Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE MEDICARE CONTRACTOR'S PAYMENTS TO MARYLAND PROVIDERS IN JURISDICTION 12 FOR FULL VIALS OF HERCEPTIN WERE SOMETIMES INCORRECT

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

Stephen Virbitsky
Regional Inspector General

August 2012
A-03-12-00014

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

BACKGROUND

Herceptin (trastuzumab) is a Medicare-covered biological drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial containing 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. A vial of Herceptin reconstituted with bacteriostatic water is stable for 28 days when stored properly. An entire multiuse vial of Herceptin represents 44 units for billing Medicare. However, for multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded amounts of the drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. This audit is part of a nationwide review of the drug Herceptin. The pilot of these reviews found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

Title XVIII of the Social Security Act established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to process and pay Medicare claims submitted for outpatient services. The Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims. The CWF can detect certain improper payments during prepayment validation.

Providers should use the appropriate Healthcare Common Procedure Coding System (HCPCS) code for the drug administered and report units of service in multiples of the units shown in the HCPCS narrative description.

This report includes the results of our review for Maryland providers in Jurisdiction 12. We presented the results of our review of payments for Herceptin made to providers in the remaining four States in Jurisdiction 12 (Delaware, the District of Columbia, New Jersey, and Pennsylvania) in a separate report (*Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect*, A-03-11-00014).

During our audit period (January 2008 through December 2010), Novitas Solutions, Inc. (Novitas), formerly Highmark Medicare Services, was the Medicare contractor for three of the five States in Jurisdiction 12 (the District of Columbia, Maryland, and Pennsylvania). In December 2008, Novitas assumed full responsibility for the Jurisdiction 12 workload, including claims paid for Delaware and New Jersey.

For Maryland, the Medicare contractor processed 4,465 line items totaling approximately $9.8 million for Herceptin. Of these 4,465 line items, 1,113 line items totaling approximately $2.7 million had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent to 1 or more full multiuse vials of Herceptin. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

OBJECTIVE

Our objective was to determine whether payments for full vials of the drug Herceptin that the Medicare contractor made to Maryland providers in Jurisdiction 12 were correct.

SUMMARY OF FINDINGS

Some payments for one or more full vials of Herceptin that the Medicare contractors made to Maryland providers in Jurisdiction 12 were incorrect. Of the 1,113 selected line items, 319 were incorrect and included overpayments totaling $351,904 that the providers had not identified or refunded by the beginning of our audit. Payments for the remaining 794 line items were correct.

For the 319 incorrect line items that had not been refunded, providers:

- reported incorrect units of service and incorrect billed charges on 307 line items, resulting in overpayments totaling $323,507;

- did not provide supporting documentation for 11 line items, resulting in overpayments totaling $26,383; and

- reported the correct units of service but incorrect billed charges on 1 line item, resulting in an overpayment totaling $2,014.

The providers attributed the incorrectly billed charges to chargemaster errors, clerical errors, and billing systems that could not prevent or detect the incorrect billing of units of service. (A provider's 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 and whether to charge for waste.) The Medicare contractor made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place during our audit period to prevent or detect the overpayments.

RECOMMENDATIONS

We recommend that Novitas:

- recover the $351,904 in identified overpayments,

- implement a system edit that identifies for review excessive billed charges for multiuse-vial drugs submitted by Maryland providers, and

- use the results of this audit in its provider education activities.

NOVITAS SOLUTIONS, INC., COMMENTS

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

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NOVITAS SOLUTIONS, INC., COMMENTS

INTRODUCTION

BACKGROUND

Herceptin[1] is a Medicare-covered biological drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial containing 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded amounts of the drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. This audit is part of a nationwide review of the drug Herceptin. The pilot of these reviews[2] found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

Medicare Contractors

Title XVIII of the Social Security Act (the Act) established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. The Centers for Medicare & Medicaid Services (CMS) administers the program.

CMS contracts with Medicare contractors to, among other things, process and pay claims submitted for outpatient services.[3] The Medicare contractors' responsibilities include determining reimbursement amounts, conducting reviews and audits, and safeguarding against fraud and abuse. Federal guidance provides that Medicare contractors must maintain adequate internal controls over automatic data processing systems to prevent increased program costs and erroneous or delayed payments. To process providers' claims for outpatient services, the Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF). The CWF can detect certain improper payments during prepayment validation.

Claims for Outpatient Drugs and Biologicals

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains line items that detail each provided service. Providers must use the appropriate Healthcare Common Procedure Coding System (HCPCS)[4] code for drugs

[1] Herceptin is Genentech's registered trademark for the biological drug trastuzumab. Biologicals are substances made from a living organism or its products that are used to prevent, diagnose, treat, or relieve symptoms of a disease.

[2] Report number A-05-10-00091, issued July 10, 2012.

[3] Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors (MAC). Most, but not all, of the MACs are fully operational; for jurisdictions where the MACs are not fully operational, the fiscal intermediaries and carriers continue to process claims. In this report, the term "Medicare contractor" means the fiscal intermediary, carrier, or MAC, whichever is applicable.

[4] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

administered and report units of service in multiples of the units shown in the HCPCS narrative description. Because a provider must discard the remainder of a single-use vial after administering a portion of it to a Medicare patient, the Medicare program pays for the amount discarded as well as the drug administered. However, unlike single-use vials, multi-use vials are not subject to payment for discarded amounts of the drug. Therefore, a Medicare payment for an entire multi-use vial is likely to be incorrect.

Novitas Solutions, Inc.

This report includes the results of our review of Maryland providers in Jurisdiction 12. We presented the results of our review of payments for Herceptin made to providers in the remaining four States in Jurisdiction 12 (Delaware, the District of Columbia, New Jersey, and Pennsylvania), in a separate report.[5] We reviewed payments to providers in Maryland separately because the providers receive Medicare payments under a waiver specific to the State.

During our audit period (January 2008 through December 2010), Novitas Solutions, Inc. (Novitas), formerly Highmark Medicare Services, was the Medicare contractor for three of the five States in Jurisdiction 12: the District of Columbia, Maryland, and Pennsylvania. In December 2008, Novitas assumed full responsibility for the Jurisdiction 12 workload, including claims paid for Delaware and New Jersey.

Medicare Payments Under the Maryland Waiver

Section 1814(b)(3) of the Act gives States the authority to request a waiver from paying for Medicare and Medicaid services in accordance with procedures outlined in the Act as long as "… some or all of the hospitals in a State have been reimbursed for services … pursuant to a reimbursement system approved as a demonstration project under section 402 of the Social Security Amendments of 1967 or section 222 of the Social Security Amendments of 1972." The Medicare Claims Processing Manual (the Manual), Pub. No. 100-04, chapter 4, section 141 states that, in accordance with the waiver, hospitals in Maryland are paid 94 percent of submitted charges subject to any Part B deductible and coinsurance. The Manual further states that Maryland hospitals paid under the waiver are not excluded from reporting HCPCS.[6]

Unlike providers in other States, which are paid based on Medicare's established rates (adjusted for geographical location and other cost factors), Maryland providers, including hospitals, are paid according to billing rates set by the Maryland Health Services Cost Review Commission. Providers submit charges based on those billing rates and receive a payment totaling 94 percent of the submitted charges: 74 percent less any Part B deductible from payers[7] and 20 percent coinsurance plus any Part B deductible from beneficiaries. Although Maryland providers are

[5] *Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect* (A-03-11-00014).

[6] Chapter 4, section 10.1 of the Manual.

[7] All payers, including Medicare, Medicaid, insurance companies, and health maintenance organizations, are required to pay Maryland providers the same amount.

required to use HCPCS codes, this waiver system does not determine payment based on units for most services billed.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether payments for full vials of the drug Herceptin that the Medicare contractor made to Maryland providers in Jurisdiction 12 were correct.

Scope

During our audit period, the Medicare contractor in Jurisdiction 12 processed 4,465 outpatient Part B line items for Herceptin totaling $9,796,480 for Maryland. Of the 4,465 line items, 1,113 totaling $2,721,712 had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent to 1 or more full multiuse vials of Herceptin. In this audit we did not review entire claims; rather, we reviewed specific line items within the claims.

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

We conducted our fieldwork from October 2011 through February 2012 by contacting Novitas in Camp Hill, Pennsylvania, and 13 providers in Maryland 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 which payments were made for HCPCS code J9355 (Herceptin);
- identified the 1,113 line items in our scope that the Medicare contractor paid to 13 providers;
- contacted the 13 providers that received Medicare payments for the selected line items to determine whether the information for the selected line items was correct and, if not, why the information was incorrect;
- reviewed documentation that the providers furnished to verify whether each selected line item was billed correctly; specifically we reviewed documentation to support:
    - a physician's order for the medication,

- the administration of the medication for the amount ordered, and
- the type of solution (bacteriostatic water for injection or sterile water for injection) used to reconstitute the Herceptin;

- coordinated the calculation of overpayments with the Medicare contractor; and
- discussed the results of our review with the Medicare contractor officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Some payments for one or more full vials of Herceptin that the Medicare contractor made to Maryland providers in Jurisdiction 12 were incorrect. Of the 1,113 selected line items, 319 were incorrect and included overpayments totaling $351,904 that the providers had not identified or refunded by the beginning of our audit. Payments for the remaining 794 line items were correct.

For the 319 incorrect line items that had not been refunded, providers:

- reported incorrect units of service and incorrect billed charges on 307 line items, resulting in overpayments totaling $323,507;
- did not provide supporting documentation for 11 line items, resulting in overpayments totaling $26,383; and
- reported the correct units of service but incorrect billed charges on 1 line item, resulting in an overpayment totaling $2,014.

The providers attributed the incorrectly billed charges to chargemaster[8] errors, clerical errors, and billing systems that could not prevent or detect the incorrect billing of units of service. The Medicare contractor made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place during our audit period to prevent or detect the overpayments.

FEDERAL REQUIREMENTS

Section 1833(e) of the Social Security Act 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 …."

[8] A provider's 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 and whether to charge for waste.

Chapter 23, section 20.3 of the Manual states: "providers must use HCPCS codes … for most outpatient services." Chapter 17, section 70, of the Manual states, "[w]here 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 are provided, units are shown as 4 …."

Chapter 17, section 40, of the Manual states, "[m]ulti-use vials are not subject to payment for discarded amounts of drug or biological." Further, chapter 1, section 80.3.2.2, of the Manual states: "In order to be processed correctly and promptly, a bill must be completed accurately."

MEDICARE BILLING FOR HERCEPTIN

The HCPCS code for Herceptin is J9355, with a narrative description of "injection, trastuzumab 10 mg [milligrams]." The manufacturer supplies Herceptin in a carton containing a multiuse vial of 440 milligrams of the drug and one 20-milliliter vial of bacteriostatic water for injection containing a solution of 1.1 percent of benzyl alcohol as a preservative. An entire multiuse vial of 440 milligrams of reconstituted Herceptin would be reported as 44 units for billing Medicare. A vial of Herceptin reconstituted with bacteriostatic water is stable for 28 days when stored properly. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded.

OVERPAYMENTS OCCURRED ON SOME LINE ITEMS REVIEWED

Incorrect Number of Units of Services and Billed Charges

Seven providers reported incorrect units of service and billed charges on 307 line items, resulting in overpayments totaling $323,507. For the 307 line items, providers billed Medicare for 44, 88, 132, 572, and 4,444 units of service of Herceptin (1, 2, 3, 13, and 101 vials, respectively), rather than for the amount of the drug actually administered. For 304 of the 307 line items, the billed units of service represent the number of units administered rounded up to the next multiple of 44 and the billed charges related to the billed units. For the remaining three line items, the billed units of service did not correlate to the amount of the drug actually administered or to the billed charges. Because Medicare pays Maryland providers based on billed charges, these lines were overpaid.

For example, one provider administered 1,193 milligrams of Herceptin to a patient and billed $4,391 for 132 units of service (1,320 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the correct number of units to bill for 1,193 milligrams was 120[9] and the provider should have billed $3,992. On 229 separate occasions, this type of error occurred and as a result, the Medicare contractor paid the provider $480,122 when it should only have paid $313,616, an overpayment of $166,506.

As a result of these unit-of-service errors, the Medicare contractor paid 7 providers a total of $787,344 when it should have paid $463,837 an overpayment of $323,507.

[9] 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 to report the administered dose.

Unsupported Services

Four providers billed Medicare for 11 line items for which the providers did not provide any documentation to support that a patient was seen or received treatment. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined $26,383 in overpayments that they received.

Correct Number of Units of Service and Incorrect Billed Charges

One provider correctly reported the units of service administered but incorrectly billed the charges on one line item, resulting in an overpayment totaling $2,014. The provider correctly billed Medicare for 2 vials of Herceptin (88 units of service) but billed Medicare $4,027, which represented the charges for 176 units of service. Because Medicare pays Maryland providers based on billed charges, these lines were overpaid.

CAUSES OF INCORRECT MEDICARE PAYMENTS

Provider Billing Errors

Providers attributed the incorrect billing to chargemaster errors, clerical errors, or billing systems that could not prevent or detect the incorrect reporting of units of service

Medicare Contractor System Edits

The Medicare contractor made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place during our audit period 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.[10]

RECOMMENDATIONS

We recommend that Novitas:

- recover the $351,904 in identified overpayments,
- implement a system edit that identifies for review excessive billed charges for multiuse-vial drugs submitted by Maryland providers, and
- use the results of this audit in its provider education activities.

[10] 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 findings and recommendations and described corrective actions that it had taken or planned to take. Novitas' comments are included in their entirety as the Appendix.

OTHER MATTERS: INCORRECT UNITS OF SERVICE BUT CORRECT BILLED CHARGES AND PAYMENTS

As we reported, 794 line items that we reviewed were paid correctly. However, five providers reported incorrect units of service on 741 of these lines items. The providers incorrectly billed Medicare for 1 to 67 vials of Herceptin (44 to 2,948 units of service); however, they correctly billed the charges for the number of units of service administered rather than the number of units reported. For example, one provider administered 974 milligrams of Herceptin to a patient but reported 132 billed units of service (1,320 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the correct number of units to bill for 974 milligrams was 98. The provider's chargemaster calculated the correct amount to bill Medicare for the units administered ($8,681) but rounded up the units of service to 132, the equivalent of 3 full vials of Herceptin. Although the number of units billed was incorrect, the billed charges were correct and Medicare correctly paid the provider $6,424 (74 percent of $8,681).

For 526 of the 741 line items, one provider billed for 1 or more full vials of Herceptin but reported the correct billed charges for the actual number of units administered. Because Medicare pays Maryland providers based on billed charges and not the number of units billed, these line items were paid correctly, resulting in no overpayments.

APPENDIX

APPENDIX: NOVITAS SOLUTIONS, INC., COMMENTS

Novitas Solutions, Inc.
ISO 9001-2008 CERTIFIED

August 10, 2012

RE: Report Number A-03-12-00014

Mr. Stephen Virbitsky
Regional Inspector General
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106

Dear Mr. Virbitsky,

This letter is in response to your letter addressed to Novitas Solutions, Inc. (Novitas), dated July 17, 2012, regarding the draft report for audit number A-03-12-00014, *The Medicare Contractor's Payments to Maryland Providers in Jurisdiction 12 for Full Vials of Herceptin Were Sometimes Incorrect.*

Recommendation that Novitas recover the $351,904 in identified overpayments:

Response: Novitas concurs with the recommendation and will initiate claims history adjustments on claims that providers have not already adjusted and will recover overpayments per CMS guidelines.

Recommendation that Novitas implement a system edit that identifies for review excessive billed charges for multiuse-vial drugs submitted by Maryland providers:

Response: Novitas concurs with the recommendation to implement an edit. We will conduct an analysis of the data in order to properly implement an edit to address the issue consistent with the Maryland waiver and the capabilities of the CMS standard system.

Recommendation that Novitas use the results of this audit in its provider education activities:

Response: Novitas concurs with the recommendation and will incorporate the results of this audit into its provider education activities (e.g. Medicare presentations and published articles.)

If there are any questions or concerns, please do not hesitate to contact me at (717) 526-6215 or Michele Daley-Ryan at (717) 526-6229.

Sincerely,

E. James Bylotas

E. James Bylotas
Director, Quality & Performance Management
Novitas Solutions, Inc.

Cc: Sandy Coston, Chief Executive Officer, Novitas Solutions, Inc.
Michele Daley-Ryan, Manager, Monitoring and Inspections, Novitas Solutions, Inc.