DEPARTMENT OF HEALTH & HUMAN SERVICES





Office of Audit Services, Region IV 61 Forsyth Street, SW, Suite 3T41 Atlanta, GA 30303

December 12, 2011

Report Number: A-04-11-06139

Mr. Dean M. Harrison President and CEO Northwestern Memorial Healthcare 251 E. Huron Chicago, IL 60611

Dear Mr. Harrison:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Northwestern Memorial Hospital in Chicago, Illinois, Met Applicable Medicare Payment Requirements for Yttrium-90 Brachytherapy Claims*. We will forward a copy of this report to the HHS action official noted below.

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 direct them to the HHS action official. Please refer to report number A-04-11-06139 in all correspondence.

Sincerely,

/Lori S. Pilcher/
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

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, Missouri 64106

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NORTHWESTERN MEMORIAL HOSPITAL IN CHICAGO, ILLINOIS, MET APPLICABLE MEDICARE PAYMENT REQUIREMENTS FOR YTTRIUM-90 BRACHYTHERAPY CLAIMS



Daniel R. Levinson Inspector General

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Office of Inspector General

http://oig.hhs.gov

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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.

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, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Brachytherapy

Brachytherapy is a radiation therapy used to treat cancer. The American Medical Association defines "clinical brachytherapy" as "the use of either natural or man-made radioelements applied into or around a treatment field of interest. The supervision of radioelements and dose interpretation are performed solely by the therapeutic radiologist." The American Brachytherapy Society defines "permanent" brachytherapy as a treatment in which seeds or sources remain inside the body and "temporary" brachytherapy as placement of radiation sources for a set duration before being removed. Two types of permanent sources are radioactive seeds and Yttrium-90 microspheres.

Yttrium-90 Microspheres

Two Yttrium-90 products are approved by the Food and Drug Administration and commercially available: Theraspheres, manufactured by MDS Nordion in Canada, and SIR-Spheres, manufactured by Sirtex Medical Limited in Australia. Yttrium-90 microspheres are brachytherapy sources used to treat cancer that has spread to the liver. The interventional radiologist delivers the microspheres using a catheter. Both manufacturers indicate that each therapeutic treatment order is intended for a single patient.

Medicare Payments for Brachytherapy Sources

Yttrium-90 microspheres are reimbursed using Healthcare Common Procedure Coding System code C2616. Section 1833(t) (16) (C) of the Act states that the payment for a device or radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or radiopharmaceutical furnished, adjusted to cost. The formula for the calculation of this cost is the extension of the hospital's cost-to-charge ratios times the Medicare charges for the sources. ¹

NORTHWESTERN MEMORIAL HOSPITAL

Northwestern Memorial Hospital (Northwestern) is an 894-bed academic medical center located in Chicago, Illinois. From September 1, 2008, through August 31, 2010, Northwestern billed Medicare for 177 Yttrium-90 microsphere brachytherapy treatments.

¹ The Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275, § 142 amended § 1833(t)(16)(C) of the Act to extend this payment methodology through December 31, 2009.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Northwestern met applicable Medicare payment requirements for Yttrium-90 brachytherapy claims.

Scope

We reviewed all 177 Medicare outpatient Yttrium-90 brachytherapy paid claims totaling \$3,439,533 for Northwestern's cost-reporting periods from September 1, 2008, through August 31, 2010.

We limited our review of Northwestern'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 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 performed fieldwork in May 2011 at Northwestern in Chicago, Illinois.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed Illinois Administrative Codes regulating control of radioactive materials;
- used CMS's National Claims History file to identify paid outpatient Medicare claims containing brachytherapy HCPCS codes;
- selected all 177 outpatient Medicare claims containing Yttrium-90 brachytherapy HCPCS codes for Northwestern from September 1, 2008, through August 31, 2010;
- reviewed Medicare claim forms, patient medical records and Northwestern's additional supporting documentation for the identified claims;
- reviewed required logs, inventories, and additional documentation supporting that Northwestern met all State regulatory requirements for the proper handling, tracking, and disposal of radioactive sources required for Medicare payment for brachytherapy sources; and
- reviewed purchase orders, invoices, proof of payment, and medical records to determine
 whether any brachytherapy sources billed to Medicare were either unused or used in the
 treatment of multiple patients.

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 REVIEW

Northwestern met applicable Medicare payment requirements for all 177 claims for Yttrium-90 brachytherapy. Therefore, we are making no recommendations.