



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX  
90 – 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

October 29, 2010

Report Number: A-09-10-02044

Mr. Michael Hamerlik  
President and Chief Executive Officer  
Noridian Administrative Services, LLC  
900 42<sup>nd</sup> Street South  
Fargo, ND 58103

Dear Mr. Hamerlik:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Contractor Payments for Neulasta Injections in Alaska, Arizona, and Washington for 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.

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If you have any questions or comments about this report, please do not hesitate to call Lorralli Herrera, Senior Auditor, at (619) 557-6131, extension 105, or through email at [Lorralli.Herrera@oig.hhs.gov](mailto:Lorralli.Herrera@oig.hhs.gov), or contact Alice Norwood, Audit Manager, at (415) 437-8360 or through email at [Alice.Norwood@oig.hhs.gov](mailto:Alice.Norwood@oig.hhs.gov). Please refer to report number A-09-10-02044 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

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Department of Health & Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICARE  
CONTRACTOR PAYMENTS FOR  
NEULASTA INJECTIONS IN  
ALASKA, ARIZONA, AND WASHINGTON  
FOR CALENDAR YEARS  
2004 THROUGH 2007**



Daniel R. Levinson  
Inspector General

October 2010  
A-09-10-02044

# *Office of Inspector General*

<http://oig.hhs.gov>

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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.

Before October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers. For purposes of this report, the term “Medicare contractor” means the fiscal intermediary, carrier, or Medicare administrative contractor, whichever is applicable.

Medicare contractors process and pay Medicare Part B claims submitted by physicians and medical suppliers (providers). Medicare contractors also review provider records to ensure proper payment and assist in applying safeguards against unnecessary utilization of services. To process providers’ Part B claims, Medicare contractors use the Medicare Multi-Carrier Claims System and CMS’s Common Working File. These systems can detect certain improper payments during prepayment validation.

Individuals receiving chemotherapy often suffer from a low white blood cell count. Providers inject patients with pegfilgrastim (Neulasta), usually in 6-milligram doses, to stimulate bone marrow and promote the growth of white blood cells. Before January 1, 2004, CMS assigned Healthcare Common Procedure Coding System (HCPCS) code Q4053 to Neulasta injections and defined one service unit as 1 milligram. Effective January 1, 2004, CMS changed the HCPCS code for Neulasta to J2505 and defined one service unit as 6 milligrams, which represented a standard dose.

During calendar years (CY) 2004 through 2007, Noridian Administrative Services, LLC (Noridian), was the Medicare contractor for providers in Alaska, Arizona, and Washington. (Before December 2006, Noridian Mutual Insurance Company (Noridian Insurance) was the Medicare contractor for providers in Arizona.) During this period, Noridian and Noridian Insurance processed and paid more than 108 million Part B claims, of which 41,317 claims included Neulasta injections in these three States.

### **OBJECTIVE**

Our objective was to consolidate the results of our reviews of six selected Medicare Part B providers in Alaska, Arizona, and Washington that billed Medicare for Neulasta injections. Those reviews determined whether the six providers billed Medicare for the correct number of service units of Neulasta.

### **SUMMARY OF RESULTS**

For 156 Medicare claims reviewed, 6 providers in Alaska, Arizona, and Washington billed Medicare for the incorrect number of service units of Neulasta. Consequently, during CYs 2004 through 2007, Noridian and Noridian Insurance paid these providers \$461,945 instead of

\$308,867, resulting in overpayments totaling \$153,078. Noridian and Noridian Insurance made these overpayments because the providers billed for more than one service unit for every 6 milligrams of Neulasta administered.

## **RECOMMENDATION**

We recommend that Noridian consider reviewing Neulasta claims with the incorrect number of service units that were not part of this review.

## **NORIDIAN COMMENTS**

In its comments on our draft report, Noridian concurred with our recommendation and provided information on actions taken to implement the recommendation. Noridian'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 Contractors

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

CMS guidance requires Medicare contractors to pay for certain drugs based on the published average sales price.<sup>2</sup> CMS guidance also requires providers to bill accurately and to report units of service as the number of times that the provider performed a service or procedure. During CYs 2004 through 2007, providers nationwide submitted approximately 3.2 billion Part B claims, totaling over \$294 billion, to Medicare contractors. Of these claims, over 1 million claims for pegfilgrastim (Neulasta)<sup>3</sup> injections resulted in payments of approximately \$1.7 billion.

#### Medically Unlikely Edits

In January 2007, during our audit period, CMS required Medicare contractors 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. According to the CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, Transmittal 178, Change Request 5402 (December 8, 2006), a medically unlikely edit tests claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of service units. Medicare contractors must deny the entire claim line when the service units billed exceed the specified number.

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<sup>1</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 between October 2005 and October 2011. Most, but not all, of the Medicare administrative contractors are fully operational; for jurisdictions where the Medicare administrative contractors are not fully operational, fiscal intermediaries and carriers continue to process claims. For purposes of the report, the term "Medicare contractor" means the fiscal intermediary, carrier, or Medicare administrative contractor, whichever is applicable.

<sup>2</sup> Pursuant to 42 CFR § 414.707(a)(1), the payment allowance limit in calendar year (CY) 2004 was 85 percent of the average wholesale price. However, beginning January 1, 2005, 42 CFR § 414.904(a) established the payment allowance limit as 106 percent of the average sales price.

<sup>3</sup> Neulasta is Amgen's registered trademark for the medication pegfilgrastim.

## **Payment for Neulasta**

Individuals receiving chemotherapy often suffer from a low white blood cell count. Providers inject patients with Neulasta, usually in 6-milligram doses, to stimulate bone marrow and promote the growth of white blood cells. For Part B drugs, including Neulasta, Medicare contractors determine the provider payment amount as the lesser of the Part B drug fee schedule amount times the number of units billed or the claimed amount.

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 they usually administer the drug in 6-milligram doses (generally from a prefilled syringe). Effective January 1, 2004, the HCPCS code changed to J2505 and identified a 6-milligram dose as one unit.

CMS documented the new HCPCS code J2505 for Neulasta with changes to its *Medicare Claims Processing Manual*, Pub. No. 100-04. On December 24, 2003, CMS issued Transmittal 54, Change Request 3022, to Medicare contractors that defined a service unit under HCPCS code J2505 as “injection, pegfilgrastim [Neulasta] 6mg.” On May 12, 2006, CMS issued Transmittal 949, Change Request 4380, to Medicare contractors (fiscal intermediaries but not carriers) clarifying the billing procedures for Neulasta. The change request stated: “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 HCPCS code J2505 as one dose of 6 milligrams was published three times in the Federal Register in 2004, beginning on January 6, 2004.

## **Medicare Contractors for Alaska, Arizona, and Washington**

During CYs 2004 through 2007, Noridian Administrative Services, LLC (Noridian), a subsidiary of Noridian Mutual Insurance Company (Noridian Insurance), was the Medicare contractor for providers in Alaska, Arizona, and Washington.<sup>4</sup> During this period, Noridian and Noridian Insurance processed and paid more than 108 million Part B claims, of which 41,317 claims included Neulasta injections in these three States.

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

### **Objective**

Our objective was to consolidate the results of our reviews of six selected Medicare Part B providers in Alaska, Arizona, and Washington that billed Medicare for Neulasta injections. Those reviews determined whether the six providers billed Medicare for the correct number of service units of Neulasta.

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<sup>4</sup> During our audit period, Noridian was the Medicare Part B carrier for Alaska and Washington, and in December 2006, it assumed responsibility as the Medicare administrative contractor for Arizona. Before December 2006, Noridian Insurance was the Medicare Part B carrier for Arizona. At the time of our audit, CMS had not selected the Medicare administrative contractor for Alaska and Washington.

## **Scope**

To select the providers, we identified paid Medicare Part B claims for Neulasta injections for which providers billed more than one service unit and had potential overpayments greater than \$5,000. We identified and reviewed 156 claims billed by 6 providers in Alaska, Arizona, and Washington that Noridian and Noridian Insurance processed and paid during CYs 2004 through 2007.

We did not review the six providers' internal controls because our objective did not require an understanding of controls over the submission of claims. However, we performed a limited review of internal controls applicable to the processing and paying of claims for Neulasta injections at the current Medicare contractor, Noridian. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

We conducted our fieldwork from February to October 2009, which included contacting the six providers in Alaska, Arizona, and Washington that received payments for Neulasta injections. In addition, we contacted officials from Noridian located in Fargo, North Dakota, from March to September 2010.

## **Methodology**

To determine whether the selected providers billed Medicare for the correct number of service units of Neulasta, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- used CMS's National Claims History file to identify paid Medicare Part B claims with more than one service unit of Neulasta that had not been reviewed in other audits;
- contacted the providers to determine whether the service units of Neulasta were billed correctly and, if not, why the service units were billed incorrectly;
- reviewed Medicare claim forms, patient medical records, and providers' additional supporting documentation that supported the identified claims;
- used the Medicare Part B drug fee schedules, published by CMS, to calculate overpayments identified in CYs 2004 through 2006; and
- confirmed with the providers that overpayments occurred.

We issued a restricted report to each of the six providers from October to December 2009.

We also interviewed staff from Noridian to determine whether it issued guidance to its providers and had any policies, system edits, or other claims processing controls to prevent overpayments for Neulasta.

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.

## **RESULTS OF REVIEWS AND RECOMMENDATION**

For 156 Medicare claims reviewed, 6 providers in Alaska, Arizona, and Washington billed Medicare for the incorrect number of service units of Neulasta. Consequently, during CYs 2004 through 2007, Noridian and Noridian Insurance paid these providers \$461,945 instead of \$308,867, resulting in overpayments totaling \$153,078.<sup>5</sup> Noridian and Noridian Insurance made these overpayments because the providers billed for more than one service unit for every 6 milligrams of Neulasta administered.

### **MEDICARE REQUIREMENTS**

CMS's *Carriers Manual*, Pub. No. 14, part 2, section 5261.1, requires that Medicare contractors process claims accurately in accordance with Medicare program laws, regulations, and instructions. Section 5261.3 of the manual requires Medicare contractors to develop a medical review program that "effectively and continually analyzes data that identifies aberrancies, emerging trends and areas of potential abuse, overutilization or inappropriate care, and focusing 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 Medicare contractors to pay for certain drugs based on the published average sales price. The maximum allowable payment equals the lesser of the Part B drug fee schedule amount times the number of units billed or the claimed amount. The Medicare contractor pays the provider 80 percent of the maximum allowable payment amount; the beneficiary pays the remaining 20 percent.

CMS's Transmittal 54, Change Request 3022, defined a service unit under HCPCS code J2505 as "injection, pegfilgrastim [Neulasta] 6mg." Therefore, during our audit period, for every 6 milligrams of Neulasta administered to a patient, providers should have billed Medicare for one service unit. The transmittal instructed Medicare contractors to inform providers of this requirement.

### **INCORRECT NUMBER OF SERVICE UNITS BILLED**

For all 156 claims reviewed, the 6 providers billed Medicare for the incorrect number of service units of Neulasta. Rather than billing one service unit for every 6 milligrams of Neulasta administered, as Medicare required, providers billed more than one service unit for every 6 milligrams. Specifically, for 155 of the 156 claims, 5 providers incorrectly billed for 6 service units rather than 1 service unit for every 6 milligrams of Neulasta. For the remaining claim, 1 provider billed for 4 service units rather than 1 service unit for every 6 milligrams of Neulasta.

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<sup>5</sup>All overpayments occurred for services provided during CYs 2004 through 2006.

Consequently, Noridian and Noridian Insurance paid these providers \$461,945 instead of \$308,867, resulting in overpayments totaling \$153,078.

The table below summarizes the results for all six providers reviewed.

**Neulasta Overpayments at the Six Providers**

<b>Provider</b>	<b>State</b>	<b>Calendar Year</b>	<b>No. of Claims</b>	<b>Medicare Payment</b>	<b>Correct Payment</b>	<b>Overpayment</b>
1	AK	2006	5	\$51,638	\$8,606	\$43,032
2	AZ	2004	20	94,464	38,114	56,350
3	AZ	2004	128	287,531	256,760	30,771
4	WA	2006	1	10,314	1,719	8,595
5	WA	2005	1	9,974	1,662	8,312
6	WA	2004	1	8,024	2,006	6,018
<b>Total</b>			<b>156</b>	<b>\$461,945</b>	<b>\$308,867</b>	<b>\$153,078</b>

All six providers agreed with our findings that they billed for the incorrect number of service units of Neulasta and refunded the overpayments to Medicare. The providers attributed the incorrect billing primarily to the change in the number of milligrams per service unit of Neulasta from 1 milligram to 6 milligrams.

**MEDICARE SYSTEM EDITS**

The medically unlikely edits that CMS required Medicare contractors to use starting in January 2007 did not include Neulasta injections. Therefore, during our audit period, Noridian and Noridian Insurance processed claims submitted by providers for more than one service unit of Neulasta.

**RECOMMENDATION**

We recommend that Noridian consider reviewing Neulasta claims with the incorrect number of service units that were not part of this review.

**NORIDIAN COMMENTS**

In its comments on our draft report, Noridian concurred with our recommendation and provided information on actions taken to implement the recommendation. Noridian’s comments are included in their entirety as the Appendix.

## **OTHER MATTER**

We reviewed CMS's National Claims History file to determine whether there were paid Medicare Part B claims with more than one service unit of Neulasta after our audit period. We identified two claims for Washington providers that billed Medicare for more than one service unit in CY 2008 with potential overpayments greater than \$5,000. Based on the Medicare Part B drug fee schedules published by CMS, we estimated that these providers received approximately \$10,000 in potential overpayments for more than one service unit of Neulasta.

In its comments on our draft report, Noridian provided information on actions taken to recoup the overpayments for these claims.

# **APPENDIX**

## APPENDIX: NORIDIAN ADMINISTRATIVE SERVICES, LLC, COMMENTS



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October 15, 2010

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San Francisco, CA 94103

RE: Report Number A-09-10-02044

Dear Ms. Ahlstrand:

Thank you for the opportunity to respond to the draft report of the U.S. Department of Health & Human Services, Office of Inspector General (OIG) dated September 30, 2010, entitled, *Review of Medicare Contractor Payments for Neulasta Injections in Alaska, Arizona, and Washington for Calendar Years 2004 Through 2007*.

We concur with the recommendation that Noridian review Neulasta claims with the incorrect number of service units that were not part of this review.

Noridian did review all Neulasta claims for the states of Alaska, Washington, Oregon, Montana, North Dakota, South Dakota, Wyoming, Utah and Arizona that were not part of this review. Noridian has recovered all overpayments related to this issue. In addition, Noridian has installed a claims processing edit that will only allow payment for 1 unit of J2505 Pegfilgrastim/Neulasta. Additionally, these corrective actions have addressed the item described in the "Other Matter" section of the report.

Please advise if additional information is needed or if further clarification is needed on any of our responses.

Sincerely,

/ Paul O'Donnell /

Paul O'Donnell  
Vice President  
Noridian Administrative Services, LLC