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

June 19, 2012

Report Number: A-03-12-00009

Mr. Frank Riccardi
Chief Compliance Officer
Virginia Commonwealth University Medical Center
P.O. Box 980471
Richmond, VA 23298-0471

Dear Mr. Riccardi:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Virginia Commonwealth University Medical Center Incorrectly Billed Medicare for the Biological Drug Myozyme*. 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-03-12-00009 in all correspondence.

Sincerely,

/Stephen Virbitsky/
Regional Inspector General
for Audit Services

Enclosure

Cc: Ms. Yvonna Ruff, Director, Part A Claims, Palmetto GBA, LLC

Direct Reply to HHS Action Official:

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

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

VIRGINIA COMMONWEALTH UNIVERSITY MEDICAL CENTER INCORRECTLY BILLED MEDICARE FOR THE BIOLOGICAL DRUG MYOZYME

Daniel R. Levinson
Inspector General

June 2012
A-03-12-00009

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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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

Myozyme (alglucosidase alfa) is a biological drug used for the treatment of patients with Pompe disease, a debilitating, progressive, and often fatal hereditary disorder with onset in infancy or later in life. Providers bill Medicare 5 units of service for each single-use 50-milligram vial of Myozyme. The recommended dose for Myozyme is 20 milligrams for each kilogram of body weight. A patient weighing 100 kilograms (220 pounds) would require a recommended dose of 2,000 milligrams (40 vials). Therefore, billed units in excess of 200 (40 vials times 5 units per vial) are likely to result in an overpayment.

In 2010, Lumizyme, a new formulation of alglucosidase alfa, was approved for the treatment of patients with late onset of the disease. Providers bill Medicare 50 units of service for each single-use 50-milligram vial of Lumizyme. Both Myozyme and Lumizyme are registered trademarks for the biological drug alglucosidase alfa, manufactured by Genzyme Corporation, a wholly owned subsidiary of Sanofi-aventis.

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. Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims.

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. CMS assigned HCPCS code J0220 for Myozyme, with a narrative description of "injection, alglucosidase alfa, 10 mg [milligrams]," and HCPCS code C9277 for Lumizyme, with a narrative description of "injection, alglucosidase alfa (Lumizyme), 1 mg [milligram]."

During our audit period (January 1, 2010, through December 31, 2011), Virginia Commonwealth University Medical Center (the Medical Center) received payments from Medicare totaling $717,648 for 12 line items for Myozyme administered to one beneficiary. Of these 12 line items, 2 line items totaling $532,623 were each billed for 1,700 units. 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 the Medical Center billed and was correctly paid by Medicare for the biological drug Myozyme.

SUMMARY OF FINDING

The two line items that we reviewed were incorrect. For each line item, the Medical Center incorrectly billed Medicare for 1,700 units of service for Myozyme, rather than for 1,700 units of service for Lumizyme, the formulation of the drug alglucosidase alfa actually administered. The Medical Center used the incorrect HCPCS code and as a result, it received a total of $532,623 for the two line items when it should have received only $48,208, an overpayment of $484,415. At the time of our audit, these overpayments remained outstanding from the Medical Center.

RECOMMENDATIONS

We recommend that the Medical Center:

- refund to the Medicare contractor the $484,415 in identified overpayments and
- strengthen controls to ensure full compliance with Medicare requirements.

MEDICAL CENTER COMMENTS

In response to our audit inquiry, the Medical Center agreed with our finding and described the action it planned to take to correct the errors. The Medical Center's comments, excluding attachments that provided technical support for the finding, are included as the appendix.

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INTRODUCTION

BACKGROUND

Myozyme (alglucosidase alfa) is a biological drug used for the treatment of patients with Pompe disease, a debilitating, progressive, and often fatal hereditary disorder with onset in infancy or later in life. Providers bill Medicare 5 units of service for each single-use 50-milligram vial of Myozyme. The recommended dose for Myozyme is 20 milligrams for each kilogram of body weight. A patient weighing 100 kilograms (220 pounds) would require a recommended dose of 2,000 milligrams (40 vials). Therefore, billed units in excess of 200 (40 vials times 5 units per vial) are likely to result in an overpayment.

In 2010, Lumizyme, a new formulation of alglucosidase alfa, was approved for the treatment of patients with late onset of the disease. Providers bill Medicare 50 units of service for each single-use 50-milligram vial of Lumizyme.[1]

The Medicare Program

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, among other things, process and pay claims submitted for outpatient services. Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims.

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)[2] code for drugs administered and report units of service in multiples of the units shown in the HCPCS narrative description. When 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.

Virginia Commonwealth University Medical Center

Virginia Commonwealth University Medical Center (the Medical Center) is a 719-bed acute care hospital located in Richmond, Virginia. The Medical Center is part of the Virginia

[1] Both Myozyme and Lumizyme are registered trademarks for the biological drug alglucosidase alfa, manufactured by Genzyme Corporation, a wholly owned subsidiary of Sanofi-aventis. Biological drugs are substances made from a living organism or its products that are used to prevent, diagnose, treat, or relieve symptoms of a disease.

[2] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

Commonwealth University Health System. Palmetto GBA, LLC (Palmetto), is the current Medicare contractor for the Medical Center.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Medical Center billed and was correctly paid by Medicare for the biological drug Myozyme.

Scope

During our audit period (January 1, 2010, through December 31, 2011), the Medical Center received payments from Medicare totaling $717,648 for 12 line items for Myozyme administered to one beneficiary. For 10 of the 12 line items, the Medical Center billed Medicare for 170 units or less; for each of the remaining 2 line items the Medical Center billed Medicare for 1,700 units.

We limited our review to the two line items for which the Medical Center billed for 1,700 units each and was paid $532,623, because the number of units billed was greater than the recommended dose. We did not review the remaining 10 line items because the units billed were consistent with the recommended dose.

We limited our review of the Medical Center'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 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 during April and May 2012 by contacting the Medical Center in Richmond, Virginia, and Palmetto in Columbia, South Carolina.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- analyzed CMS's National Claims History file to identify claims for injected drugs potentially at risk for noncompliance with selected Medicare billing requirements;
- identified two line items totaling $532,623 for Myozyme (HCPCS code J0220) billed by the Medical Center for unit counts (1,700 units for each line item) that appear to exceed the recommended dose;
- contacted the Medical Center to determine whether the billed units for the selected line items were correct and, if not, why the billed units were incorrect;

- reviewed patient medical records, specifically the physician orders and drug administration records, to verify whether each selected line item was billed correctly;

- coordinated the calculation of overpayments with the Medicare contractor; and

- discussed the results of our review with Medical Center 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.

FINDING AND RECOMMENDATIONS

The two line items that we reviewed were incorrect. For each line item, the Medical Center incorrectly billed Medicare for 1,700 units of service for Myozyme, rather than for 1,700 units of service for Lumizyme, the formulation of the drug alglucosidase alfa actually administered. The Medical Center used the incorrect HCPCS code and as a result, it received a total of $532,623 for the two line items when it should have received only $48,208, an overpayment of $484,415. At the time of our audit, these overpayments remained outstanding from the Medical Center.

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 *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 17, section 90.2.A states: "It is also of great importance that hospitals billing for these products [drugs, biologicals, and radiopharmaceuticals] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity … that was used in the care of the patient." 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, and 200 mg are provided, units are shown as 4 …." 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."

MEDICARE BILLING FOR MYOZYME AND LUMIZYME

Myozyme (alglucosidase alfa) is a biological drug used for the treatment of patients with Pompe disease with onset in infancy or later in life. CMS assigned HCPCS code J0220 for Myozyme, with a narrative description of "injection, alglucosidase alfa, 10 mg [milligrams]." Providers bill Medicare 5 units of service (50 milligrams divided by 10 milligrams per unit) for each single-use 50-milligram vial of Myozyme.

Lumizyme is a formulation of alglucosidase alfa used for the treatment of patients with late onset of Pompe disease. Effective January 1, 2011, CMS assigned HCPCS code C9277 for Lumizyme, with a narrative description of "injection, alglucosidase alfa (Lumizyme), 1 mg [milligram]." Providers bill Medicare 50 units of service (50 milligrams divided by 1 milligram per unit) for each single-use 50-milligram vial of Lumizyme.

The recommended dose for both Myozyme and Lumizyme is 20 milligrams for each kilogram of body weight. Providers administer multiple single-use vials during each patient treatment and bill Medicare for each vial administered, including any waste. A patient weighing 100 kilograms (220 pounds) would require a recommended dose of 2,000 milligrams (40 vials). For Myozyme, the provider would bill Medicare for 200 units; for Lumizyme, 2,000 units.[3]

INCORRECT HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODE

For the two line items reviewed, the Medical Center used the incorrect HCPCS code, resulting in overpayments totaling $484,415. For both line items, the Medical Center billed Medicare for 1,700 units of service using HCPCS code J0220 (Myozyme) rather than HCPCS code C9277 (Lumizyme), the formulation of alglucosidase alfa actually administered. As a result, the Medical Center received payments totaling $532,623 for the two line items reviewed when it should have received only $48,208, an overpayment of $484,415. At the time of our audit, these overpayments remained outstanding.

RECOMMENDATIONS

We recommend that the Medical Center:

- refund to the Medicare contractor the $484,415 in identified overpayments and
- strengthen controls to ensure full compliance with Medicare requirements.

MEDICAL CENTER COMMENTS

In response to our audit inquiry, the Medical Center agreed with our finding and described the action it planned to take to correct the errors. The Medical Center's comments, excluding attachments that provided technical support for the finding, are included as the appendix.

[3] Effective January 1, 2012, Medicare changed the narrative description for HCPCS code J0220 to "alglucosidase alfa 10 mg, *not otherwise specified*," and changed the code and the narrative description for HCPCS code C9277 to HCPCS code J0221, "alglucosidase alfa 10 mg, (Lumizyme)."

APPENDIX

APPENDIX: MEDICAL CENTER COMMENTS

VCU
Virginia Commonwealth University
Medical Center
In the tradition of the Medical College of Virginia

MCV Campus
Department of Assurance Services
830 East Main Street, Suite 1800
P.O. Box 980471
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May 22, 2012

Mr. John Carlucci
Senior Auditor
Office of Audit Services, Region III
150 S. Independence Mall West
Philadelphia, PA 19105

Subject: Report Number **A-03-12-00009**

In response to our conversation and your letter of April 27, 2012, Virginia Commonwealth University Health System (VCUHS) is in agreement with the over-payment of $484.415. Our records did not support the billing of 1700 units of J0220 (Myozyme). The documentation reflects the administration of 1700 mg (1 mg = 1 unit) of C9277 (Lumizyme) for services provided in 2011. I have also attached the HCPCS Codebook from 2011 with instructions regarding C9277. Per your instructions, we have begun the process to refund and submit corrected billing to the Region 11 MAC, Palmetto.

If you have any questions or if additional information is required, please contact my office at (804) 828-0500.

Sincerely,

Jill McCormack

Jill McCormack, Director
Compliance Services

Cc Linda B. McLaughlin, Director
Financial/Governmental Services