



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



July 5, 2012

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

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

**SUBJECT:** The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect (A-05-10-00091)

Attached, for your information, is an advance copy of our final report on the Medicare contractor's payments in Jurisdictions 6, 8, and 15 to providers for full vials of Herceptin. We will issue this report to National Government Services 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](mailto:Brian.Ritchie@oig.hhs.gov) or Sheri L. Fulcher, Regional Inspector General for Audit Services, Region V, at (312) 353-2618 or through email at [Sheri.Fulcher@oig.hhs.gov](mailto:Sheri.Fulcher@oig.hhs.gov). Please refer to report number A-05-10-00091.

Attachment



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION V  
233 NORTH MICHIGAN, SUITE 1360  
CHICAGO, IL 60601

July 10, 2012

Report Number: A-05-10-00091

Mr. Mike Kapp  
President  
National Government Services  
8115 Knue Road  
Indianapolis, IN 46250

Dear Mr. Kapp:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers 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 Jaime Saucedo, Audit Manager, at (312) 353-8693 or through email at [Jaime.Saucedo@oig.hhs.gov](mailto:Jaime.Saucedo@oig.hhs.gov). Please refer to report number A-05-10-00091 in all correspondence.

Sincerely,

/Sheri L. Fulcher/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Ms. Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management and Fee for Service Operations  
601 East 12<sup>th</sup> Street, Room 235  
Kansas City, MO 64106

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S  
PAYMENTS IN  
JURISDICTIONS 6, 8, AND 15 TO  
PROVIDERS FOR  
FULL VIALS OF HERCEPTIN  
WERE OFTEN INCORRECT**



Daniel R. Levinson  
Inspector General

July 2012  
A-05-10-00091

# ***Office of Inspector General***

<http://oig.hhs.gov>

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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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# *Notices*

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**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
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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, also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days.

For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. Previous Office of Inspector General reviews have noted that providers may not be billing Herceptin lines of service correctly.

Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services administers the program.

Effective January 1, 2007, National Government Services became the Medicare contractor in Illinois, Indiana, Michigan, Ohio, and Wisconsin. During our audit period (January 1, 2007, through December 31, 2009), 23,085 line items for Herceptin totaling approximately \$38.7 million were processed in these States. Of these 23,085 line items, 3,966 totaling approximately \$9.6 million had 44, 88, 132, or 176 units of service that represent billings equivalent to entire multiuse vials. In this audit, we did not review entire claims; rather, we reviewed the specific line items within the claims that met these criteria.

### **OBJECTIVE**

Our objective was to determine whether Medicare payments that National Government Services made to providers for full vials of Herceptin were correct.

### **SUMMARY OF FINDINGS**

Most Medicare payments that National Government Services made to providers for full vials of Herceptin were incorrect. Specifically, of the 3,966 selected line items, 3,093 (78 percent) were incorrect and included overpayments totaling \$3,351,807, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 257 line items totaling \$240,781 before our fieldwork. The 616 remaining line items were correct.

On each of the 3,093 incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect

billing of units of service. National Government Services made these incorrect payments because neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments.

## **RECOMMENDATIONS**

We recommend that National Government Services:

- recover the \$3,351,807 in identified overpayments,
- implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s), and
- use the results of this audit in its provider education activities.

## **NATIONAL GOVERNMENT SERVICES COMMENTS**

In written comments on our draft report, National Government Services stated that the claims list identifying \$3,351,807 in overpayments had been reviewed and the claims canceled or adjusted accordingly, with recoveries to be confirmed by National Government Services' claims and overpayment recovery units. National Government Services also stated that it was researching the feasibility of implementing a system edit to address our second recommendation. Regarding our third recommendation, National Government Services stated that provider outreach activities would be transitioned to the Wisconsin Physicians Service Insurance Corporation effective May 23, 2012, for the workload reviewed, and the audit recommendation would be incorporated into the transition schedule.

National Government Services' comments are included in their entirety as the Appendix.



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# INTRODUCTION

## BACKGROUND

Herceptin<sup>1</sup> is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. However, for multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded amounts. Previous Office of Inspector General reviews<sup>2</sup> have noted that providers may not be billing Herceptin lines of service correctly.

Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

### Medicare Contractors

CMS contracts with Medicare contractors to, among other things, process and pay Medicare claims submitted for outpatient services.<sup>3</sup> 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 Drugs

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains line items that detail each provided service. 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.<sup>4</sup> Multiuse vials are not subject to payment for discarded amounts of the drug.

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<sup>1</sup> Herceptin is Genentech's registered trademark for the drug trastuzumab.

<sup>2</sup> These reports include A-05-10-00017, issued September 7, 2011; A-05-10-00016, issued October 17, 2011; and A-05-10-00025, issued December 13, 2011. Although these reports dealt with various types of incorrect payments, some related to incorrect billings equivalent to entire multiuse vials of Herceptin.

<sup>3</sup> 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) between October 2005 and October 2011. 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.

<sup>4</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

Multiuse vials are typically used for more than one date of service and can be stored for up to 28 days. Therefore, a payment for an entire multiuse vial is likely to be incorrect.

## **Herceptin**

Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent of benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded. The HCPCS code for Herceptin is J9355, with a narrative description of “injection, trastuzumab 10mg.” An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

## **National Government Services**

Effective January 1, 2007, National Government Services became the Medicare contractor in Illinois, Indiana, Michigan, Ohio, and Wisconsin. During our audit period (January 1, 2007, through December 31, 2009), 23,085 line items were processed for Herceptin in these States.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether Medicare payments that National Government Services made to providers for full vials of Herceptin were correct.

### **Scope**

During our audit period, National Government Services processed 23,085 outpatient Part B service line items of Herceptin totaling approximately \$38.7 million. Of these 23,085 line items, 3,966 items totaling approximately \$9.6 million had 44, 88, 132, or 176 units of service that represented billings equivalent to entire multiuse vials.

We limited our review of National Government Services’ 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.

Our fieldwork was conducted from November 2010 through May 2011 and included contacting National Government Services in Indianapolis, Indiana, and the 142 providers in Illinois, Indiana, Michigan, Ohio, and Wisconsin that received the selected Medicare payments.

## 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 in which payments were made for HCPCS code J9355 (Herceptin);
- identified 3,966 line items with unit counts<sup>5</sup> of 44, 88, 132, or 176, totaling approximately \$9.6 million, that National Government Services paid to 142 providers;
- contacted the 142 providers that received Medicare payments associated with the selected line items to determine whether the information conveyed in 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:
  - the medical condition of the beneficiary in determining the necessity of the medication,
  - physician’s orders for medication,
  - that the medication was administered, and
  - the type of solution used to reconstitute the Herceptin (BWFJ containing 1.1 percent benzyl alcohol or sterile water);
- coordinated the calculation of overpayments with National Government Services; and
- discussed the results of our review with National Government Services on November 29, 2011.

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 Medicare payments that National Government Services made to providers for full vials of Herceptin were incorrect. Specifically, of the 3,966 selected line items, 3,093 (78 percent) were incorrect and included overpayments totaling \$3,351,807, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning

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<sup>5</sup> At National Government Services, we did not have any instances of line items with unit counts of 176.

of our audit. Providers refunded overpayments on 257 line items totaling \$240,781 before our fieldwork. The 616 remaining line items were correct.

On each of the 3,093 incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. National Government Services 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**

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." According to chapter 17, section 70, of the Manual, when a provider is billing for a drug "[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, and 200 mg are provided, units are shown as 4 ...."

Chapter 17, section 40, of the Manual also states: "Multi-use vials are not subject to payment for discarded amounts of drug ...." Finally, 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."

## **OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED**

Providers reported incorrect units of service on 3,093 (78 percent) of the 3,966 line items reviewed, resulting in overpayments totaling \$3,351,807 (35 percent) of the \$9.6 million total dollars reviewed. Providers billed Medicare for the entire vial containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, one provider administered 140 milligrams of Herceptin to a patient and billed for 44 units of service (440 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 140 milligrams is 14.<sup>6</sup> This error occurred on 51 separate occasions for 1 patient; as a result, National Government Services paid the provider \$108,763 when it should have paid \$33,932, an overpayment of \$74,831.

## **CAUSES OF INCORRECT MEDICARE PAYMENTS**

The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. National Government Services made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place to prevent or detect the overpayments. In effect, CMS

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<sup>6</sup> 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 to report the dose.

relied on beneficiaries to review their *Medicare Summary Notice*<sup>7</sup> and disclose any overpayments.

## **RECOMMENDATIONS**

We recommend that National Government Services:

- recover the \$3,351,807 in identified overpayments,
- implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s), and
- use the results of this audit in its provider education activities.

## **NATIONAL GOVERNMENT SERVICES COMMENTS**

In written comments on our draft report, National Government Services stated that the claims list identifying \$3,351,807 in overpayments had been reviewed and the claims canceled or adjusted accordingly, with recoveries to be confirmed by National Government Services' claims and overpayment recovery units. National Government Services also stated that it was researching the feasibility of implementing a system edit to address our second recommendation. Regarding our third recommendation, National Government Services stated that provider outreach activities would be transitioned to the Wisconsin Physicians Service Insurance Corporation effective May 23, 2012, for the workload reviewed, and the audit recommendation would be incorporated into the transition schedule.

National Government Services' comments are included in their entirety as the Appendix.

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<sup>7</sup> 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: NATIONAL GOVERNMENT SERVICES COMMENTS



National Government Services, Inc.  
8115 Knue Road  
Indianapolis, Indiana 46250-1936  
*A CMS Contracted Agent*

## Medicare

May 21, 2012

Ms. Sheri Fulcher  
Regional Inspector General for Audit Services  
Office of Inspector General  
Office of Audit Services, Region V  
233 North Michigan, Suite 1360  
Chicago, IL 60601

Report Number: A-05-10-00091

Dear Ms. Fulcher,

The following presents our response to the comments made in your report dated April 20, 2012:

Recommendation 1 – Recover the \$3,351,807 in identified overpayments

The claims listing has been reviewed and worked accordingly. As required, claims have been cancelled or adjusted, with a status provided as applicable. The recoveries will be confirmed by both the NGS Claims and Overpayment Recovery units to ensure completion.

NOTE: There are workloads included in the OIG review that have since transitioned from NGS. These include both the transitions of J11 (00453) and J15 (00160 & 00332).

Recommendation 2 – Implement system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s).

The feasibility of implementing a system edit is currently being researched. Several questions require further understanding to include the specifics of the drug Herceptin being administered, the potential impact on the Medical Review Strategy plans, and the manual processes that may be required.

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

Provider Outreach activities will be transitioned to the Wisconsin Physicians Service Insurance Corporation (WPS) effective May 23<sup>rd</sup> for the workload reviewed. The audit recommendation will be incorporated into the current transition schedule.

Sincerely yours,

/s/ Tricia Backofen  
Director NGS Operations Excellence

