Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE MEDICARE CONTRACTOR FOR JURISDICTION 13 OVERPAID PROVIDERS FOR SELECTED OUTPATIENT DRUGS

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Office of Inspector General

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EXECUTIVE SUMMARY

The Medicare contractor for Jurisdiction 13 overpaid providers by $2.7 million for selected outpatient drugs over 3 years. One provider identified additional overpayments of $27,000 as a result of our review.

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 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 13 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), National Government Services, Inc. (NGS), was the Medicare contractor for Jurisdiction 13 (Connecticut and New York). For the two States, the Medicare contractor paid providers $900 million for 1.6 million line items for selected outpatient drugs. We reviewed 1,138 line items with total payments of $9.7 million that were at risk for overpayment.

WHAT WE FOUND

Payments that the Medicare contractor for Jurisdiction 13 made to providers for 667 of the 1,138 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $2,697,072 and underpayments of $1,694 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers had refunded $126,987 of overpayments for another 30 line items. The remaining 441 line items were correct.

For the 665 incorrect line items with overpayments of $2,697,072 that had not been refunded, providers reported incorrect units of service, did not provide supporting documentation, reported a combination of incorrect units of service and incorrect HCPCS codes, used incorrect HCPCS codes, and billed for noncovered use of a drug. For the two incorrect line items with underpayments of $1,694 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims. One provider also identified 13 additional line items that we did not review that resulted in overpayments of $26,902.

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 the overpayments.

WHAT WE RECOMMEND

We recommend that NGS:

- recover the $2,697,072 in identified overpayments,
- verify the payment of $1,694 in identified underpayments,
- verify the recovery of $26,902 in additional provider-identified overpayments, and
- use the results of this audit in its ongoing provider education activities.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS AND OUR RESPONSE

In written comments on our draft report, NGS agreed with our first, second, and fourth recommendations and described actions that it planned to take to address these recommendations. Regarding our third recommendation, NGS asked us for specific claims information and stated that it will research the associated claims upon receipt of this information.

We provided NGS with the claims information requested to verify the recovery of these overpayments.

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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 contractor[1]) 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 13.)

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 13 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 and effective internal controls.[4] These controls, including those over automatic data processing

[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.

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

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

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[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 the Medicare contractors.

[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.

National Government Services, Inc.

During our audit period (July 1, 2009, through June 30, 2012), National Government Services, Inc. (NGS), was the Medicare contractor for Jurisdiction 13 (Connecticut and New York).

HOW WE CONDUCTED THIS REVIEW

During our audit period, the Medicare contractor for Jurisdiction 13 paid providers $900 million for 1.6 million line items for selected outpatient drugs. We reviewed 1,138 line items[8] with total payments of $9.7 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 13 made to providers for 667 of the 1,138 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $2,697,072 and underpayments of $1,694 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers had refunded $126,987 of overpayments for another 30 line items. The remaining 441 line items were correct.

For the 665 incorrect line items with overpayments of $2,697,072 that had not been refunded, providers:

- reported incorrect units of service on 406 line items, resulting in overpayments of $1,886,008;

- did not provide supporting documentation for 56 line items, resulting in overpayments of $485,707;

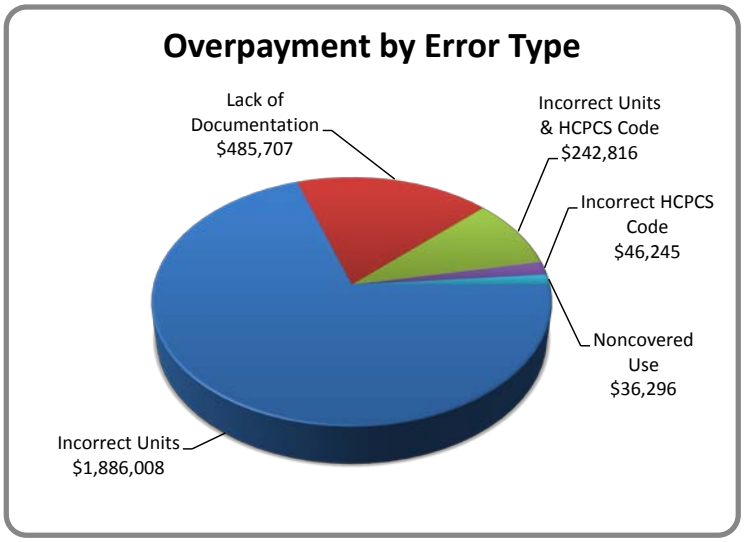
[8] In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

[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.

- reported a combination of incorrect units of service and incorrect HCPCS codes on 182 line items, resulting in overpayments of $242,816;

- used incorrect HCPCS codes on 3 line items, resulting in overpayments of $46,245; and

- billed for the noncovered use of a drug on 18 line items, resulting in overpayments of $36,296.



For the two incorrect line items with underpayments of $1,694 that had not been adjusted, we notified the providers of the underpayments so that they could decide whether to submit adjustment claims. One provider also identified 13 additional lines items that we did not review that had overpayments of $26,902.

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 406 line items, resulting in overpayments of $1,886,008. The incorrect units of service involved 53 different outpatient drugs. The following are examples:

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

- One provider administered 250 micrograms (10 units) of palonosetron hydrochloride to a patient and billed for 100 units of service (2,500 micrograms). On 91 separate occasions, this error occurred. As a result, the Medicare contractor paid the provider $131,847 for the 91 line items when it should have paid $13,616, an overpayment of $118,231.

- Another provider administered 37.8 to 108 milligrams of adenosine to several patients and billed for 13 to 36 units of service (390 to 1,080 milligrams). Using the HCPCS description of adenosine (injection, adenosine for diagnostic use, 30 milligrams), the correct number of units to bill for 37.8 and 108 milligrams were 2 and 4, respectively.[11] As a result of these errors, the Medicare contractor paid the provider $61,012 when it should have paid $7,300, an overpayment of $53,712.

In total, the Medicare contractor paid 65 providers $2,319,440 when it should have paid $433,432, an overpayment of $1,886,008.

Lack of Supporting Documentation

Twenty-five providers billed Medicare on 56 line items for which the providers did not provide any documentation to support that a patient had received the drug service billed. In total, the Medicare contractor paid the providers $485,707 when it should have paid $0, an overpayment of $485,707.

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 182 line items. These errors resulted in overpayments of $242,816. For example, 9 providers billed Medicare on 21 line items for 1 to 23 units of service for leuprolide acetate injections (HCPCS code J1950, 3.75 milligrams per unit), which is indicated for the treatment of endometriosis, uterine leiomyoma, and malignant neoplasm of the breast. However, the providers should have billed Medicare for 1 to 4 units of service for leuprolide acetate injections (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 these errors, the Medicare contractor paid the providers $62,431 when it should have paid $11,549, an overpayment of $50,882.

In total, the Medicare contractor paid 13 providers $282,283 when it should have paid $39,467, an overpayment of $242,816.

Incorrect Healthcare Common Procedure Coding System Codes

Providers used incorrect HCPCS codes on three line items, resulting in overpayments of $46,245. For example, one provider billed Medicare on 1 line item for 17 units of pegaspargase, injection (HCPCS code J9266). However, the provider should have billed for 17 units of

[11] If the drug dose used in the care of a patient is not a multiple of the dose specified in the HCPCS narrative description, the provider rounds to the next highest unit (the Manual, chapter 17, § 10).

irinotecan, injection (HCPCS code J9206), the drug actually administered. As a result of this error, the Medicare contractor paid the provider $40,417 when it should have paid $64, an overpayment of $40,353.

In total, the Medicare contractor paid three providers $49,363 when it should have paid $3,118, an overpayment of $46,245.

Noncovered Use of a Drug

Providers billed Medicare for the noncovered use of an outpatient drug on 18 line items. These errors resulted in overpayments of $36,296. For example, one provider billed Medicare for the noncovered use of the drug reteplase (HCPCS code J2993, 18.1 milligrams per unit). Reteplase is approved by the Food and Drug Administration (FDA) to treat cardiac conditions using a single-use dose. However, the provider split a single dose into multiple doses and used them as a thrombolytic agent to clean dialysis patient catheters.[12] The provider then billed Medicare for one full single-use dose of reteplase.

Providers must identify on their claims that the billed service was for the unlabeled use of a drug.[13] However, the provider submitted these line items as if the drug had been administered for its covered use. Consequently, the Medicare contractor did not know that the 18 line items were for a small amount of the covered dose and were given for an unlabeled use that required a case-by-case payment determination.

In total, the Medicare contractor paid three providers $36,296 when it should have paid $0, an overpayment of $36,296.

UNDERPAYMENTS TO PROVIDERS THAT BILLED INCORRECTLY

Two providers billed Medicare on two line items for outpatient drug services that included incorrect units of service or a combination of incorrect units of service and incorrect HCPCS codes, resulting in underpayments of $1,694. We identified these underpayments and notified the providers so that they could decide whether to submit adjustment claims for the underpayment amounts.

ADDITIONAL OVERPAYMENTS IDENTIFIED BY PROVIDERS

One provider identified 13 additional line items that we did not review that had overpayments of $26,902. The provider identified these overpayments as a result of our review. These overpayments were either outside our audit period or were for quantities that we did not select for review.

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[12] The Manual, chapter 8, section 60.2.1.1, identifies thrombolytics as drugs "used to declot central venous catheters" during the treatment of a patient's renal condition. During the audit period, thrombolytics were separately billable drugs.

[13] Providers should indicate the unlabeled use of a drug or biological (*Medicare Benefit Policy Manual*, CMS Pub. No. 100-02, chapter 15, § 50.4.2). Providers use the remarks section of the claim for this purpose.

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 systems errors included chargemaster[14] 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.[15]

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 $2,697,072 in identified overpayments,
- verify the payment of $1,694 in identified underpayments,
- verify the recovery of $26,902 in additional provider-identified overpayments, and
- use the results of this audit in its ongoing provider education activities.

NATIONAL GOVERNMENT SERVICES, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NGS agreed with our first, second, and fourth recommendations and described actions that it planned to take to address these recommendations. Regarding our third recommendation, NGS asked us for specific claims information and stated that it will research the associated claims upon receipt of this information. NGS' comments are included in their entirety as Appendix D.

We provided NGS with the claims information requested to verify the recovery of these overpayments.

[14] 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 (1) a factor that converts a drug's dosage to the number of units to bill and (2) whether to charge for waste.

[15] 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.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS: JURISDICTION 13

Report Title	Report Number	Date Issued
The Medicare Contractor's Payments to Providers in Jurisdiction 13 for Full Vials of Herceptin Were Often Incorrect	A-02-12-01003	05/22/2013
Review of Medicare Outpatient Billing for Selected Drugs at Catskill Regional Medical Center	A-09-12-02007	03/16/2012
Review of Selected Medicare Payments Exceeding Charges for Outpatient Services Processed by National Government Services in Jurisdiction 13 for Period January 1, 2006, Through June 30, 2009	A-02-10-01008	10/03/2011
Review of High-Dollar Payments for Medicare Part B Claims Processed by First Coast Service Options, Inc., for Calendar Years 2004-2006	A-01-09-00513	10/13/2009
Review of High-Dollar Payments for Medicare Part B Outpatient Claims Processed by National Government Services for the Period January 1, 2003, Through December 31, 2005	A-02-07-01039	09/30/2008
Review of High-Dollar Payments for Medicare Part B Claims Processed by National Government Services for New York Providers for the Period January 1, 2003, Through December 31, 2005	A-02-07-01043	04/22/2008
Review of High-Dollar Payments for Medicare Part B Outpatient Claims Processed by HealthNow New York, Inc., for the Period January 1, 2003, Through December 31, 2005	A-02-07-01042	02/01/2008
Review of High-Dollar Payments for Medicare Part B Claims Processed by Group Health Incorporated for the Period January 1, 2003, Through December 31, 2005	A-02-07-01045	01/04/2008

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractor paid providers in Jurisdiction 13 $900 million for 1.6 million line items for selected outpatient drugs. We reviewed 1,138 line items, totaling $9.7 million that the Medicare contractor paid to 101 providers. 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 OPPS that include a pass-through payment.[16] "K" identifies drugs, biologicals, therapeutic radiopharmaceuticals, brachytherapy sources of radiation, blood, and blood products paid using the OPPS 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 October 2012 through December 2013 and performed fieldwork by contacting NGS in South Portland, Maine, and 101 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 billing requirements;
- selected 1,138 line items at risk of error, totaling $9,722,704, that the Medicare contractor paid to 101 providers;

[16] 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 schedule.

- requested that 101 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;
- discussed the results of our review with providers and the Medicare contractor; and
- summarized the results of overpayments for line items that were not included in our review but were identified by the provider as a result of our audit.

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.

APPENDIX D: NATIONAL GOVERNMENT SERVICES, INC., COMMENTS

MEDICARE

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April 25, 2014

Mr. James Edert
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Report Number: A-02-13-01011

Dear Mr. Edert,

The following represents our response to the comments made in your report dated March 11, 2014:

Recommendation 1 - Recover the $2,697,072 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 $1,694 in identified underpayments
To date we have not started our review of the claims listed with this audit. Currently we have 13 other OIG audits that are in progress and we will begin review of this audit as the earlier ones are resolved.

Recommendation 3 - Verify the recovery of $26,902 in additional provider-identified overpayments
We are unable to verify this information without knowing the specific claims involved, and we are unable to validate which claims on the attached spreadsheet (if any) make up this $26,902 amount. Please provide the claim specific information and NGS will research accordingly.

Recommendation 4 - 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 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