



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

February 6, 2012

Report Number: A-04-11-06135

Ms. Suzanne Freeman  
Divisional President  
Carolinas Medical Center  
P.O. Box 32861  
Charlotte, NC 28232-2861

Dear Ms. Freeman:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Outpatient Brachytherapy Medicare Payments to Carolinas Medical Center*. 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 Andrew Funtal, Audit Manager, at (404) 562-7762 or through email at [Andrew.Funtal@oig.hhs.gov](mailto:Andrew.Funtal@oig.hhs.gov). Please refer to report number A-04-11-06135 in all correspondence.

Sincerely,

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

Enclosure

**Direct Reply to HHS Action Official:**

Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management & Fee for Service Operations  
Centers for Medicare & Medicaid Services  
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Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF OUTPATIENT  
BRACHYTHERAPY MEDICARE PAYMENTS  
TO CAROLINAS MEDICAL CENTER**



Daniel R. Levinson  
Inspector General

February 2012  
A-04-11-06135

# *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 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 administers the program.

Brachytherapy is an advanced cancer treatment in which radioactive seeds, or sources, are permanently or temporarily placed in or near the tumor itself, giving a radiation dose to the tumor while reducing the radiation exposure in the surrounding healthy tissues.

Carolinas Medical Center (Carolinas) is an 874-bed acute care hospital located in Charlotte, North Carolina. From January 1, 2008, through June 30, 2010, Carolinas billed Medicare for 234 brachytherapy treatments: 72 for Iodine-125 and Paladium-103 seeds, 73 for Iridium-192 treatments, and 89 for Yttrium-90 microsphere treatments.

### **OBJECTIVE**

Our objective was to determine whether Carolinas met applicable Medicare payment requirements for brachytherapy claims.

### **SUMMARY OF FINDINGS**

Carolinas met applicable Medicare payment requirements for all 72 seed claims and all 89 Yttrium-90 claims. However, 8 of the 73 claims for Iridium-192 did not meet applicable Medicare payment requirements resulting in overpayments of \$5,959. These eight claims were in error for the following reasons:

- For 7 of the 8 claims, Carolinas reported administering 130 service units, instead of the 17 service units it actually used, which resulted in overpayments of \$5,907.
- For one of the eight claims, Carolinas inadvertently billed for four service units, but only three were supported by the medical records, which resulted in an overpayment of \$52.

Carolinas attributed these errors to its new coding staff.

### **RECOMMENDATION**

We recommend that Carolinas refund \$5,959 in Medicare overpayments for improper brachytherapy claims.

### **CAROLINAS COMMENTS**

In its comments on the draft report, Carolinas concurred with our findings and is in the process of working with Palmetto GBA to refund the overpayments we recommended. Carolinas stated

that the billing errors occurred because of inadvertent keying errors. Carolinas further stated that it has trained all staff responsible for coding and entering charges to reduce the occurrence of errors.

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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, 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, and one type of temporary source is Iridium-192.

### Radioactive Seeds

Prostate seed implantation is a type of brachytherapy in which radioactive metallic seeds smaller than a grain of rice are permanently placed inside the prostate gland via an injection. This therapy delivers a dose of radiation directly to the tumor. The number of seeds needed for treatment is determined by the size of the prostate gland and the dose of radiation prescribed. Typically, between 70 and 150 Iodine-125 or Palladium-103 seeds are placed during a single procedure.

### Iridium-192

Iridium-192 is a temporary single-source brachytherapy in the form of a wire and is used for High Dose Radiation (HDR) treatments on multiple patients. An HDR afterloader remotely administers the dosage to the patient. The afterloader delivers the wire dose through separate channels, which consist of small openings on the side of the machine. Depending on the type of dosage being administered, the wire source extends through one of the channels and into an application cylinder to administer treatment to the patient at different dwell positions (insertion points within the body). The wire source sits at a dwell position for a timed duration before retracting to a new dwell position for another timed duration.

### 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**

The brachytherapy seeds, Iridium-192, and Yttrium-90 microspheres are reimbursed using Healthcare Common Procedure Coding System codes C1716 through C1719, C2616, and C2634 through C2699. 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 ratio times the Medicare charges for the sources.<sup>1</sup>

### **Carolinas Medical Center**

Carolinas Medical Center (Carolinas) is an 874-bed acute care hospital located in Charlotte, North Carolina. Carolinas is part of the Carolinas Healthcare System. From January 1, 2008, through June 30, 2010, Carolinas billed Medicare for 234 brachytherapy treatments: 72 for Iodine-125 and Paladium-103 seeds, 73 for Iridium-192 treatments, and 89 for Yttrium-90 microsphere treatments.

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

### **Objective**

Our objective was to determine whether Carolinas met applicable Medicare payment requirements for brachytherapy claims.

### **Scope**

We reviewed all 234 Medicare outpatient brachytherapy paid claims totaling \$2,264,224 for Carolinas' cost reporting periods from January 1, 2008, through June 30, 2010.

We limited our review of Carolinas' 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 from February through March 2011 at Carolinas in Charlotte, North Carolina.

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<sup>1</sup> 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.

## Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the *North Carolina Regulations for Protection Against Radiation* that regulate control of radioactive materials;
- used CMS's National Claims History file to identify paid outpatient Medicare claims containing brachytherapy Healthcare Common Procedure Coding System (HCPCS) codes;
- selected all 234 outpatient Medicare claims containing brachytherapy HCPCS codes for Carolinas for January 1, 2008, through June 30, 2010;
- reviewed Medicare claim forms, patient medical records and Carolinas' additional supporting documentation for the identified claims;
- reviewed required logs, inventories, and additional documentation supporting that provider 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.

## FINDINGS AND RECOMMENDATION

Carolinas met applicable Medicare payment requirements for all 72 seed claims and all 89 Yttrium-90 claims. However, 8 of the 73 claims for Iridium-192 did not meet applicable Medicare payment requirements resulting in overpayments of \$5,959. These eight claims were in error for the following reasons:

- For 7 of the 8 claims, Carolinas reported administering 130 service units, instead of the 17 service units it actually used, which resulted in overpayments of \$5,907.

- For one of the eight claims, Carolinas inadvertently billed for four service units, but only three were supported by the medical records, which resulted in an overpayment of \$52.

Carolinas attributed these errors to its new coding staff.

## **FEDERAL REQUIREMENTS**

### **Medicare Requirements for Cost Reimbursement Payments**

*The Medicare Claims Processing Manual*, Publication 100-04, chapter 4, section 61.4.1 states:

Each unit of a billable source is identified by the unit measurement in the respective source's long descriptor. Seed-like sources are generally billed and paid "per source" based on the number of units of the source HCPCS code reported, including the billing of the number of sources within a stranded configuration of sources. Providers therefore must bill the number of units of a source used with the brachytherapy service rendered.

### **Nuclear Regulatory Commission Requirements**

The U.S. Nuclear Regulatory Commission (NRC) regulates nuclear materials, including those used in nuclear medicine. The NRC provides assistance to States expressing interest in establishing programs to assume NRC regulatory authority. Section 274 of the Atomic Energy Act of 1954, as amended, provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate by-product material, source material, and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Atomic Energy Act of 1954, amended. North Carolina signed such an agreement with NRC.

## **MEDICARE OVERPAYMENTS**

### **Overpayments Resulting From Incorrect Number of Service Units**

Carolinas erroneously billed for 114 service units on 8 claims for Iridium-192. For seven of these eight improper claims, Carolinas reported 130 service units, the number of dwell positions (insertion points in the body), instead of 17 service units, the number of sources used. For the remaining claim, Carolinas inadvertently billed for 4 service units, but only 3 were supported by the medical records.

The overstatement of service units for these 8 claims resulted in Medicare overpayments totaling \$5,959.

## **OVERSTATEMENT OF SERVICE UNITS**

Carolinas attributed these errors to its new coding staff.

## **RECOMMENDATION**

We recommend that Carolinas refund \$5,959 in Medicare overpayments for improper brachytherapy claims.

## **CAROLINAS COMMENTS**

In its comments on the draft report, Carolinas concurred with our findings and is in the process of working with Palmetto GBA to refund the overpayments we recommended. Carolinas stated that the billing errors occurred because of inadvertent keying errors. Carolinas further stated that it has trained all staff responsible for coding and entering charges to reduce the occurrence of errors.

# **APPENDIX**



**Carolinan HealthCare System  
Carolinan Medical Center**

1000 Blythe Boulevard  
Charlotte, NC 28232

November 30, 2011

Carolinan Medical Center #340113  
Report Number: A-04-11-06135

Lori S. Pilcher  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Office of Inspector General, Office of Audit Services, Region IV  
61 Forsyth Street, SW, Suite 3T41  
Atlanta, Georgia 30303

Dear Ms. Pilcher:

Carolinan Medical Center (CMC) has received a draft report from the Department of Health & Human Services, Office of the Inspector General entitled "*Review of Outpatient Brachytherapy Medicare Payments to Carolinas Medical Center*". Carolinas Medical Center has had an opportunity to review the report and is generally in agreement with the findings.

As the report states, the OIG reviewed 234 brachytherapy treatments provided at CMC from January 1, 2008 through June 30, 2010. The auditors concluded that CMC had received \$5,959 in overpayments for this period and recommends that these overpayments are refunded to the Medicare program. The OIG, in addition, requests a statement of corrective actions taken or planned for each concurrence.

CMC concurs with the OIG's findings regarding the overpayments cited in the report. Refunds are in the process of being processed with Palmetto GBA, the North Carolina A/B MAC. A root cause analysis was performed contemporaneous with the audit field engagement to detect the circumstances that led to these unintentional claims errors. Our internal investigation revealed that the dwell points calculation required to determine the accurate CPT code for High-Density Radiation (HDR) therapy, was inadvertently keyed into the service unit field in these circumstances. Education has been provided to all staff responsible for coding and entering charges to reduce the risk of these types of errors from occurring in the future.

CMC will continue to monitor the audited areas and will update controls to promote compliance as necessary.

CMC is dedicated to maintaining accurate claims billing. Our Corporate Compliance Program has systems in place to continuously monitor coding and billing. If errors are detected internally or identified by an external organization, we are committed to resolving the errors and refunding any associated overpayments. If CMC determines other claims overpayments occurred as a result of these inadvertent errors, they will be refunded in accord with required timeframes.

CMC appreciates the opportunity to remediate these unintentional billing errors. We acknowledge the complexity of the clinical service and how it relates to the billing and coding regulations in this instance. Please do not hesitate to contact me or Sara Herron, VP Corporate Compliance, at (704) 512-5931 or through email at [sara.herron@carolinanhealthcare.org](mailto:sara.herron@carolinanhealthcare.org) if you have questions about the hospital's effort in this regard or if you require additional information.

Sincerely,

Suzanne Freeman, President  
Carolinan Medical Center