DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Office of Audit Services, Region V
233 North Michigan Avenue
Suite 1360
Chicago, IL 60601

May 28, 2010

Report Number: A-05-09-00070

Ms. Jared Adair
Senior Vice President
Wisconsin Physicians Service, Medicare
1707 W Broadway
Madison, WI 53713

Dear Ms. Adair:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Part B Claims for Neulasta—Wisconsin Physicians Service for the Calendar Years 2004 through 2007*. 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 Sheri Fulcher, Audit Manager, at (312) 353-1823 or through email at Sheri.Fulcher@oig.hhs.gov. Please refer to report number A-05-09-00070 in all correspondence.

Sincerely,

/James C. Cox/
Regional Inspector General
for Audit Services

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 235
Kansas City, MO 64106

cc: Kelly Hartung, WPS

Enclosure

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART B CLAIMS FOR NEULASTA — WISCONSIN PHYSICIANS SERVICE FOR THE CALENDAR YEARS 2004 THROUGH 2007

Daniel R. Levinson
Inspector General

May 2010
A-05-09-00070

Office of Inspector General

http://oig.hhs.gov

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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

Pursuant to Title XVIII of the Social Security Act (the 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.

Prior to October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers to process and pay Medicare Part B claims submitted by physicians and medical suppliers (providers). The Medicare Modernization Act of 2003, P.L. No. 108-173, which became effective October 1, 2005, amended section 1842(a) of the Act to require that Medicare administrative contractors replace carriers and fiscal intermediaries by October 2011. Carriers also review provider records to ensure proper payment and assist in applying safeguards against unnecessary utilization of services. To process providers' claims, carriers use the Medicare Multi-Carrier System (MCS) and CMS's Common Working File. These systems can detect certain improper payments during prepayment validation.

Individuals receiving chemotherapy treatments often suffer from a lack of white blood cells. The drug Pegfilgrastim (Neulasta) is injected to stimulate the bone marrow and promote the growth of white blood cells. In 2003, CMS assigned the administration of Neulasta injections the Healthcare Common Procedure Coding System (HCPCS) code Q4053, which defined the unit size as 1 milligram. Providers billed for six units because the drug is usually injected using a pre-filled syringe containing 6 milligrams of Neulasta. Beginning January 1, 2004, the HCPCS code changed to J2505, which defined a unit as 6 milligrams rather than 1 milligram.

Wisconsin Physicians Service (WPS) was the Medicare Part B carrier for providers in Illinois, Michigan, Minnesota, and Wisconsin during calendar years (CYs) 2004 through 2007. During this period, WPS processed more than 364 million Part B claims for these four States, including over 130,000 claims for Neulasta injections.

OBJECTIVE

Our objective was to determine whether Medicare payments for Neulasta injection claims paid by WPS during CYs 2004 through 2007 were appropriate.

SUMMARY OF FINDING

Medicare payments for Neulasta injection claims paid by WPS during CYs 2004 through 2007 were not always appropriate. WPS overpaid $655,149 for 462 claims submitted by 44 providers during CYs 2004 through 2007. Of the $655,149 inappropriate Neulasta injection payments, a total of $646,845 for 461 claims remained outstanding at the start of our audit. Prior to our audit, one provider had refunded an overpayment for one claim of $8,304.

These inappropriate Neulasta injection payments occurred because providers claimed excessive units of service. Although providers used the new HCPCS code J2505, some continued to

submit claims for six units of service and carriers did not always identify the error. The Medicare MCS did not have sufficient edits in place during CYs 2004 through 2007 to detect and prevent payments for such erroneous claims.

RECOMMENDATIONS

We recommend that WPS:

- recover the $646,845 in identified Neulasta injection overpayments and
- improve internal controls related to Neulasta injection claims processing and payments.

WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION COMMENTS

In written comments to our draft report, WPS stated that it is actively addressing this report's recommendations, recouping confirmed overpayments, and abiding by the four-year reopening guidelines. WPS's comments are included in their entirety as the Appendix.

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INTRODUCTION

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the 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 Part B Carriers

Prior to October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers to process and pay Medicare Part B claims submitted by physicians and medical suppliers (providers).[1] Carriers also review provider records to ensure proper payment and assist in applying safeguards against unnecessary utilization of services. To process providers' claims, carriers use the Medicare Multi-Carrier System (MCS) and CMS's Common Working File. These systems can detect certain improper payments during prepayment validation.

CMS guidance requires carriers to pay for certain drugs based on the CMS published average sales price (ASP).[2] CMS guidance also requires providers to bill accurately and to report units of service as the number of times that a service or procedure was performed. During calendar years (CYs) 2004 through 2007, providers nationwide submitted more than 3.2 billion claims totaling over $294 billion to carriers. Of these, 1,007,048 claims for Neulasta injections[3] resulted in payments of approximately $1.9 billion.

Medically Unlikely Edits

In January 2007, CMS required carriers to implement units-of-service edits referred to as "medically unlikely edits." CMS designed these edits to detect and deny unlikely Medicare claims on a prepayment basis. Pursuant to the *Medicare Program Integrity Manual*, Pub. No. 100-08, Transmittal 178, Change Request 5402, a "medically unlikely edit" tests claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of units of service. Carriers must deny the entire claim line when the units of service billed exceed the specified number.

Neulasta

Individuals receiving chemotherapy treatments often suffer from a lack of white blood cells. The drug Pegfilgrastim (Neulasta) is injected to stimulate the bone marrow and promote the growth

[1] The Medicare Modernization Act of 2003, P.L. No. 108-173, which became effective on October 1, 2005, amended section 1842(a) of the Act to require that Medicare administrative contractors replace carriers and fiscal intermediaries by October 2011.

[2] Pursuant to 42 CFR § 414.707(a)(1), the payment allowance limit in CY 2004 was 85 percent of the average wholesale price. Beginning January 1, 2005, 42 CFR § 414.904(a) established the payment allowance limit as 106 percent of the average sales price.

[3] Neulasta is Amgen's trademark for the medication pegfilgrastim, which was administered during our audit period using a pre-filled syringe containing 6 milligrams of Neulasta.

of white blood cells. In 2003, CMS assigned the administration of Neulasta injections the Healthcare Common Procedure Coding System (HCPCS) code Q4053, which defined the unit size as 1 milligram (mg). Providers billed for six units because the drug is usually injected using a pre-filled syringe containing 6 milligrams (mg) of Neulasta. Beginning January 1, 2004, the HCPCS code changed to J2505, where one unit is a single 6-mg dose.

CMS documented the new code HCPCS J2505, described as an injection of 6 mgs of Neulasta, beginning with Transmittal 54 for Pub. 100-04, the CMS *Medicare Claims Processing Manual*, in December 2003. CMS issued Transmittal 949, Change Request 4380 on May 12, 2006, to fiscal intermediaries and Medicare administrative contractors (but not to carriers) clarifying the billing procedures for Neulasta. The change request stated that "Claims for Pegfilgrastim J2505 [Neulasta] shall be submitted to Medicare contractors so that the units billed represent the number of multiples of 6MG provided, not the number of MGs." Similarly, notification of the description of HCPS J2505 as one single dose of 6 mgs was published three times in the Federal Register in 2004, beginning on January 6, 2004.

Wisconsin Physicians Service

Wisconsin Physicians Service (WPS) was the Medicare Part B carrier for providers in Illinois, Michigan, Minnesota, and Wisconsin during calendar years CYs 2004 through 2007. During this period, WPS processed more than 364 million Part B claims for these four States, including over 130,000 claims for Neulasta injections.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments for Neulasta injection claims paid by WPS during CYs 2004 through 2007 were appropriate.

Scope

We reviewed all WPS Part B paid claims for Neulasta injections in Illinois, Michigan, Minnesota, and Wisconsin for CYs 2004 through 2007 that (i) exceeded $2,006[4] (ii) were for six units or more; (iii) were not questioned in our earlier Excessive Payments audit (CIN A-05-08-00022) and (iv) for which the total potential overpayment exceeded $5,000 for a provider.[5]

We limited our review of WPS's internal controls to those applicable to processing and paying for Neulasta injections because our objective did not require an understanding of all internal controls over the submission 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.

[4] The highest allowable Medicare payment to Part B providers during the audit period for one unit of service of Neulasta injection was $2,006.

[5] By provider, we are referring to the tax identification number provided in CMS's National Claims History.

We performed our fieldwork from May 2009 through December 2009.

Methodology

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations and guidance;
- used CMS's National Claims History file to identify a universe of Medicare Part B claims submitted and paid for Neulasta injections;
- reviewed CMS's Recovery Audit Contractor documents to verify that payments already reviewed were not included in the universe;
- reviewed a universe of 462 claims for Neulasta injections that had payments totaling $1,555,543 in CYs 2004 through 2007;
- contacted providers to determine whether the claims were billed correctly, and if not, reasons for any claims billed in error;
- reviewed policies, system edits, and manual claims processing controls that WPS had in place during the audit period to detect or prevent overpayments for Neulasta injections; and
- summarized the results of the review, including the total amount of overpayment on the claims.

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

Medicare payments for Neulasta injection claims paid by WPS during CYs 2004 through 2007 were not always appropriate. WPS overpaid $655,149 for 462 claims submitted by 44 providers during CYs 2004 through 2007. Of the $655,149 inappropriate Neulasta injection payments, a total of $646,845 for 461 claims remained outstanding at the start of our audit. Prior to our audit, one provider had refunded an overpayment for one claim of $8,304.

These inappropriate Neulasta injection payments occurred because providers claimed excessive units of service. Although providers used the new HCPCS code J2505, some continued to

submit claims for six units of service and carriers did not always identify the error. The Medicare MCS did not have sufficient edits in place during CYs 2004 through 2007 to detect and prevent payments for such erroneous claims.

MEDICARE REQUIREMENTS

The CMS *Medicare Carriers Manual*, Pub. No. 14 part 2, section 5261.1 requires that carriers process claims accurately in accordance with Medicare program laws, regulations, and general instructions. Further section 5261.3 requires that carriers effectively and continually analyze "data that identifies aberrancies, emerging trends and areas of potential abuse, overutilization, or inappropriate care, and ... on areas where the trust fund is most at risk, i.e., highest volume and/or highest dollar codes."

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 17, section 20, requires carriers to pay for certain drugs based on the CMS published ASP.[6] Beginning in 2004, CMS assigned the administration of Neulasta injections the HCPCS code J2505, which represented a single dosage vial containing 6 mgs of the drug. Medicare pays up to 80 percent of the lesser of the claimed amount or the ASP Drug Pricing File payment allowance limit.

EXCESSIVE UNITS OF SERVICE

WPS overpaid 44 providers $655,149 for 462 claims for Neulasta injections, because providers submitted claims with excessive units of service. At the start of our audit, 461 claims totaling $646,845 remained outstanding. One provider refunded an overpayment for one claim of $8,304 prior to our audit. Although providers used the new HCPCS code J2505, they continued to bill six units, which totals 36 mgs or the equivalent of six Neulasta injections instead of one unit of 6 mgs for each Neulasta injection. When a provider incorrectly bills for six units of Neulasta injections rather than one unit, the payment allowance limit for the six units resulted in an overpayment.

For example, in CY 2004, a provider incorrectly billed six units of Neulasta injections, instead of one unit, which resulted in an overpayment of $2,733. The CY 2004 Medicare payment allowance limit for the administration of six units of Neulasta injections was $12,036, while one unit of Neulasta injections was $2,006. The provider submitted a claim totaling $5,924 for six units, an amount below the $12,036 ceiling for six units. Therefore, WPS subsequently paid $4,739 (80 percent of the $5,924 billed amount) to the provider because the claim was below the ceiling for six units, resulting in an overpayment of $2,733 ($4,739 paid less the $2,006 ceiling for one unit).

Providers attributed the incorrect submission of units to clerical errors made by their billing staff and changes made to billing codes.

[6] Pursuant to 42 CFR § 414.707(a)(1), the payment allowance limit in CY 2004 was 85 percent of the average wholesale price. Beginning January 1, 2005, 42 CFR § 414.904(a) established the payment allowance limit as 106 percent of the average sales price.

MEDICARE MULTI-CARRIER SYSTEM EDITS

The Medicare MCS used to process claims at WPS did not have edits in place to detect and prevent the processing of claims for more than one unit of service of Neulasta injections. As a result, WPS processed claims submitted by providers for more units of Neulasta injections than were administered. System edits were not in place and system controls were not adequate to ensure proper payment for Neulasta injections. The claims for six or more units of Neulasta injections (exceeding the applicable one unit of service beginning in calendar year 2004) were inappropriate, and should have been identified as erroneous during claims processing.

RECOMMENDATIONS

We recommend that WPS:

- recover the $646,845 in identified Neulasta injection overpayments and

- improve internal controls related to Neulasta injections claim processing and payment.

WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION COMMENTS

In written comments to our draft report, WPS stated that it is actively addressing this report's recommendations, recouping confirmed overpayments, and abiding by the four-year reopening guidelines. WPS's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION COMMENTS

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare

April 23, 2010

Mr. James Cox
Regional Inspector General for Audit Service
Office of Audit Services, Region V
233 North Michigan Avenue, Suite 1360
Chicago, Illinois 60601

Re: Office of Inspector General (OIG) Draft Report A-05-09-00070

Dear Mr. James Cox,

This letter is in response to the OIG draft report titled "Review of Medicare Part B Claims for Neulasta-Wisconsin Physicians Service for the Calendar Years 2004 through 2007."

The OIG reviewed Medicare Part B claims for Pegfilgrastim (Neulasta) injection payments made by Wisconsin Physicians Service (WPS). The results of the review indicated WPS overpaid $655,149 for 462 claims submitted by 44 providers. Of the $655,149 overpaid, a total of $646,845 remained outstanding at the start of the audit. Prior to the audit, one Medicare provider had refunded $8,304. The OIG draft indicated *"in 2003, CMS assigned the administration of Neulasta injections the Healthcare Common Procedure Coding Systems (HCPCS) code Q7053, which defined the unit size of 1 milligram. Providers billed for 6 units because the drug is usually administered via a pre-filled syringe of 0.6 milliliters, which is equivalent to 6 milligrams. Beginning January 1, 2004, the HCPCS code changed to J2505, which defined a unit as 6 milligrams rather than 1 milligram."*

OIG recommendations to WPS:

- *Recover the $646,845 in identified Neulasta injection overpayments and*
- *Improve internal controls related to Neulasta injections claim processing and payment.*

WPS is actively addressing the recommendations outlined in this report. WPS will recoup confirmed overpayments, abiding by the four-year reopening guidelines.

If you have any questions, or need any additional information please contact me at (402) 351-6915.

Sincerely,

Mark DeFoil
Director, Contract Coordination

cc: Joni Jones, CMS
Shawnelle Hopkins, CMS
Sheri Fulcher, OIG