

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR
FOR JURISDICTION 14 OVERPAID
PROVIDERS FOR SELECTED
OUTPATIENT DRUGS**

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



John D. Hagg
Acting Assistant Inspector General
for Audit Services

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Office of Inspector General

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EXECUTIVE SUMMARY

The Medicare contractor for Jurisdiction 14 overpaid providers by \$1.3 million for selected outpatient drugs over 3 years.

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor) in each Medicare jurisdiction. From July 1, 2009, through June 30, 2012, Medicare contractors nationwide paid hospitals \$11.5 billion for outpatient drugs, which also include biologicals and radiopharmaceuticals. Previous Office of Inspector General reviews of outpatient services have found that Medicare contractors overpaid providers for selected outpatient drugs. This report is part of a series of reports focusing on payments for selected outpatient drugs.

The objective of this review was to determine whether payments that the Medicare contractor for Jurisdiction 14 made to providers for selected outpatient drugs were correct.

BACKGROUND

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 accurate reporting of the HCPCS codes and units of service for each claim line item billed. CMS designed a series of automatic system edits that Medicare contractors use to review the units billed by providers, identify errors in billed amounts, and ensure that billed units that exceed the edit threshold for a likely dose are validated before the claim line items are paid. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

During our audit period (July 1, 2009, through June 30, 2012), NHIC, Corp., was the Medicare contractor for Jurisdiction 14 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont). For the five States, the Medicare contractor paid \$767.7 million for 1.2 million line items for selected outpatient drugs. We reviewed 779 line items with total payments of \$7.1 million that were at risk for overpayment.

Effective October 2013, National Government Services, Inc. (NGS), became the Medicare contractor for Jurisdiction K, which covers the five States formerly under Jurisdiction 14 and the two States (Connecticut and New York) formerly under Jurisdiction 13. NGS assumed responsibility for claims paid by NHIC, Corp.; accordingly, we have addressed our findings and recommendations to NGS for review and comment.

WHAT WE FOUND

Payments that the Medicare contractor for Jurisdiction 14 made to providers for 295 of the 779 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted

in overpayments of \$1,318,065 and underpayments of \$5,009 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers refunded \$205,948 of overpayments for another 53 line items. The remaining 431 line items were correct.

For the 290 incorrect line items with overpayments of \$1,318,065 that had not been refunded, providers reported incorrect units of service, did not provide supporting documentation, used incorrect HCPCS codes, reported a combination of incorrect units of service and incorrect HCPCS codes, billed separately for an outpatient drug for which payment was packaged with the primary service, and billed for noncovered use of a drug. For the five incorrect line items with underpayments of \$5,009 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims.

Providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. The Medicare contractor overpaid these providers because there were insufficient edits in place to prevent or detect overpayments.

WHAT WE RECOMMEND

We recommend that NGS:

- recover the \$1,318,065 in identified overpayments,
- verify the payment of \$5,009 in identified underpayments, and
- use the results of this audit in its ongoing provider education activities.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS

In written comments on our draft report, NGS stated that it would review the line items paid in error to adjust and recover any overpayments and verify underpayments accordingly. NGS said that it had recently conducted educational sessions with providers, instructing them on the proper billing of drugs and biologicals, and that it would enhance its educational materials as needed based on the results of this review.

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INTRODUCTION

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor¹) in each Medicare jurisdiction. From July 1, 2009, through June 30, 2012, Medicare contractors nationwide paid hospitals \$11.5 billion for outpatient drugs, which also include biologicals and radiopharmaceuticals.²

Previous Office of Inspector General reports have found that Medicare contractors overpaid providers by more than \$122.4 million for outpatient drugs. 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 of payments for outpatient drugs in reviews of payments that exceeded provider charges by at least \$1,000 and identified approximately \$11.7 million of payments for outpatient drugs in reviews of payments at high risk for overpayments.³ (See Appendix A for a list of reports related to Jurisdiction 14.)

This report is part of a series of reports focusing on payments for selected outpatient drugs.

OBJECTIVE

Our objective was to determine whether payments that the Medicare contractor for Jurisdiction 14 made to providers for selected outpatient drugs were correct.

BACKGROUND

Medicare Part B

Part B of Medicare provides supplementary medical insurance, including coverage for the cost of outpatient drugs. CMS administers Part B and contracts with Medicare contractors to, among other things, determine reimbursement amounts and pay claims, conduct reviews and audits, and safeguard against fraud and abuse. Medicare contractors must establish and maintain efficient

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 Biologicals are medicinal preparations made from living organisms and their products (for example, serums, vaccines, antigens, and antitoxins); radiopharmaceuticals are radioactive drugs used for diagnostic or therapeutic purposes.

³ Although the selected provider and Herceptin audits included only outpatient drugs, the payments-greater-than-charges audits, with overpayments totaling \$106 million, and the excessive-claim-payments audits, with overpayments totaling \$44 million, included all types of outpatient services. Some of the reviews of payments that exceeded provider charges covered amounts between \$500 and \$1,000. We considered high-risk payments as those that exceeded \$10,000 for claims under Part B and exceeded \$50,000 for claims for outpatient services. We estimated the total overpayment amount for selected outpatient drug services for these audits.

and effective internal controls.⁴ These controls, including those over automatic data processing systems, are intended to prevent increased program costs caused by incorrect or delayed payments. Medicare contractors use the Common Working File (CWF) and Fiscal Intermediary Standard System (FISS) to validate providers' claims for outpatient services before paying the claims. Medicare contractors calculate the payment for each outpatient service using FISS's Hospital Outpatient Prospective Payment System (OPPS). These three systems can also detect certain improper payments.

Healthcare Common Procedure Coding System Codes

Medicare contractors pay providers using established rates for each hospital outpatient unit of service claimed, subject to any Part B deductible and coinsurance. Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted claim may contain multiple line items that detail most provided services.⁵ 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 shown as 4.

Medicare Contractor Edits

To reduce payment errors, CMS introduced a number of claims-review initiatives that identify and address incorrect billing due to coverage or coding errors made by providers. One of these review initiatives, established in January 2007, is the "Medically Unlikely Edits" prepayment claims review program. Medically unlikely edits are developed and maintained by the CMS National Correct Coding Initiative contractor.⁶

Medically unlikely edits are automatic prepayment edits within the FISS that compare the billed units with the maximum units of service for a given HCPCS code. The maximum units of service are the maximum number of units that a provider would reasonably administer to a patient for that service on a single date of service. A medically unlikely edit denies line items for units of service that exceed the maximum units for the HCPCS code billed.

Medically unlikely edits, which are updated each quarter, do not exist for all HCPCS codes. Before implementing new medically unlikely edits, CMS offers national health care

⁴ CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, section 10.

⁵ Some claim line items included on outpatient claims do not identify the specific services provided but just identify the revenue code and billed charges. These line items are generally not paid because the services are bundled into other services that are specifically identified.

⁶ The contractor, Correct Coding Solutions, LLC, provides a revised medically unlikely edit table to CMS each quarter. CMS then distributes the revised medically unlikely edit table with the revised national correct coding initiative table to Medicare contractors.

organizations the opportunity to review and comment on the proposed edits. Medicare contractors must include the medically unlikely edits in their payment systems.⁷

NHIC, Corp., and National Government Services, Inc.

During our audit period (July 1, 2009, through June 30, 2012), NHIC, Corp., was the Medicare contractor for Jurisdiction 14 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont).

Effective October 2013, National Government Services, Inc. (NGS), became the Medicare contractor for Jurisdiction K, which covers the five States formerly under Jurisdiction 14 and the two States (Connecticut and New York) formerly under Jurisdiction 13. NGS assumed responsibility for claims paid by NHIC, Corp.; accordingly we have addressed our findings and recommendations to NGS for review and comment.

HOW WE CONDUCTED THIS REVIEW

During our audit period, the Medicare contractor for Jurisdiction 14 paid providers \$767.7 million for 1.2 million line items for selected outpatient drugs. We reviewed 779 line items⁸ with total payments of \$7.1 million that were at risk for overpayment. These line items were for outpatient drugs with payment status indicator code “G” or “K.”⁹ We used computer matching, data mining, and other analytical techniques to identify the line items potentially at risk for noncompliance with Medicare billing requirements. We evaluated compliance with selected billing requirements, but we did not use medical review to determine whether services were medically necessary.

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.

See Appendix B for the details of our scope and methodology.

FINDINGS

Payments that the Medicare contractor for Jurisdiction 14 made to providers for 295 of the 779 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted

⁷ CMS makes the majority of medically unlikely edits publicly available on its Web site. However, CMS does not publish all medically unlikely edit values, particularly for outpatient drugs, because of fraud and abuse concerns.

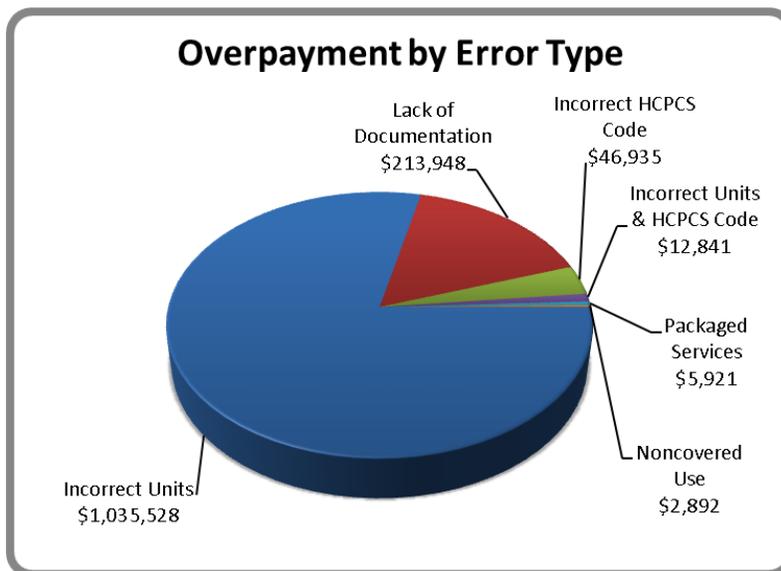
⁸ In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

⁹ “G” and “K” identify drugs that are separately paid by Medicare. “G” identifies drugs and biologicals paid using the OPPS that include a pass-through payment. (Pass-through payments are additional payments made for a short time to cover the cost for certain innovative medical devices, drugs, and biologicals that exceed Medicare’s OPPS payment amount.) “K” identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPPS without a pass-through payment.

in overpayments of \$1,318,065 and underpayments of \$5,009 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers had refunded \$205,948 of overpayments for another 53 line items. The remaining 431 line items were correct.

For the 290 incorrect line items with overpayments of \$1,318,065 that had not been refunded, providers:

- reported incorrect units of service on 220 line items, resulting in overpayments of \$1,035,528;
- did not provide supporting documentation for 45 line items, resulting in overpayments of \$213,948;
- used incorrect HCPCS codes on 17 line items, resulting in overpayments of \$46,935;



- reported a combination of incorrect units of service and incorrect HCPCS codes on 6 line items, resulting in overpayments of \$12,841;
- billed separately for an outpatient drug for which payment was packaged with the primary service on 1 line item, resulting in overpayments of \$5,921; and
- billed for the noncovered use of a drug on 1 line item, resulting in overpayments of \$2,892.

For the five incorrect line items with underpayments of \$5,009 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims.

Providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. The Medicare contractor overpaid these providers because neither the CWF nor the FISS had sufficient edits in place to prevent or detect the overpayments.

FEDERAL REQUIREMENTS

The Social Security Act (the Act) and CMS Pub. No. 100-04, *Medicare Claims Processing Manual* (the Manual), 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 number of units of service for each outpatient drug administered to a Medicare beneficiary using the correct HCPCS code.¹⁰

See Appendix C for details on the Federal requirements related to Medicare contractor payment and provider billing for selected outpatient drugs.

OVERPAYMENTS TO PROVIDERS THAT BILLED INCORRECTLY OR DID NOT DOCUMENT THAT THE SERVICES BILLED HAD BEEN PERFORMED

Incorrect Number of Units of Service

Providers reported incorrect units of service on 220 line items, resulting in overpayments of \$1,035,528. The incorrect units of service involved 35 different outpatient drugs. The following are examples:

- One provider administered 25 milligrams of risperidone to a patient and billed for 2,500 units of service. Using the HCPCS description (injection, risperidone, long acting, 0.5 milligrams), the correct number of units to bill for 25 milligrams was 50. On two separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider \$15,331 when it should have paid \$3,476, an overpayment of \$11,855.
- Another provider administered 76 milligrams (8 units of service) of doxorubicin hydrochloride liposome to a patient but incorrectly billed for 32 units of service (320 milligrams). Because the administration end time identified in the medical record was not entered in the pharmacy computer system until an automatic discharge time was entered, the units were automatically calculated using the incorrect end times. As a result, the Medicare contractor paid the provider \$13,793 when it should have paid \$2,964, an overpayment of \$10,829.

In total, the Medicare contractor paid 44 providers \$1,882,374 when it should have paid \$846,846, an overpayment of \$1,035,528.

Lack of Supporting Documentation

Ten providers billed Medicare on 45 line items for which the providers did not provide any documentation to support that a patient had received the drug service billed. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined \$213,948 in overpayments that they received.

¹⁰ These requirements are found in the Act, § 1833(e), and the Manual, chapter 17, section 90.2.A.

Incorrect Healthcare Common Procedure Coding System Codes

Providers used incorrect HCPCS codes on 17 line items, resulting in overpayments of \$46,935. For example, 1 provider billed Medicare on 1 line item for 500 units of epoetin alfa (HCPCS code J0885). However, the provider should have billed for 500 units of darbopoetin alfa (HCPCS code J0881), the drug actually administered. As a result of this error, the Medicare contractor paid the provider \$3,760 when it should have paid \$1,104, an overpayment of \$2,656.

In total, the Medicare contractor paid five providers \$62,675 when it should have paid \$15,740, an overpayment of \$46,935.

Combination of Incorrect Number of Units of Service and Incorrect Healthcare Common Procedure Coding System Codes

Providers reported a combination of incorrect units of service and incorrect HCPCS codes on six line items. These errors resulted in overpayments of \$12,841. For example, a provider billed Medicare on 1 line item for 8 units of service for leuprolide acetate injection (HCPCS code J1950, 3.75 milligrams per unit), which is indicated for treatment of endometriosis, uterine leiomyoma, and malignant neoplasms of the breast. However, the provider should have billed Medicare for 4 units of service for leuprolide acetate injection (HCPCS code J9217, 7.5 milligrams per unit), which is indicated for the treatment of prostate cancer and was the dose actually administered. As a result of this error, the Medicare contractor paid the provider \$3,817 when it should have paid \$701, an overpayment of \$3,116.

In total, the Medicare contractor paid five providers \$19,289 when it should have paid \$6,448, an overpayment of \$12,841.

Billed Separately for Packaged Services

One provider billed Medicare on one line item for zoledronic acid (HCPCS code J3487) rather than ondansetron hydrochloride (HCPCS code J2405) the drug actually administered. This error resulted in an overpayment of \$5,921. Ondansetron hydrochloride is a packaged service. Medicare pays for outpatient drugs that are considered primary procedures but does not pay separately for outpatient drugs when their payment is packaged in the payment of a primary procedure.

In total, the Medicare contractor paid the provider \$5,921 when it should have paid \$0, an overpayment of \$5,921.

Noncovered Use of a Drug

A provider billed Medicare for the noncovered use of an outpatient drug on one line item, resulting in an overpayment of \$2,892. The provider administered 22.5 milligrams (6 units) of leuprolide acetate injection (HCPCS code J1950, 3.75 milligrams per unit), which is indicated for the treatment of endometriosis and uterine leiomyomas and malignant neoplasms of the breast. However, the beneficiary's diagnosis was not covered under the Medicare contractor's

local coverage determination. Medicare does not pay for drugs administered for services not considered reasonable and necessary. As a result of this error, the Medicare contractor paid the provider \$2,892 when it should have paid \$0, an overpayment of \$2,892.

UNDERPAYMENTS TO PROVIDERS THAT BILLED INCORRECTLY

Two providers billed Medicare on five line items for outpatient drug services that included either incorrect units of service, or a combination of incorrect units of service and incorrect HCPCS codes, resulting in underpayments of \$5,009. We identified these underpayments to the providers so that they could decide whether to submit adjustment claims for the underpayment amounts.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The providers attributed the incorrect billings to clerical errors and to provider billing systems that could not prevent or detect the incorrect billing of outpatient drug services. These billing system errors included chargemaster¹¹ errors and other system errors.

The Medicare contractor overpaid these providers because neither the CWF nor the FISS had sufficient edits in place to prevent or detect the overpayments. In effect, CMS relied on providers to notify the Medicare contractor of incorrect payments and on beneficiaries to review their *Medicare Summary Notice* and disclose any overpayments.¹²

Other required edits in the CWF and FISS did not detect the errors that we found because the edits suspended only those payments that exceeded a payment amount threshold but did not flag payments that exceeded maximum billing units. Medically unlikely edits, which deny line items for excessive units of service billed, do not exist for all HCPCS codes.

RECOMMENDATIONS

We recommend that NGS:

- recover the \$1,318,065 in identified overpayments,
- verify the payment of \$5,009 in identified underpayments, and
- use the results of this audit in its ongoing provider education activities.

¹¹ A provider's chargemaster is an automatic data processing system that providers use as part of their billing systems. The chargemaster contains data on every chargeable item or procedure that the provider offers, including a factor that converts a drug's dosage to the number of units to bill.

¹² The Medicare contractor sends a *Medicare Summary Notice*—an explanation of benefits—to the beneficiary after the provider files a claim for services. The notice explains the services billed, the approved amount, the Medicare payment, and the amount due from the beneficiary.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS

In written comments on our draft report, NGS stated that it would review the line items paid in error to adjust and recover any overpayments and verify underpayments accordingly. NGS said that it had recently conducted educational sessions with providers, instructing them on the proper billing of drugs and biologicals, and that it would enhance its educational materials as needed based on the results of this review. NGS's comments are included in their entirety as Appendix D.

**APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS:
JURISDICTION 14**

Report Title	Report Number	Date Issued
<i>Medicare Contractors' Payments in Jurisdiction 14 for Full Vials of Herceptin Were Often Incorrect</i>	A-01-11-00539	08/17/2012
<i>Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by NHIC, Corp., in Jurisdiction 14 for the Period January 1, 2006, Through June 30, 2009</i>	A-01-10-00502	12/21/2011
<i>Review of High-Dollar Payments for Medicare Part B Claims Processed by First Coast Service Options, Inc., for Calendar Years 2004-2006</i>	A-01-09-00513	10/13/2009
<i>Review of High-Dollar Payments for Medicare Part B Claims Processed by NHIC, Corp., for Calendar Years 2004-2006</i>	A-01-08-00514	02/9/2009
<i>Review of High-Dollar Payments for Medicare Outpatient Claims Processed by National Government Services, Inc., of New Hampshire and Vermont for Calendar Years 2004 Through 2006</i>	A-01-08-00522	10/17/2008
<i>Review of High-Dollar Payments for Medicare Outpatient Claims Processed by National Government Services, Inc., of Massachusetts for Calendar Years 2004 and 2005</i>	A-01-08-00521	10/17/2008
<i>Review of High-Dollar Payments for Medicare Outpatient Claims Processed by Pinnacle Business Solutions, Inc., for Calendar Years 2004 Through 2006</i>	A-01-08-00512	08/18/2008
<i>Review of High-Dollar Payments for Rhode Island Medicare Part B Claims Processed by Pinnacle Business Solutions, Inc., for Calendar Year 2004 Through 2006</i>	A-01-08-00504	07/14/2008

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractor for Jurisdiction 14 paid providers \$767.7 million for 1.2 million line items for selected outpatient drugs. We reviewed 779 line items, totaling \$7,101,839 million that the Medicare contractor paid to 60 providers.¹³ We did not review entire claims; rather, we reviewed specific line items within the claims. These line items included selected outpatient drugs with payment status indicator code “G” or “K.” “G” identifies drugs and biologicals paid using the OPSS that include a pass-through payment.¹⁴ “K” identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPSS without a pass-through payment.

We did not review the overall internal control structure of the Medicare contractor or the providers because our objective did not require us to do so. Rather, we limited our review to (1) the Medicare contractor’s internal controls to prevent the overpayment of Medicare claims associated with the selected outpatient drugs and (2) providers’ internal controls to prevent incorrect billing for outpatient drugs. Our review allowed 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 our audit from December 2012 through March 2014 and performed fieldwork by contacting NHIC in Chico, California, and 60 providers that received the selected Medicare payments during our audit period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS’s National Claims History file to identify outpatient line items for selected outpatient drugs (HCPCS codes with status indicator code “G” or “K”) for which Medicare payments were made during our audit period;
- used computer matching, data mining, and other analytical techniques to identify payments for outpatient drugs 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 because these line items were at risk for noncompliance with Medicare

¹³ The audit included a small number of line items for services provided before July 1, 2009, that were paid during our audit period and a small number of line items for services provided before June 30, 2012, that were paid after that date.

¹⁴ Pass-through payments are additional payments made for a short time to cover the cost for certain innovative medical devices, drugs, and biologicals that exceed Medicare’s OPSS payment amount.

billing requirements;

- selected 779 line items at risk of error, totaling \$7,101,839 that the Medicare contractor paid to 60 providers;
- requested that 60 providers furnish documentation to support the services billed, including:
 - the physician's order supporting the outpatient drug and amount ordered,
 - the drug administration record supporting that the outpatient drug was administered in the amount ordered, and
 - relevant financial or administrative notes related to the Medicare claim;
- reviewed the documentation provided to determine whether:
 - the billed information for the selected line items was correct and, if not, why the line item was incorrect,
 - the providers identified and adjusted the claim items before our review, and
 - the claimed units of the outpatient drug were based on dosing instructions provided with the packaging and any limitation on use (such as single-use or multiuse);
- calculated overpayment amounts, including adjustments to the claim due to changes in the allocation of the coinsurance amounts, in accordance with Federal requirements and Medicare payment procedures or used the amount determined by the Medicare contractor; and
- discussed the results of our review with the Medicare contractor.

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: FEDERAL REQUIREMENTS RELATED TO MEDICARE CONTRACTOR PAYMENT AND PROVIDER BILLING FOR SELECTED OUTPATIENT DRUGS

FEDERAL LAW AND REGULATIONS

The Act, section 1833(e), states: “No payment shall be made to any provider of services ... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider ... for the period with respect to which the amounts are being paid”

Further, the Act, sections 1861(s)(2) and 1861(t), define the terms “medical and other health services” and “drugs and biologicals,” respectively. These sections identify those drug and biological services that are covered services under the Medicare Part B program and also identify any noncovered or excluded drug and biological services.

Federal regulations provide the methodology that Medicare uses to calculate payment for drugs and biologicals, including the calculation of the coinsurance payment, which is limited to the inpatient deductible amount for each year (42 CFR § 419.41).

CENTERS FOR MEDICARE & MEDICAID SERVICES GUIDANCE

CMS Pub. No. 100-06, *Medicare Financial Management Manual*, chapter 7, section 10, states: “[CMS] contractors shall administer the Medicare program efficiently and economically to achieve the program objectives.” Further, the Federal Managers’ Financial Integrity Act of 1982 (FMFIA) “establishes internal control requirements that shall be met by CMS. For CMS to meet the requirements of FMFIA, CMS contractors shall demonstrate that they comply with the FMFIA guidelines.” Consequently, “the contractor shall establish and maintain efficient and effective internal controls to perform the requirements of the contract”

The Manual, chapter 1, section 80.3.2.2, states: “In order to be processed correctly and promptly, a bill must be completed accurately.”

The Manual, chapter 23, section 20.3, states: “providers must use HCPCS codes ... for most outpatient services.”

The Manual, chapter 4, section 20.4, states: “The definition of service units ... is the number of times the service or procedure [HCPCS code] being reported was performed.”

The Manual, chapter 17, section 90.2.A, states: “It is ... of great importance that hospitals billing for these products [outpatient drugs] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.”

The Manual, chapter 17, section 10, states: “If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided.”

The Manual, chapter 17, section 70, states that, if the provider is billing for an outpatient drug for which a “HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 [milligrams], and 200 [milligrams] are provided, units are shown as 4”

The Manual, chapter 17, section 40, states:

When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

The section further notes: “Multi-use vials are not subject to payment for discarded amounts of drug or biological.”

The Manual, chapter 1, section 140.1, states that Medicare contractors must: “edit for outpatient and inpatient Part B claims that meet or exceed a reimbursement amount of \$50,000.” The section further notes that Medicare contractors must: “suspend those claims receiving the threshold edit for development and contact providers to resolve billing errors.” If the Medicare contractor determines that the reimbursement is excessive and corrections are required, the claim must be returned to the provider. If the billing is accurate and the reimbursement is not excessive, the Medicare contractors will override the edit and process the claim for payment.

CMS Pub. No. 100-02, *Medicare Benefit Policy Manual* (chapter 15, section 50.4.2), states:

An unlabeled use of a drug is a use that is not included as an indication on the drug’s label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice These decisions are made by the contractor on a case-by-case basis.



8115 Knue Road
Indianapolis, IN 46250
www.NGSMedicare.com

MEDICARE

May 23, 2014

Mr. David Lamir
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region I
JFK Federal Building
15 New Sudbury Street, Room 2425
Boston, MA 02203

Report Number: A-01-13-00504

Dear Mr. Lamir,

The following represents our response to the comments made in your report dated April 23, 2014:

Recommendation 1 - Recover the \$1,318,065 in identified overpayments

The claims will be reviewed for adjustment and worked accordingly by our Claims unit. As the claims are adjusted, the Overpayment Recovery unit will track the recoupments with the accompanying adjusted claim DCN. Due to the large number of claims involved, our Performance Analysis team will also be engaged to assist in obtaining the recouped amount.

Recommendation 2 - Verify the payment of \$5,009 in identified underpayments

To date we have not started our review of the claims listed with this audit. Currently we have other OIG audits that are in progress and we will begin review of this audit as the earlier ones are resolved.

Recommendation 3 - Use the results of this audit in its ongoing provider education activities

Provider Outreach and Education (POE) has recently completed educational sessions on billing Drugs and Biologicals for hospitals. Based on the results of this OIG audit, POE will enhance its current educational material as needed to encompass these audit findings and will schedule repeat sessions.

Hospitals identified through this audit will receive specific invitations to these upcoming educational sessions, which will continue to be offered to the full provider community within JK. The program will



address the full scope of issues associated with correct drug-billing processes, with a focus on the problems identified by the OIG:

- Reporting units of service accurately when billing for drugs
- Supporting documentation necessary to describe the service fully
- HCPCS coding for drug services
- Covered versus non-covered drug usage and administration

Sincerely yours,

/s/ Scott Kimbell

Scott Kimbell,
Jurisdiction K Program Manager