DEPARTMENT OF HEALTH & HUMAN SERVICES **OFFICE OF INSPECTOR GENERAL**

Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

June 23, 2010

Report Number: A-03-09-00022

Mr. Ernest L. Lopez
Chief Financial Officer
TrailBlazer Health Enterprises, LLC
8330 LBJ Freeway
Dallas, TX 75243

Dear Mr. Lopez:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Medicare Part B Carrier Payments for Neulasta Injections in Virginia 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.

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 at (215) 861-4470, 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-03-09-00022 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 235
Kansas City, MO 64106

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PART B CARRIER PAYMENTS FOR NEULASTA INJECTIONS IN VIRGINIA FOR CALENDAR YEARS 2004 THROUGH 2007

Daniel R. Levinson
Inspector General

June 2010
A-03-09-00022

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. 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 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. Physicians inject patients with pegfilgrastim (Neulasta), usually in 6-milligram doses, to stimulate bone marrow and promote the growth of white blood cells. Prior to January 1, 2004, CMS assigned Healthcare Common Procedure Coding System (HCPCS) code Q4053 to Neulasta injections and defined one unit of service as 1 milligram. On January 1, 2004, CMS changed the HCPCS code for Neulasta to J2505 and defined one unit of service as 6 milligrams, which represented a standard dose.

TrailBlazer Health Enterprises, LLC (TrailBlazer), was the Medicare Part B carrier for Virginia. During calendar years (CY) 2004 through 2007, TrailBlazer processed and paid almost 65 million Part B claims, of which 22,612 claims included Neulasta injections in Virginia. At the time of our audit, CMS had not selected the Medicare administrative contractor for Virginia.

OBJECTIVE

Our objective was to determine whether Medicare payments made by TrailBlazer for Neulasta injections in Virginia were appropriate.

SUMMARY OF FINDING

Medicare payments made by TrailBlazer for Neulasta injections in Virginia were generally appropriate. However, TrailBlazer paid one provider $3,304 for one payment when it should have paid $1,711, an overpayment of $1,593. (After we had identified the error, TrailBlazer indicated that the provider submitted a revised claim for adjustment and requested an offset of the overpayment amount against a current payment.)

TrailBlazer made the overpayment because the provider incorrectly claimed excessive units of service on one claim.

RECOMMENDATIONS

We recommend that TrailBlazer:

- verify that it has recovered the $1,593 overpayment and
- consider including its Neulasta edit in the "Medically Unlikely Edits."

TRAILBLAZER COMMENTS

TrailBlazer concurred with the finding and recommendations. As a result of the audit, TrailBlazer recovered the overpayments totaling $1,593 plus $14.94 interest on November 6, 2009. In addition, beginning July 2010, Neulasta will be subject to CMS's "Medically Unlikely Edits" that will deny Neulasta services when the billed quantity exceeds the maximum unit field of the edit. TrailBlazer's comments are included in 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

Prior to October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers.[1] 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 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.[2] CMS guidance also requires providers to bill accurately and to report units of service as the number of times 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, over 1 million claims included approximately $1.7 billion for pegfilgrastim (Neulasta[3]) injections.

"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, 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. Medicare contractors must deny the entire claim line when the units of service billed exceed the specified number.

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[1] 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 fiscal intermediary, carrier, or Medicare administrative contractor, whichever is applicable.

[2] In accordance with 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.

[3] 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. Physicians inject patients with Neulasta, usually in 6-milligram (mg) 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 mg. Providers billed for six units because they usually administer the drug in 6-mg doses (generally from a pre-filled syringe). Beginning January 1, 2004, the HCPCS code changed to J2505 and identified a 6-mg dose as one unit.

CMS documented the new HCPCS code J2505 for Neulasta with changes to its *Medicare Claims Processing Manual*, Pub. No. 100-4. On December 24, 2003, CMS issued Transmittal 54, Change Request 3022, to Medicare contractors that defined a unit of service under HCPCS code J2505 as "injection, pegfilgrastim 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 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 HCPCS code J2505 as one single dose of 6 mg was published three times in the Federal Register in 2004, beginning on January 6, 2004.

TrailBlazer Health Enterprises, LLC

TrailBlazer Health Enterprises, LLC (TrailBlazer), which administers the Medicare program under contracting arrangements with CMS, was the Medicare Part B carrier for Virginia.[4] During CYs 2004 through 2007, TrailBlazer processed and paid almost 65 million Part B claims, of which 22,612 claims included Neulasta injections in Virginia.

In December 2005, TrailBlazer implemented a system edit that suspended all claims for Neulasta when the provider billed for more than one unit.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments made by TrailBlazer for Neulasta injections in Virginia were appropriate.

Scope

We reviewed payments that TrailBlazer processed and paid in Virginia for Neulasta injections provided to Medicare patients during CYs 2004 through 2007. We limited our review of

[4] TrailBlazer headquarters is located in Dallas, Texas.

TrailBlazer'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.[5]

We performed our fieldwork from September through November 2009. Our fieldwork included contacting TrailBlazer, located in Dallas, Texas, and one provider in Virginia that received payments for Neulasta injections.

Methodology

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- used CMS's National Claims History file to identify Part B claims for Neulasta injections for six or more units of service with a paid amount greater than $2,006 that were not reviewed in other audits;
- identified one claim with Neulasta injections totaling $3,304 that was provided by one physicians to one Medicare patient;
- reviewed available Common Working File data for the one claim to determine whether the claim had been canceled and superseded by a revised claim and whether the payment remained outstanding at the time of our audit;
- analyzed Common Working File data for canceled claims for which revised claims had been submitted to determine whether the provider received an overpayment for the initial claim;
- contacted the provider to determine whether the claim for Neulasta was billed correctly and, if not, why the claim was billed incorrectly; and
- coordinated our claim review, including a review of system edits and manual processing controls, and the calculation of the overpayment, with TrailBlazer.

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.

[5] When the Common Working File history was not available due to the age of the claim, we obtained a claim history from TrailBlazer that contained comparable information.

FINDING AND RECOMMENDATIONS

Medicare payments made by TrailBlazer for Neulasta injections in Virginia were generally appropriate. However, TrailBlazer paid one provider $3,304 for the one payment reviewed when it should have paid $1,711, an overpayment of $1,593. (We identified this overpayment during the audit and TrailBlazer subsequently indicated that the provider requested an offset of the overpayment amount against a current payment.)

TrailBlazer made the overpayment because the provider incorrectly claimed excessive units of service on one claim.

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 payment amount; the beneficiary pays the remaining 20 percent.

EXCESSIVE UNITS OF SERVICE

TrailBlazer overpaid $1,593 for one claim for excessive units of service incorrectly billed by one Virginia provider. For the one claim reviewed, the provider incorrectly billed for 40 units of service rather than 1 unit of service for 6 mg of Neulasta.

The provider knew or should have known that the claim was billed in error because it exceeded the maximum allowable payment for a 6-mg dose of Neulasta by $1,593; however, the provider did not identify the reason for the error. After we had identified the error, TrailBlazer indicated that the provider submitted a revised claim for adjustment and requested an offset of the overpayment amount against a current payment.

TrailBlazer paid the one claim for excessive units of service because it did not have edits in place during CYs 2004 or 2005 to ensure that the units of Neulasta billed corresponded to the units administered.

TRAILBLAZER SYSTEM EDITS

In December 2005, TrailBlazer implemented a system edit that suspended all claims for which the provider billed for more than one unit of Neulasta.

In January 2007, CMS required Medicare contractors to implement units-of-service edits referred to as "medically unlikely edits." These edits detect and deny unlikely Medicare claims on a prepayment basis by testing claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of units of service. However, the medically unlikely edits did not include Neulasta injections.

RECOMMENDATIONS

We recommend that TrailBlazer:

- verify that it has recovered the $1,593 overpayment and
- consider including its Neulasta edit in the "Medically Unlikely Edits."

TRAILBLAZER COMMENTS

TrailBlazer concurred with the finding and recommendations. As a result of the audit, TrailBlazer recovered the overpayments totaling $1,593 plus $14.94 interest on November 6, 2009. In addition, beginning July 2010, Neulasta will be subject to CMS's "Medically Unlikely Edits" that will deny Neulasta services when the billed quantity exceeds the maximum unit field of the edit. TrailBlazer's comments are included in the Appendix.

APPENDIX

MEDICARE

June 15, 2010

Stephen Virbitsky
Regional Inspector General for Audit Services
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Report Number: A-03-09-00022

Dear Mr. Virbitsky:

We received the May 3, 2010, draft report entitled "Medicare Part B Carrier Payments for Neulasta Injections in Virginia for Calendar Years 2004 Through 2007." In the draft report, the OIG recommended that TrailBlazer:

- Verify we have recovered the $1,593 overpayment; and
- Consider including its Neulasta edit in the "Medically Unlikely Edits."

Please consider the following responses to these recommendations for inclusion in the final report:

Recovery of Overpayments: On September 24, 2009, TrailBlazer issued a demand letter for the $1,593 overpayment determined during this OIG review. On November 6, 2009, the full amount of the overpayment plus $14.94 in interest was collected by offset. Confirmation of the collection of this debt was submitted to [redacted] on December 16, 2009.

Medically Unlikely Edit (MUE): Effective with the Multi-Carrier System (MCS) July 2010 quarterly release, Neulasta will be subject to MUE 207A. Under this new MUE, claims with Neulasta units exceeding the maximum unit field on the MU screen in MCS will auto deny with the denial reason code DA90. This MUE is at the direction of CMS.

If you have any questions regarding our response, please contact me.

Sincerely,

/s/ Melissa H. Rhoades

Melissa Halstead Rhoades
Area Director & Medicare CFO

cc: Terry Bird, Contracting Officer Technical Rep., Southern MAC Program Mgmt. Division
Gil R. Glover, President & Chief Operating Officer
Scott J. Manning, Vice President, Financial Management Operations
Kevin Bidwell, Vice President & Compliance Officer

Office of Inspector General Note - The deleted text has been redacted because it is personally identifiable information.