Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE MEDICARE CONTRACTOR FOR JURISDICTION 12 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 12 overpaid providers by $3.7 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 12 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), Novitas Solutions, Inc. (Novitas), formerly Highmark Medicare Services, was the Medicare contractor for Jurisdiction 12 (Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania). However, we excluded from our review all but one Maryland provider because the excluded providers were paid under a waiver that differed from the standard Medicare outpatient payment system.

During the audit period, the Medicare contractor paid providers $997 million for 1.8 million line items for selected outpatient drugs. We reviewed 1,254 line items with total payments of $13.2 million that were at risk for overpayment.

WHAT WE FOUND

Payments that the Medicare contractor for Jurisdiction 12 made to providers for 607 of the 1,254 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $3,717,681 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers refunded $569,572 of overpayments for another 59 line items. The remaining 588 line items were correct.

For the 607 incorrect line items with overpayments of $3,717,681 that had not been refunded, providers reported incorrect units of service, did not provide supporting documentation, billed separately for outpatient drugs for which payment was packaged with the primary service, reported a combination of incorrect units of service and incorrect HCPCS codes, billed for noncovered use of a drug, and used incorrect HCPCS codes.

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 Novitas:

- recover the $3,717,681 in identified overpayments and
- use the results of this audit in its ongoing provider education activities.

NOVITAS SOLUTIONS, INC., COMMENTS

In written comments on our draft report, Novitas concurred with our recommendations and described corrective actions it had taken or planned to take to address them.

TABLE OF CONTENTS

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 12.)

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 12 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 Medicare administrative contractor.

[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 automated 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.

Novitas Solutions, Inc.

During our audit period (July 1, 2009, through June 30, 2012), Novitas Solutions, Inc. (Novitas), was the Medicare contractor for Jurisdiction 12 (Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania).[8] However, we excluded from our review all but one Maryland provider because the excluded providers were paid under a waiver that differed from the standard Medicare outpatient payment system.

HOW WE CONDUCTED THIS REVIEW

During our audit period, the Medicare contractor for Jurisdiction 12 paid providers $997 million for 1.8 million line items for selected outpatient drugs. We reviewed 1,254 line items[9] with total payments of $13.2 million that were at risk for overpayment. These line items were for outpatient drugs with payment status indicator code "G" or "K."[10] 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 12 made to providers for 607 of the 1,254 line items for outpatient drugs we reviewed were not correct. These incorrect payments resulted in overpayments of $3,717,681 that the providers had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, providers refunded $569,572 of overpayments for another 59 line items. The remaining 588 line items were correct.

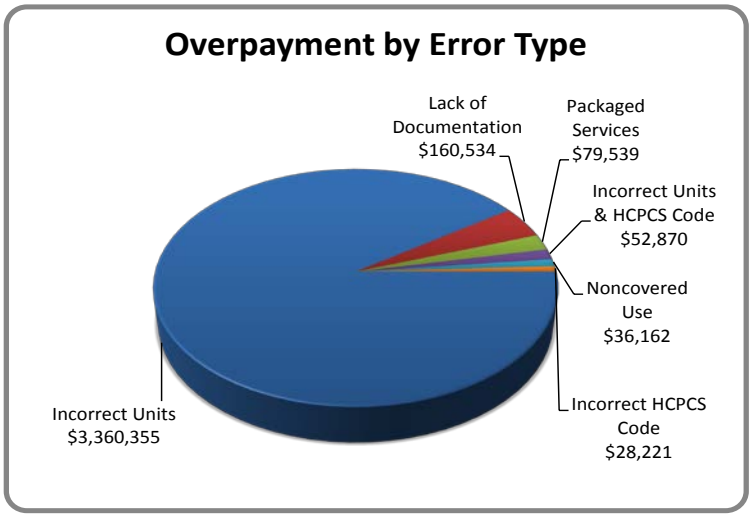
[8] In January 2012, Diversified Service Options, Inc., acquired Highmark Medicare Services, which was renamed Novitas.

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

[10] "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 under the OPPS without a pass-through payment.

For the 607 incorrect line items with overpayments of $3,717,681 that had not been refunded, providers:

- reported incorrect units of service on 503 line items, resulting in overpayments of $3,360,355;
- did not provide supporting documentation for 28 line items, resulting in overpayments of $160,534;
- billed separately for outpatient drugs for which payment was packaged with the primary service on 25 line items, resulting in overpayments of $79,539;



- reported a combination of incorrect units of service and incorrect HCPCS codes on 26 line items, resulting in overpayments of $52,870;
- billed for the noncovered use of a drug on 20 line items, resulting in overpayments of $36,162; and
- used incorrect HCPCS codes on 5 line items, resulting in overpayments of $28,221.

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.[11]

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

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

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 503 line items, resulting in overpayments of $3,360,355. The incorrect units of service involved 70 different outpatient drugs. The following are examples:

- One provider administered 1,800 milligrams of gemicitabine hydrochloride to a patient and billed for 220 units of service. Using the HCPCS description (injection, gemicitabine hydrochloride, 200 milligrams), the correct number of units to bill for 1,800 milligrams was 9. On 17 separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider $439,009 when it should have paid $14,755, an overpayment of $424,254.

- Another provider administered 700 milligrams of rituximab hydrochloride to a patient and billed for 42 units of service. Using the HCPCS description (injection, rituximab hydrochloride, 100 milligrams), the correct number of units to bill for 700 milligrams was 7. On 43 separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider $465,813 when it should have paid $132,231, an overpayment of $333,582.

In total, the Medicare contractor paid 107 providers $4,424,130 when it should have paid $1,063,775, an overpayment of $3,360,355.

Lack of Supporting Documentation

Fourteen providers billed Medicare for 28 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 $160,534 in overpayments that they received.

Billed Separately for Packaged Services

For selected outpatient drugs that have multiple HCPCS codes, providers billed Medicare on 25 line items using the HCPCS code that Medicare pays separately instead of the HCPCS code that Medicare does not pay separately, resulting in overpayments of $79,539. These line items involved two different packaged outpatient drugs.

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. Medicare has different HCPCS codes for similar drugs to distinguish which are paid separately and which are not paid separately.

For example, six providers billed Medicare for the lipid formulation of doxorubicin hydrochloride (HCPCS code J9001) rather than the nonlipid formulation of doxorubicin hydrochloride (HCPCS code J9000), the drug actually administered. During the dates of service

that each provider administered this drug, Medicare packaged the nonlipid formulation in the payment for related services and did not provide for separate reimbursement under the OPPS. On 24 separate occasions, this error occurred; as a result, the Medicare contractor paid the providers $76,169 when it should have paid $0, an overpayment of $76,169.

In total, the Medicare contractor paid seven providers $79,539 for packaged drugs when it should have paid $0, an overpayment of $79,539.

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 26 line items. These errors resulted in overpayments of $52,870.

For example, five providers billed Medicare on 19 line items for 6 to 8 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 3 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 $45,308 when it should have paid $8,855, an overpayment of $36,453.

In total, the Medicare contractor paid 9 providers $65,353 when it should have paid $12,483, an overpayment of $52,870.

Noncovered Use of a Drug

Providers billed Medicare for the noncovered use of an outpatient drug on 20 line items. These errors resulted in overpayments of $36,162. Six providers 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, each provider split a single dose into multiple doses and used them as a thrombolytic agent to clean dialysis patient catheters.[12] The providers then billed Medicare for one or more full single-use doses of reteplase for each multiple dose administered.

Providers must identify on their claims that the billed service was for the unlabeled use of a drug.[13] However, each provider submitted these line items as if the single-use dose had been administered for the covered use. Consequently, the Medicare contractor did not know that the 20 line items were for a small amount of the covered dose, given for an unlabeled use that required a case-by-case payment determination.

[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, section 50.4.2). Providers use the remarks section of the claim for this purpose.

In total, the Medicare contractor paid the six providers a total of $36,162 when it should have paid $0, an overpayment of $36,162.

Incorrect Healthcare Common Procedure Coding System Codes

Providers used incorrect HCPCS codes on five line items, resulting in overpayments of $28,221. For example, 1 provider billed Medicare on 1 line item for 300 units of service unrelated to the drug administered. The provider incorrectly billed HCPCS code J9293 (mitoxantrone hydrochloride). The provider should have billed for 300 units of HCPCS code J9263 (oxaliplatin injection), the drug actually administered. As a result of this error, the Medicare contractor paid the provider $18,862 when it should have paid $2,263, an overpayment of $16,599.

In total, the Medicare contractor paid the providers $32,370 when it should have paid $4,149, an overpayment of $28,221.

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 Novitas:

- recover the $3,717,681 in identified overpayments and
- use the results of this audit in its ongoing provider education activities.

[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.

NOVITAS SOLUTIONS, INC., COMMENTS

In written comments on our draft report, Novitas concurred with our recommendations and described corrective actions it had taken or planned to take to address them. Novitas' comments are included in their entirety as Appendix D.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS MEDICARE OVERPAYMENTS IN JURISDICTION 12

Report Title	Report Number	Date Issued
The Medicare Contractor's Payments to Maryland Providers in Jurisdiction 12 for Full Vials of Herceptin Were Sometimes Incorrect	A-03-12-00014	08/16/2012
Medicare Contractor's Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect	A-03-11-00014	07/31/2012
Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by Highmark Medicare Services in Jurisdiction 12 for the Period January 1, 2006, Through June 30, 2009	A-03-10-00004	08/16/2011
Review of Medicare Payments Exceeding Charges by $500 to $1,000 for Outpatient Services Processed by Highmark Medicare Services in Jurisdiction 12 for the Period January 1, 2006, Through June 30, 2009	A-03-11-00004	08/12/2011
Review of High-Dollar Payments for Maryland and District of Columbia Outpatient Claims Processed by CareFirst of Maryland for the Period January 1, 2003, Through September 30, 2005	A-03-07-00012	08/26/2009
Review of High-Dollar Payments for Pennsylvania Outpatient Claims Processed by Highmark Medicare Services for Calendar Years 2003–2005	A-03-07-00011	08/14/2009
Review of High-Dollar Payments for Pennsylvania Medicare Part B Claims Processed by Highmark Medicare Services for the period January 1, 2003, Through December 31, 2005	A-03-07-00016	02/12/2009
Review of High-Dollar Payments for Maryland and District of Columbia Medicare Hospital Outpatient Claims Processed by Highmark Medicare Services for the Period October 1 Through December 31, 2005	A-03-07-00014	11/12/2008

Report Title	Report Number	Date Issued
Review of High-Dollar Payments for Maryland Medicare Part B Claims Processed by TrailBlazer Health Enterprises for the Period January 1, 2003, Through December 31, 2005	A-03-07-00017	08/20/2008
Review of High-Dollar Payments for Delaware Medicare Part B Claims Processed by TrailBlazer Health Enterprises for the Period January 1, 2003, Through December 31, 2005	A-03-07-00018	06/19/2008
Review of High-Dollar Payments for District of Columbia Medicare Part B Claims Processed by TrailBlazer Health Enterprises for the Period January 1, 2003, Through December 31, 2005	A-03-07-00019	06/19/2008

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period (July 1, 2009, through June 30, 2012), the Medicare contractor for Jurisdiction 12 paid providers $997 million for 1.8 million line items for selected outpatient drugs. We reviewed 1,254 line items, totaling $13,190,919 that the Medicare contractor paid to 128 providers.[16] 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.[17] "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 March 2013 and performed fieldwork by contacting Novitas, in Camp Hill, Pennsylvania, and 128 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;

[16] 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.

[17] 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.

- selected 1,254 line items at risk of error, totaling $13,190,919, that the Medicare contractor paid to 128 providers;

- requested that the 128 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 prior to 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 claims 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 providers and 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 mg [milligrams], and 200 mg [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 submit 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: NOVITAS SOLUTIONS, INC., COMMENTS

Sandy Coston
CEO
Novitas Solutions, Inc.
Sandy Coston@dsocorp.com

January 9, 2014

Mr. John Carlucci
Office of Audit Services
Office of Inspector General

Reference: A-03-13-00012

Dear Mr. Carlucci:

We received the U.S. Department of Health & Human Services, Office of Inspector General (OIG) draft report entitled, *"The Medicare Contractor for Jurisdiction 12 Overpaid Providers for Selected Outpatient Drugs"* and reviewed the findings and recommendations. We appreciate the opportunity to review and provide comments prior to release of the final report.

In the draft report, you outlined two recommendations that we have addressed as follows:

Recommendation:
Recover the $3,717,681 in identified overpayments.

Response:
Upon receipt of the specific claim information, we will pursue recovery of the overpaid amounts.

Recommendation:
Use the results of this audit in its ongoing provider education activities.

Response:
Claims Processing will work with Provider Education to create reminders to providers regarding the correct billing of Outpatient drugs.

Again, we appreciate the opportunity to review and provide comments prior to release of the final report. If you have any questions regarding our responses, please contact Mr. Gregory W. England at (904) 791-8364.

Sincerely,

/Sandy Coston/

cc: Gregory W. England

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