held discussions with CMS to identify actions that it took during and after the period July 2009 through June 2012 to prevent overpayments for selected outpatient drugs. We also analyzed the nationwide prepayment edits for selected outpatient drugs and determined what effect the edits would have had on the overpaid line items from our 13 reviews if the edits had been in place during our audit period. In addition, we identified outpatient drugs billed from July 2012 through June 2014 that were not part of the scope of our individual reviews and that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service. We then calculated the potential overpayment amounts for these line items.

WHAT WE FOUND

Medicare contractors in 13 jurisdictions overpaid providers \$35.8 million for selected outpatient drugs during our audit period. For the majority of the overpayments (88 percent), providers billed either incorrect units of service or a combination of incorrect units of service and incorrect HCPCS codes. During our audit period, the Medicare claims processing systems did not have sufficient prepayment edits in place to prevent all overpayments. In particular, MUEs did not exist for many of the HCPCS codes associated with the outpatient drugs in our review. The 13 Medicare contractors concurred with our recommendations in the individual reports to recover the identified overpayments and use the results of our audits in ongoing provider education. CMS informed us that, as of May 4, 2015, Medicare contractors had recovered 63 percent of the \$35.8 million in overpayments and 10 of the 13 Medicare contractors had used the results of our audits in ongoing provider education.

We identified actions taken during and after our audit period by CMS to prevent overpayments to providers incorrectly billing for outpatient drugs. CMS has educated providers on avoiding common Medicare billing errors through published articles and newsletters. In addition, during our audit period, CMS required Medicare contractors to begin implementing line item MUEs for certain HCPCS codes related to outpatient drugs. Since the initial implementation of the MUE initiative for outpatient drugs, CMS has continued to add or update MUEs every quarter. After our audit period, CMS began converting some line item MUEs to date-of-service MUEs. For date-of-service MUEs, all units of service on all line items for the same HCPCS code with the

same date of service are added up and compared with the MUE value. If the total units of service billed for the HCPCS code exceed the MUE value, the MUE will deny all of these line items. If the Medicare contractors had had these line item and date-of-service MUEs in place during our entire audit period, \$23.7 million, or 66 percent, of the \$35.8 million in total overpayments could have been prevented.

We identified potential overpayments for outpatient drugs that were billed after our audit period. Specifically, Medicare contractors could recover as much as \$11.5 million in overpayments if they were to review payments to providers for line items billed from July 2012 through June 2014 that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service.

WHAT WE RECOMMEND

We recommend that CMS:

- ensure that Medicare contractors collect the remaining overpayments identified in our individual reviews;
- continue to educate providers on correct billing of outpatient drugs;
- instruct Medicare contractors to review payments to providers for outpatient drugs billed from July 2012 through June 2014, which could represent overpayments of \$11.5 million; and
- continue to implement line item and date-of-service MUEs for additional outpatient drugs.

CMS COMMENTS AND OUR RESPONSE

In written comments on our draft report, CMS concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. Regarding our third recommendation, CMS requested that we provide the claim data necessary to determine whether overpayments exist and whether to collect any overpayments identified. We plan to provide those data to CMS.

INTRODUCTION	1
Why We Did This Review	1
Objectives	1
Background	1
Medicare Part B	1
Provider Submission of Part B Claims and the Use of Healthcare Common	
Procedure Coding System Codes	2
Medicare Contractor Controls Related to Payment of Provider Claims	2
Medically Unlikely Edits	
Office of Inspector General Reviews of Payments for	
Selected Outpatient Drugs	3
How We Conducted This Review	3
FINDINGS	4
Medicare Contractors Overpaid Providers for Selected Outpatient Drugs	4
Providers Billed the Incorrect Units of Service	
Providers Billed a Combination of Incorrect Units of Service	
and Incorrect Healthcare Common Procedure Coding System Codes	6
Providers Made Other Types of Errors	6
CMS Has Taken Actions To Prevent Overpayments for Outpatient Drugs	6
CMS Has Educated Providers on Avoiding Common Medicare	0
Billing Errors	6
CMS Established Prepayment Edits	
CMS Established Trepayment Edits	/
Medicare Contractors Could Recover Additional Potential Overpayments	8
	0
RECOMMENDATIONS	8
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	9
APPENDIXES	
A: Jurisdiction and Medicare Contractor for Each State and Territory	10
B: Related Office of Inspector General Reports	12
C: Audit Scope and Methodology	13

TABLE OF CONTENTS

D:	Overpayments to Providers for Selected Outpatient Drugs by Jurisdiction				
E:	CMS Comments	16			

INTRODUCTION

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary in each Medicare jurisdiction.¹ From July 1, 2009, through June 30, 2012 (audit period), Medicare contractors nationwide paid providers² \$11.5 billion for 26 million claim line items for outpatient drugs. Previous Office of Inspector General (OIG) reviews of outpatient services found that Medicare contractors overpaid providers by more than \$122.4 million for outpatient drugs.³ Because of the significant overpayments identified in those reviews, we performed 13 individual reviews of payments for selected outpatient drugs at the Medicare contractors.

OBJECTIVES

Our objectives were to (1) summarize the results of our individual reviews, which determined whether payments that the Medicare contractors made to providers for selected outpatient drugs were correct; (2) identify actions that CMS has taken to prevent overpayments for selected outpatient drugs; and (3) identify potential overpayments for outpatient drugs billed from July 2012 through June 2014 (after our audit period).

BACKGROUND

Medicare Part B

Medicare Part B provides supplementary medical insurance, including coverage for the cost of outpatient drugs for beneficiaries. CMS administers Part B and contracts with Medicare contractors to, among other things, determine reimbursement amounts and pay claims, conduct audits, and safeguard against fraud and abuse. Each Medicare contractor is responsible for processing claims submitted by providers within 1 of 13 designated regions, or jurisdictions, of the United States and its territories.⁴ Appendix A provides a table and map that show the jurisdiction and Medicare contractor for each State and territory.

¹ Currently, Medicare administrative contractors pay Medicare claims. For some jurisdictions, fiscal intermediaries paid claims during some or all of our audit period. In this report, the term "Medicare contractor" means the fiscal intermediary or Medicare administrative contractor, whichever is applicable.

² In this report, the term "providers" refers to short-term (general and specialty) hospitals, rehabilitation hospitals, psychiatric hospitals, and long-term hospitals.

³ We identified \$4.6 million of these overpayments in reviews of selected outpatient drugs at 39 providers and \$24.2 million in nationwide reviews of the drug Herceptin. We identified approximately \$81.9 million in overpayments for outpatient drugs in reviews of payments that exceeded provider charges by at least \$1,000 and identified approximately \$11.7 million in overpayments for outpatient drugs in reviews of high-risk payments.

⁴ At the time of our individual reviews, CMS was consolidating the 13 jurisdictions into 10 jurisdictions.

Provider Submission of Part B Claims and the Use of Healthcare Common Procedure Coding System Codes

Medicare contractors pay providers using established rates for each unit of service reported, subject to any Part B deductible and coinsurance. (Beneficiaries pay the deductible and coinsurance.) Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted claim may contain multiple line items that detail the services provided. Providers must use standardized codes, called Healthcare Common Procedure Coding System (HCPCS) codes, for drugs administered and report units of service in multiples of the units shown in the HCPCS narrative description. For example, if the description for the HCPCS code specifies 50 milligrams and 200 milligrams are administered, units are reported on the claim as 4.⁵

Medicare Contractor Controls Related to Payment of Provider Claims

Medicare contractors must establish and maintain efficient and effective internal controls.⁶ These controls, including those over automated data processing systems, are intended to prevent increased program costs caused by incorrect or delayed payments. Medicare contractors use the Fiscal Intermediary Standard System (FISS) and CMS's Common Working File to validate providers' claims for outpatient services before paying the claims. Medicare contractors calculate the payment for each outpatient service using the FISS's outpatient prospective payment system (OPPS). These three systems can also detect certain improper payments.

Medically Unlikely Edits

To reduce payment errors, CMS introduced a number of claim-review initiatives to identify and address incorrect billing caused by coverage or coding errors made by providers. One of these review initiatives was the implementation of Medically Unlikely Edits (MUEs). MUEs are developed and maintained by the CMS National Correct Coding Initiative contractor.⁷

MUEs are automatic prepayment edits within the FISS that compare the billed units with the maximum units of service for a given HCPCS code (MUE value). The MUE value is the maximum number of units that a provider would reasonably administer to a beneficiary for that service on a single date of service. An MUE denies payment for an entire line item when the units of service exceed the MUE value for the HCPCS code billed.⁸

⁵ The Social Security Act, section 1833(e), and CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 17, section 90.2.A, provide overall requirements related to the billing and payment of hospital outpatient services. They require that providers submit accurate and complete bills to Medicare for allowable and covered services and identify the units of service for each outpatient drug administered to a Medicare beneficiary using the correct HCPCS code.

⁶ CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, § 10.

⁷ The contractor, Correct Coding Solutions, LLC, provides a revised MUE table to CMS each quarter. CMS then distributes the revised MUE table to the Medicare contractors.

⁸ CMS's Pub. No. 100-20, One-Time Notification, Transmittal 652, Change Request 6712, dated March 17, 2010, provides information on MUEs in effect as of April 2010.

Line item MUEs, which are updated each quarter, do not exist for all HCPCS codes. Before implementing new MUEs, CMS offers national health care organizations the opportunity to review and comment on the proposed edits. Medicare contractors must include the MUEs in their payment systems.⁹

Office of Inspector General Reviews of Payments for Selected Outpatient Drugs

Of the 26 million line items for outpatient drugs processed by Medicare contractors during our audit period, we reviewed 15,912 totaling approximately \$131.2 million paid by Medicare contractors in 13 jurisdictions, and we issued 13 separate reports from January to July 2014. We reviewed a variety of outpatient drugs, including injectable drugs used for cancer treatment and pain management. Appendix B lists the 13 reports.

HOW WE CONDUCTED THIS REVIEW

We analyzed and summarized the results of our 13 individual reviews and held discussions with CMS to identify actions that it took during and after the period July 2009 through June 2012 to prevent overpayments for selected outpatient drugs. We also analyzed the nationwide prepayment edits for selected outpatient drugs and determined what effect the edits would have had on the overpaid line items from our 13 reviews if the edits had been in place during our audit period. In addition, we identified outpatient drugs billed from July 2012 through June 2014 that were not part of the scope of our individual reviews and that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service. We then calculated the potential overpayment amounts for these line items.

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 C contains the details of our audit scope and methodology.

⁹ CMS makes the majority of MUEs available on its Web site. However, CMS does not publish all MUE values, particularly those for outpatient drugs, because of fraud and abuse concerns.

FINDINGS

Medicare contractors in 13 jurisdictions overpaid providers \$35.8 million for selected outpatient drugs during our audit period. For the majority of the overpayments (88 percent), providers billed either incorrect units of service or a combination of incorrect units of service and incorrect HCPCS codes. During our audit period, neither the FISS nor the Common Working File had sufficient edits in place to prevent all overpayments. In particular, MUEs did not exist for many of the HCPCS codes associated with the outpatient drugs in our review. Appendix D provides a summary of the overpayments to providers by jurisdiction.

We identified actions taken during and after our audit period by CMS to prevent overpayments to providers incorrectly billing for outpatient drugs. CMS has educated providers on avoiding common Medicare billing errors through published articles and newsletters. In addition, CMS required Medicare contractors to implement nationwide prepayment edits, including line item and date-of-service MUEs, for certain HCPCS codes related to outpatient drugs. If the Medicare contractors had had these MUEs in place during our entire audit period, \$23.7 million, or 66 percent, of the \$35.8 million in total overpayments could have been prevented.

We identified potential overpayments for outpatient drugs that were billed after our audit period. Specifically, Medicare contractors could recover as much as \$11.5 million in overpayments if they were to review payments to providers for line items billed from July 2012 through June 2014 that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service.

MEDICARE CONTRACTORS OVERPAID PROVIDERS FOR SELECTED OUTPATIENT DRUGS

Fifty-one percent of the line items for selected outpatient drugs that we reviewed were incorrect, resulting in net overpayments¹⁰ to providers of \$35.8 million. We separated the overpayments into three types of errors, as shown in Figure 1 on the following page:

- incorrect units of service,
- combination of incorrect units of service and incorrect HCPCS codes, and
- other types of errors.

Providers that billed either incorrect units of service or a combination of incorrect units of service and incorrect HCPCS codes accounted for 88 percent (\$31.5 million) of the overpayments.

¹⁰ We combined overpayment and underpayment amounts to determine the net overpayment amount.

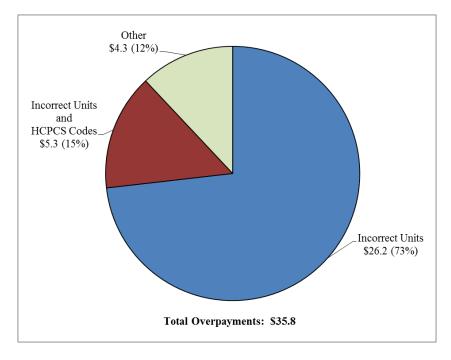


Figure 1: Overpayments by Error Type (Dollar Amounts in Millions)

The 13 Medicare contractors concurred with our recommendations in the individual reports to recover the identified net overpayments and use the results of our audits in ongoing provider education. CMS informed us that, as of May 4, 2015, Medicare contractors had recovered 63 percent of the \$35.8 million in overpayments and 10 of the 13 Medicare contractors had used the results of our audits in ongoing provider education.

Providers Billed the Incorrect Units of Service

Providers billed the incorrect units of service, resulting in net overpayments of \$26.2 million. For example, one provider administered 6 units of rituximab to a patient and incorrectly billed 60 units of service. On 21 separate occasions, the provider made this type of error, and as a result, the Medicare contractors paid the provider \$811,562 when they should have paid \$67,863, an overpayment of \$743,699.¹¹

The drugs we reviewed that were most frequently overpaid because providers billed the incorrect units of service were adenosine (HCPCS code J0152), rituximab (HCPCS code J9310), infliximab (HCPCS code J1745), leuprolide acetate (HCPCS code J9217), and bortezomib (HCPCS code J9041).

¹¹ The example is from *Medicare Contractors for Jurisdiction 15 Overpaid Providers for Selected Outpatient Drugs*, A-05-13-00013, issued March 14, 2014.

Providers Billed a Combination of Incorrect Units of Service and Incorrect Healthcare Common Procedure Coding System Codes

Providers billed a combination of incorrect units of service and incorrect HCPCS codes, resulting in net overpayments of \$5.3 million. For example, 24 providers billed Medicare on 415 line items for 2 to 12 units of service for leuprolide acetate injections (HCPCS code J1950, 3.75 milligrams per unit), which are indicated for the treatment of endometriosis, uterine leiomyoma, and malignant neoplasms of the breast. However, the providers should have billed Medicare for 1 to 6 units of service for leuprolide acetate injections (HCPCS code J9217, 7.5 milligrams per unit), which were the doses actually administered. HCPCS code J9217 is indicated for the treatment of prostate cancer. As a result of these errors, the Medicare contractor paid the providers \$1,129,692 when it should have paid \$216,688, an overpayment of \$913,004.¹²

Providers Made Other Types of Errors

Providers made other types of errors, resulting in net overpayments of \$4.3 million. Specifically, providers (1) did not provide documentation to support that a patient had received the drug service billed (\$2.1 million), (2) billed for outpatient drugs in which their payment was included in the payment for a primary procedure (\$1.1 million), (3) used incorrect HCPCS codes (\$625,000), or (4) billed Medicare for the noncovered use of outpatient drugs (\$519,000).

CMS HAS TAKEN ACTIONS TO PREVENT OVERPAYMENTS FOR OUTPATIENT DRUGS

We identified actions taken by CMS during and after our audit period to prevent overpayments to providers incorrectly billing for outpatient drugs. CMS has educated providers on avoiding common Medicare billing errors, including billing for excessive units of service, through published articles and newsletters. In addition, during our audit period, CMS required Medicare contractors to begin implementing nationwide prepayment edits for certain HCPCS codes related to outpatient drugs to prevent payments for excessive units billed. After our audit period, CMS began modifying some of these edits to identify the same services on the same date of service billed on multiple line items. If the Medicare contractors had had these edits in place during our entire audit period, \$23.7 million, or 66 percent, of the \$35.8 million in total overpayments could have been prevented.

CMS Has Educated Providers on Avoiding Common Medicare Billing Errors

CMS educates providers on avoiding common Medicare billing errors through various channels, including the Medicare Learning Network (MLN). Examples of MLN educational materials include *MLN Matters* (articles about changes to the Medicare program) and the *Medicare Quarterly Provider Compliance Newsletter* (the newsletter), which CMS first published in

¹² The example is from *The Medicare Contractor for Jurisdiction F Overpaid Providers for Selected Outpatient Drugs*, A-09-13-02003, issued January 27, 2014.

October 2010. CMS uses the newsletter to help providers understand major findings identified by Medicare contractors; review contractors;¹³ and governmental organizations, including OIG.

Both *MLN Matters* and the newsletter tailor articles by content and language to specific provider types, such as hospitals. An *MLN Matters* article entitled "January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)," issued in December 2011, stated that it is of great importance that hospitals billing for outpatient drugs make certain that the reported units of service of the reported HCPCS codes are consistent with the quantity of the drug that was used in the care of the patient. Issues of the newsletter have drawn attention to excessive-units billing errors, as well as errors due to the use of incorrect HCPCS codes.

CMS Established Prepayment Edits

CMS required Medicare contractors to implement nationwide prepayment edits for outpatient drugs, including line item MUEs during our audit period and date-of-service MUEs after our audit period.

Line-Item Medically Unlikely Edits

During our audit period, CMS required Medicare contractors to begin implementing line item MUEs for certain HCPCS codes related to outpatient drugs that deny an entire line item when the units of service billed exceed the MUE value. Line item MUEs, which CMS continues to add or update every quarter, had MUE values implemented after the line items' dates of service that could have prevented overpayments. For example, the line item MUE value of 1 unit for iodine i-131 tositumomab, therapeutic (HCPCS code A9545), could have prevented overpayments for six line items in which one provider incorrectly billed 2 units of service.¹⁴ We identified the line item MUEs established from January 2009 through December 2014, and if all of these MUEs had been in place during our audit period, they could have prevented \$19.3 million (54 percent) of the \$35.8 million in overpayments.

Date-of-Service Medically Unlikely Edits

After our audit period, CMS began converting some line item MUEs to date-of-service MUEs. A date-of-service MUE performs the following steps on units of service billed for a beneficiary:

- The MUE adds up all the units of service on all the line items for the same HCPCS code with the same date of service.
- The MUE compares the total units of service with the MUE value.

¹³ CMS contracts with review contractors (which include recovery audit contractors, program safeguard contractors, and zone program integrity contractors) to detect and correct improper payments, promote provider compliance, and identify and stop potential fraud.

¹⁴ The example is from *The Medicare Contractor for Jurisdiction 10 Overpaid Providers for Selected Outpatient Drugs*, A-04-13-00090, issued April 8, 2014.

• If the total units of service billed for the HCPCS code exceed the MUE value, the MUE denies all of the line items.

We identified the date-of-service MUEs established from April 2013 through December 2014, and if all of these MUEs had been in place during our audit period, they could have prevented \$4.4 million (12 percent) of the \$35.8 million in overpayments.

MEDICARE CONTRACTORS COULD RECOVER ADDITIONAL POTENTIAL OVERPAYMENTS

We identified potential overpayments for outpatient drugs that were billed after our audit period. Specifically, Medicare contractors could recover as much as \$11.5 million in overpayments if they were to review payments to providers for line items billed from July 2012 through June 2014 that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service:

- Providers billed units of service that exceeded the MUE values, resulting in potential overpayments of \$9.2 million. For example, 46 providers in 13 jurisdictions billed Medicare on 144 line items for 12 to 500 units of service for zoledronic acid (HCPCS code J3489). The units of service exceeded the MUE value of 5 units for this HCPCS code. As a result, the Medicare contractors potentially overpaid the providers \$499,283 for these line items.
- Providers billed units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service, resulting in potential overpayments of \$2.3 million. For example, 11 providers in 7 jurisdictions billed Medicare on 41 line items for 140 to 840 units of service for pertuzumab (HCPCS code C9292). The units of service exceeded an established threshold of 84 units for this HCPCS code.¹⁵ As a result, the Medicare contractors potentially overpaid the providers \$853,413 for these line items.

RECOMMENDATIONS

We recommend that CMS:

- ensure that Medicare contractors collect the remaining overpayments identified in our individual reviews;
- continue to educate providers on correct billing of outpatient drugs;

¹⁵ For an HCPCS code for an outpatient drug that did not have an established MUE value, we based the threshold amount on either (1) the MUE value for a subsequent HCPCS code established for the drug or (2) information in a publication, such as prescribing information from the drug manufacturer's Web site, that described the standard dosage administered to an average beneficiary.

- instruct Medicare contractors to review payments to providers for outpatient drugs billed from July 2012 through June 2014, which could represent overpayments of \$11.5 million; and
- continue to implement line item and date-of-service MUEs for additional outpatient drugs.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. Regarding our third recommendation, CMS stated that once we provide the necessary claim data, CMS will instruct the supplemental medical review contractor to review a sample of claims, claim data, or both to determine whether overpayments exist. CMS also stated that once that process is complete, it will determine whether it is appropriate to review the remaining claims and collect any overpayments identified "to the maximum extent possible within the purview of CMS policies and regulations." We plan to provide CMS with the requested claim data.

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

APPENDIX A: JURISDICTION AND MEDICARE CONTRACTOR FOR EACH STATE AND TERRITORY¹⁶

Table:	Medicare	Contractor	and State	es and Te	erritories i	for Each	Jurisdiction
--------	----------	------------	-----------	-----------	--------------	----------	--------------

Jurisdiction	Medicare Contractor	States and Territories		
	Wisconsin Physicians			
	Service Insurance			
5	Corporation (WPS)	Iowa, Kansas, Missouri, Nebraska		
	National Government			
6	Services, Inc. (NGS)	Illinois, Minnesota, Wisconsin		
8	WPS	Indiana, Michigan		
	First Coast Service			
9	Options, Inc. (First Coast)	Florida, Puerto Rico, U.S. Virgin Islands		
	Cahaba Government			
	Benefit Administrators,			
10	LLC (Cahaba)	Alabama, Georgia, Tennessee		
	Palmetto GBA, LLC	North Carolina, South Carolina, Virginia, West		
11	(Palmetto)	Virginia		
	Novitas Solutions, Inc.	Delaware, District of Columbia, Maryland, New		
12	(Novitas)	Jersey, Pennsylvania		
13	NGS	Connecticut, New York		
		Maine, Massachusetts, New Hampshire, Rhode		
14	NGS	Island, Vermont		
	CGS Administrators, LLC			
15	(CGS)	Kentucky, Ohio		
	Noridian Healthcare	American Samoa, California, Guam, Hawaii,		
E	Solutions, LLC (Noridian)	Nevada, Northern Mariana Islands		
		Alaska, Arizona, Idaho, Montana, North Dakota,		
		Oregon, South Dakota, Utah, Washington,		
F	Noridian	Wyoming		
		Arkansas, Colorado, Louisiana, Mississippi, New		
Н	Novitas	Mexico, Oklahoma, Texas		

¹⁶ The jurisdiction number, the Medicare contractor, and the geographic composition of each jurisdiction are accurate as of the issuance date of the individual report for each jurisdiction.

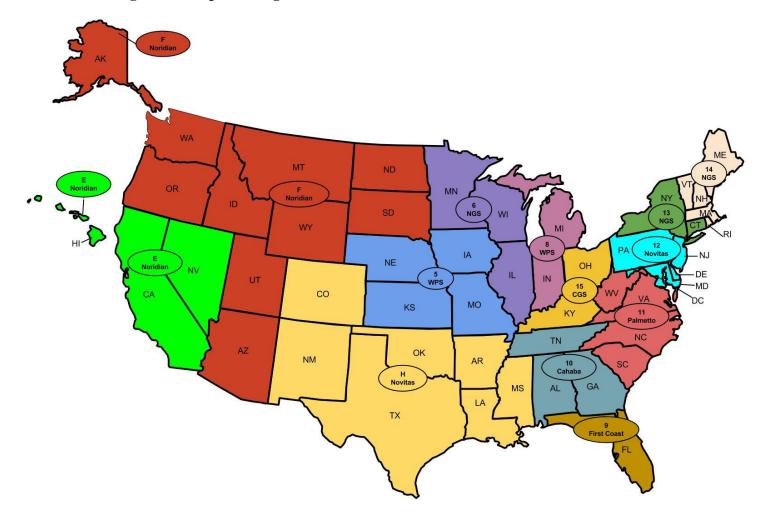


Figure 2: Map Showing Jurisdiction and Medicare Contractor for Each State¹⁷

¹⁷ The map does not show the territories in Jurisdiction 9 (Puerto Rico and U.S. Virgin Islands) or Jurisdiction E (American Samoa, Guam, and Northern Mariana Islands).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
The Medicare Contractor for Jurisdiction 5 Overpaid Providers for Selected Outpatient Drugs	<u>A-07-13-04201</u>	3/14/2014
<i>The Medicare Contractors for Jurisdiction 6 Overpaid</i> <i>Providers for Selected Outpatient Drugs</i>	<u>A-06-13-00013</u>	4/17/2014
Medicare Contractors for Jurisdiction 8 Overpaid Providers for Selected Outpatient Drugs	<u>A-05-13-00012</u>	3/18/2014
The Medicare Contractor for Jurisdiction 9 Overpaid Providers for Selected Outpatient Drugs	<u>A-04-13-07038</u>	5/6/2014
The Medicare Contractor for Jurisdiction 10 Overpaid Providers for Selected Outpatient Drugs	<u>A-04-13-00090</u>	4/8/2014
The Medicare Contractors for Jurisdiction 11 Overpaid Providers for Selected Outpatient Drugs	<u>A-03-13-00011</u>	2/6/2014
The Medicare Contractor for Jurisdiction 12 Overpaid Providers for Selected Outpatient Drugs	<u>A-03-13-00012</u>	2/6/2014
The Medicare Contractor for Jurisdiction 13 Overpaid Providers for Selected Outpatient Drugs	<u>A-02-13-01011</u>	7/3/2014
The Medicare Contractor for Jurisdiction 14 Overpaid Providers for Selected Outpatient Drugs	<u>A-01-13-00504</u>	7/18/2014
Medicare Contractors for Jurisdiction 15 Overpaid Providers for Selected Outpatient Drugs	<u>A-05-13-00013</u>	3/14/2014
The Medicare Contractors for Jurisdiction E Overpaid Providers for Selected Outpatient Drugs	<u>A-09-13-02009</u>	1/27/2014
The Medicare Contractor for Jurisdiction F Overpaid Providers for Selected Outpatient Drugs	<u>A-09-13-02003</u>	1/27/2014
The Medicare Contractors for Jurisdiction H Overpaid Providers for Selected Outpatient Drugs	<u>A-06-13-00010</u>	5/2/2014

APPENDIX C: AUDIT SCOPE AND METHODOLOGY

SCOPE

From July 1, 2009, through June 30, 2012, Medicare contractors processed 26 million Part B line items for outpatient drugs, totaling approximately \$11.5 billion. These line items consisted of outpatient drugs with payment status indicator code "G" or "K." "G" identifies drugs and biologicals paid using the OPPS that include a pass-through payment.¹⁸ "K" identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPPS without a pass-through payment. Of these 26 million line items, we selected for review 15,912 line items¹⁹ totaling approximately \$131.2 million paid by Medicare contractors in 13 jurisdictions, and we issued 13 separate audit reports from January to July 2014.

We consolidated the results of our 13 reviews of payments by Medicare contractors for selected outpatient drugs. We also identified actions that CMS had taken to prevent overpayments for outpatient drugs. In addition, we identified 2,790 line items for outpatient drugs billed from July 2012 through June 2014 that were not part of the scope of the 13 reviews and calculated the potential overpayment amounts for these line items.

We limited our review of Medicare contractors' internal controls to those that were applicable to the selected line items because our objective did not require an understanding of all internal controls over the submission and processing of claims. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

We conducted audit work from May 2014 to January 2015, which included contacting CMS in Baltimore, Maryland.

METHODOLOGY

To accomplish our objectives, we:

- reviewed applicable Federal laws, regulations, and guidance;
- analyzed and summarized the results of our 13 reviews of Medicare contractor payments for selected outpatient drugs;
- interviewed CMS staff regarding actions taken during and after our audit period to prevent overpayments related to line items for selected outpatient drugs;

¹⁸ Pass-through payments are additional payments made for a short time to cover the costs for certain innovative medical devices, drugs, and biologicals. These costs exceed Medicare's OPPS payment amounts.

¹⁹ We did not review entire claims; rather, we reviewed specific line items within the claims for which the number of units the provider billed was more than the number of units the provider would reasonably administer to a patient on a single date of service.

- reviewed CMS provider education materials related to billing for outpatient drugs;
- obtained from CMS lists of nationwide prepayment edits for selected outpatient drugs;
- analyzed the nationwide prepayment edits for selected outpatient drugs and determined what their effect would have been on the overpaid line items from our 13 reviews if the edits had been in place during our audit period;
- used computer matching, data mining, and data analysis techniques to identify 2,790 line items for outpatient drugs billed from July 2012 through June 2014 that (1) had units of service that exceeded the MUE values or (2) did not have established MUE values but had units of service that exceeded the number of units a provider would reasonably administer to a beneficiary on a single date of service;
- calculated the potential overpayment amounts for the 2,790 line items as of December 1, 2014; and
- discussed the results of our review 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 D: OVERPAYMENTS TO PROVIDERS FOR SELECTED OUTPATIENT DRUGS BY JURISDICTION

		Number of	Number of	Percentage	Net
	Medicare	Line Items	Incorrect	of Incorrect	Overpayment
Jurisdiction	Contractor	Reviewed ²⁰	Line Items	Line Items	Amount ²¹
5	WPS	1,334	723	54%	\$3,464,609
6	NGS	1,179	478	41%	2,896,995
8	WPS	1,034	549	53%	2,581,689
9	First Coast	311	112	36%	441,954
10	Cahaba	998	492	49%	1,142,247
11	Palmetto	2,135	900	42%	2,153,314
12	Novitas	1,254	607	48%	3,717,680
13	NGS	1,138	667	59%	2,695,379
14	NGS	779	295	38%	1,313,058
15	CGS	907	593	65%	5,012,610
E	Noridian	1,539	874	57%	4,205,429
F	Noridian	1,549	867	56%	3,044,608
Н	Novitas	1,755	1,001	57%	3,085,431
Totals		15,912	8,158	51%	\$35,755,003

²⁰ We did not include 491 line items that were part of the reviews for Jurisdictions 5, 6, 8, 15, and H because these line items were for services provided and paid before July 1, 2009.

²¹ We combined overpayment and underpayment amounts to determine the net overpayment amount.

APPENDIX E: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

MAY - 4 2015

200 Independence Avenue SW Washington, DC 20201

To: Daniel R. Levinson Inspector General Office of the Inspector General

From: Andrew Slavitt

Andrew Slavitt Acting Administrator On Che de-Centers for Medicare & Medicaid Services

Subject: Medicare Part B Overpaid Millions for Selected Outpatient Drugs (A-09-14-02024)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) draft report. CMS is committed to being a good steward of taxpayer dollars by preventing improper billing. CMS has taken actions to prevent overpayments for outpatient drugs, by educating providers on proper billing, and implementing system checks to prevent improper billing. CMS uses a number of claim-review initiatives to identify and address incorrect billing caused by coverage or coding errors made by providers. CMS requires Medicare contractors to use nationwide prepayment edits, which include line item and date-of service Medically Unlikely Edits (MUEs) for certain claims codes related to outpatient drugs.

OIG Recommendation

The OIG recommends that CMS ensure that Medicare contractors collect the remaining overpayments identified in our individual reviews.

CMS Response

CMS concurs with this recommendation. Of the approximately \$35 million of overpayments identified in the individual reports, CMS has already recovered approximately \$22 million. CMS will continue to work with Medicare contractors to ensure that the overpayments identified in the individual reports are collected to the maximum extent possible within the purview of CMS policies and regulations.

OIG Recommendation

The OIG recommends that CMS continue to educate providers on correct billing of outpatient drugs.

CMS Response

Page 2 - Daniel R. Levinson

CMS concurs with this recommendation. As mentioned in the OIG's report, CMS already educates providers on avoiding common Medicare billing errors through various channels, including the Medicare Learning Network (MLN). CMS uses weekly electronic newsletters and quarterly compliance newsletters to educate providers on avoiding common Medicare billing errors, including billing for excessive units of service, as well as errors due to the use of incorrect Healthcare Common Procedure Coding System (HCPS) codes. CMS will continue to use these channels to educate providers.

OIG Recommendation

The OIG recommends that CMS instruct Medicare contractors to review payments to providers for outpatient drugs billed from July 2012 through June 2014, which could represent overpayments of \$11.5 million.

CMS Response

CMS concurs with this recommendation. Once the OIG furnishes the necessary claims data, CMS will instruct the Supplemental Medical Review Contractor (SMRC) to review a sample of claims and/or claims data to determine if overpayments exist. Once complete, CMS will determine if it is appropriate to continue to review the remaining claims and collect any overpayments identified to the maximum extent possible within the purview of CMS policies and regulations.

OIG Recommendation

The OIG recommends that CMS continue to implement line item and date-of-service MUEs for additional outpatient drugs.

CMS Response

CMS concurs with this recommendation. CMS has developed and implemented MUEs for all existing drug codes for which an MUE is technically feasible and is creating MUEs for new drug codes as they are released. Excluding new drug codes established in the last 6 months, CMS has established MUEs for 97% of codes as of January 1, 2015. CMS's MUE Workgroup is in the process of reviewing every drug code MUE to determine whether they can be converted to a date-of-service MUE, and will convert all MUEs except where the conversion creates a greater vulnerability or where a date-of-service edit is otherwise inadvisable or unfeasible.