DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

July 25, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

SUBJECT: Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect (A-03-11-00014)

Attached, for your information, is an advance copy of our final report on Medicare contractors' payments to providers in four States in Jurisdiction 12 for full vials of Herceptin. These claims were initially processed by Novitas Solutions, Inc. (formerly Highmark Medicare Services); National Government Services; and Blue Cross Blue Shield of Tennessee. We will issue this report to Novitas Solutions, Inc., the current Medicare Administrative Contractor, within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov or Stephen Virbitsky, Regional Inspector General for Audit Services, Region III, at (215) 861-4470 or through email at Stephen.Virbitsky@oig.hhs.gov. Please refer to report number A-03-11-00014.

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES, REGION III
PUBLIC LEDGER BUILDING, SUITE 316
150 S. INDEPENDENCE MALL WEST
PHILADELPHIA, PA 19106

July 31, 2012

Report Number: A-03-11-00014

Ms. Sandra L. Coston
Chief Executive Officer
Novitas Solutions, Inc.
1800 Center Street
Camp Hill, PA 17089

Dear Ms. Coston:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Bernard Siegel, Audit Manager, at (215) 861-4484 or through email at Bernard.Siegel@oig.hhs.gov. Please refer to report number A-03-11-00014 in all correspondence.

Sincerely,

/Stephen Virbitsky/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 355
Kansas City, MO 64106

cc: Mr. David Vaughn
Vice President, Operations

Ms. Laura Minter
Program Manager, MAC Jurisdiction 12

Mr. E. James Bylotas
Director, Quality & Performance Management

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS TO PROVIDERS IN FOUR STATES IN JURISDICTION 12 FOR FULL VIALS OF HERCEPTIN WERE OFTEN INCORRECT

Daniel R. Levinson
Inspector General

July 2012
A-03-11-00014

Office of Inspector General

http://oig.hhs.gov

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

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

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

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

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THIS REPORT IS AVAILABLE TO THE PUBLIC

at http://oig.hhs.gov

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

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

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 for providers in four of the five States in Jurisdiction 12 (Delaware, the District of Columbia, New Jersey, and Pennsylvania). We will present the results of our review of payments for full vials of Herceptin made to providers in Maryland, the fifth State in Jurisdiction 12, in a separate report (*The Medicare Contractor's Payments to Maryland Providers in Jurisdiction 12 for Full Vials of Herceptin Were Sometimes Incorrect*, A-03-12-00014).

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 formerly paid by National Government Services for Delaware and by Blue Cross Blue Shield of Tennessee for New Jersey. Accordingly, we have addressed our findings and recommendations to Novitas for review and comment.

For the four States, the Medicare contractor processed 15,439 line items totaling approximately $25.2 million for Herceptin. Of these 15,439 line items, 1,454 line items totaling approximately $3.9 million had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent

to 1 or more full multiuse vials of Herceptin (1,452 line items) or line item payments that exceeded $10,000 each (2 line items). 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 contractors made to providers in four of the five States in Jurisdiction 12 were correct.

SUMMARY OF FINDINGS

Most payments for one or more full vials of Herceptin that the Medicare contractors made to providers in four of the five States in Jurisdiction 12 were incorrect. Of the 1,454 selected line items, 1,165 were incorrect and included overpayments totaling $1,576,374 that the providers had not identified or refunded by the beginning of our audit. Providers refunded overpayments on three line items totaling $6,548 before our fieldwork. The remaining 286 line items were correct.

For the 1,165 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,127 line items, resulting in overpayments totaling $1,448,751 and

- did not provide supporting documentation for 38 line items, resulting in overpayments totaling $127,623.

The providers attributed the incorrect payments 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.)

In some cases, providers could not store unused doses for later use because their pharmacies incorrectly reconstituted the Herceptin using sterile water instead of bacteriostatic water. When this occurred, the providers billed Medicare for the entire vial, including waste. The Medicare contractors 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 $1,576,374 in identified overpayments,

- implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials, 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.

TABLE OF CONTENTS

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 found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.[2]

Medicare Contractors

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) 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 the 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, multiuse vials are not subject to payment for discarded amounts of the drug. Therefore, a Medicare payment for an entire multiuse vial is likely to be an overpayment.

Novitas Solutions, Inc.

This report includes the results of our review of providers in four of the five States in Jurisdiction 12: Delaware, the District of Columbia, New Jersey, and Pennsylvania. Because the Medicare program in Maryland operates under a waiver, we will present the results of our review of payments for full vials of Herceptin made to providers in that State in a separate report.[5]

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 formerly paid by National Government Services for Delaware and by Blue Cross Blue Shield of Tennessee for New Jersey. Accordingly, we have addressed our findings and recommendations to Novitas for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

During our audit period, the Medicare contractors in Jurisdiction 12 processed 15,439 outpatient Part B line items for Herceptin totaling $25,198,669 for the 4 States in our review. Of the 15,439 line items, 1,454 totaling $3,935,801 had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent to 1 or more full multiuse vials of Herceptin (1,452 line items) or that exceeded $10,000 each (2 line items).[6] 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

[5] *The Medicare Contractor's Payments to Maryland Providers in Jurisdiction 12 for Full Vials of Herceptin Were Sometimes Incorrect* (A-03-12-00014).

[6] Although these high-dollar items did not represent billings equivalent to full vials, they were included because they were likely to be incorrect.

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 78 providers in the 4 States in Jurisdiction 12 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 1,454 line items in our scope that the Medicare contractors paid to 78 providers;
- contacted the 78 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

Most payments for one or more full vials of Herceptin that the Medicare contractors made to providers in four of the five States in Jurisdiction 12 were incorrect. Of the 1,454 selected line items, 1,165 were incorrect and included overpayments totaling $1,576,374 that the providers had not identified or refunded by the beginning of our audit. Providers refunded overpayments on three line items totaling $6,548 before our fieldwork. The remaining 286 line items were correct.

For the 1,165 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,127 line items, resulting in overpayments totaling $1,448,751 and

- did not provide supporting documentation for 38 line items, resulting in overpayments totaling $127,623.

The providers attributed the incorrect payments to chargemaster[7] errors, clerical errors, and billing systems that could not prevent or detect the incorrect billing of units of service. In some cases, providers could not store unused doses for later use because their pharmacies incorrectly reconstituted the Herceptin using sterile water instead of bacteriostatic water. When this occurred, the providers billed Medicare for the entire vial, including waste. The Medicare contractors 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 …."

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 23, section 20.3, 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."

[7] 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.

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 MOST LINE ITEMS REVIEWED

Incorrect Number of Units of Service

Fifty-one providers reported incorrect units of service on 1,127 line items, resulting in overpayments totaling $1,448,751. For 1,125 of the 1,127 line items, providers billed Medicare for 1 to 11 full vials of Herceptin (44 units to 440 units of service), rather than for the amount of the drug actually administered. For the remaining two line items, for payments of $10,000 or more, providers billed for more units of service than administered; however, the units did not represent multiples of full vials of Herceptin. For example:

- One provider administered 146 milligrams of Herceptin to a patient and billed for 176 units of service (1,760 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the correct number of units to bill for 146 milligrams was 15.[8] On 81 separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider $202,116 when it should have paid $58,310, an overpayment of $143,806.

- Another provider administered 335 milligrams (34 units) of Herceptin to a patient but incorrectly billed for 44 units of service (440 milligrams). The provider's pharmacy incorrectly reconstituted Herceptin using sterile water instead of bacteriostatic water, and the provider billed Medicare for the full vial, including waste. On 43 separate occasions, that provider billed for 1 full vial of Herceptin (44 units of service) for each patient dose, rather than the amount administered. As a result, the Medicare contractor paid the provider $91,672 when it should have paid $80,489, an overpayment of $11,183.

As a result of these unit-of-service errors, the Medicare contractor paid 51 providers a total of $3,157,372 when it should have paid $1,708,621, an overpayment of $1,448,751.

[8] 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

Twelve providers billed Medicare for 38 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 $127,623 in overpayments that they received.

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 billing of units of service. In several cases, the provider's pharmacy incorrectly reconstituted Herceptin using sterile water instead of bacteriostatic water. Because sterile water does not contain a preserving agent, the unused drug could not be stored for later use. When this occurred, providers treated the multiuse vial of Herceptin as a single-use vial and billed Medicare for the entire amount, including waste.

Medicare Contractor System Edits

The Medicare contractors 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 contractors of incorrect payments and on beneficiaries to review their *Medicare Summary Notice* and disclose any overpayments.[9]

RECOMMENDATIONS

We recommend that Novitas:

- recover the $1,576,374 in identified overpayments,
- implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials, 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.

[9] 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

APPENDIX: NOVITAS SOLUTIONS, INC., COMMENTS

Novitas Solutions, Inc.

ISO 9001-2008 CERTIFIED

July 5, 2012

RE: Report Number A-03-11-00014

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 June 15, 2012, regarding the draft report for audit number A-03-11-00014, *Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect.*

Recommendation that Novitas recover the $1,576,374 in identified overpayments:

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

Recommendation that Novitas implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials:

Response: Novitas concurs with the recommendation to implement an edit. In order to properly implement the edit Novitas reproduced the OIG data for the time period of January 1, 2011 through December 31, 2011 and compared those results to the OIG's 2008-2010 study. Fifty-nine (59) facilities were identified in the updated 2011 analysis. Novitas will pursue performing further analysis, such as a Medical Review special project, to address potential overpayments, at these facilities, based on the results of the OIG study.

Additionally in September, Novitas will institute a service-wide, prepayment edit on HCPCS J9355 billed in multiples of 44, with a claim volume not to exceed 50 claims per month. Medical Review will assess the appropriateness of units billed per beneficiary and beneficiaries deemed "appropriate" to receive units of 44 will be removed from future edits.

Novitas will continue to explore opportunities for additional intervention. We will seek to obtain a list of all pharmaceuticals manufactured in multi-dose vials and determine whether there are other drugs at risk for these types of aberrant billing practices.

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.)

Novitas will utilize the data from the aforementioned Medical Review activities with the appropriate Medical Review Clinical Nurse Reviewer and/or Provider Outreach and Education, depending on finding results.

If there are any questions or concerns, please do not hesitate to contact me at (717) 302-4410 or Michele Daley-Ryan at (717) 302-7516.

Sincerely,

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.