



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION IV  
61 FORSYTH STREET, SW, SUITE 3T41  
ATLANTA, GA 30303

April 30, 2012

Report Number: A-04-10-06131

Mr. Jim Wilson  
Chief Executive Officer  
Lakewood Ranch Medical Center  
8330 Lakewood Ranch Boulevard  
Bradenton, FL 34202

Dear Mr. Wilson:

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 Lakewood Ranch 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-04-10-06131 in all correspondence.

Sincerely,

/Lori S. Pilcher/  
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  
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Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF OUTPATIENT  
BRACHYTHERAPY MEDICARE PAYMENTS  
TO LAKEWOOD RANCH  
MEDICAL CENTER**



Daniel R. Levinson  
Inspector General

April 2012  
A-04-10-06131

# *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 radiation exposure in the surrounding healthy tissues.

Lakewood Ranch Medical Center (Lakewood) is a 120-bed acute care hospital located in Bradenton, Florida. Lakewood is a member of the Manatee Healthcare System and is a subsidiary of Universal Health Services, Inc., King of Prussia, Pennsylvania. In calendar years 2008 and 2009, Lakewood billed Medicare for 108 brachytherapy treatments: 65 for Yttrium-90 microspheres (SIR-Spheres), 30 for catheter insertion, 12 for Iodine-125 seeds, and 1 for Technetium-99m liquid source.

### **OBJECTIVE**

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

### **SUMMARY OF FINDINGS**

Lakewood met applicable Medicare payment requirements for all 43 claims for catheter insertion, Iodine-125 seeds, and a Technetium-99m source. However, none of the 65 SIR-Sphere claims met applicable Medicare payment requirements, resulting in overpayments of \$761,534. These 65 claims were in error for the following reasons:

- Lakewood used a single vial of SIR-Spheres to treat 2 separate patients on 43 claims, which resulted in overpayments of \$483,137.
- Lakewood lacked required Medicare documentation showing proper handling and disposal of unused brachytherapy sources on 19 claims, which resulted in overpayments of \$223,202.
- Lakewood billed for undelivered brachytherapy on two claims, which resulted in overpayments of \$38,138.
- Lakewood billed for an unsupported service on one claim, which resulted in an overpayment of \$17,057.

Lakewood improperly billed these claims because it did not have policies and procedures to account for partial vial usage or handling, tracking, or proper disposition of the unused portion of a vial, and it did not follow its procedures for ordering brachytherapy sources.

## **RECOMMENDATIONS**

We recommend that Lakewood:

- refund to the Medicare program \$761,534 in overpayments for improper brachytherapy claims;
- develop and implement procedures to ensure that all brachytherapy sources are billed correctly; and
- develop and implement procedures for handling, tracking, and disposing of all radioactive brachytherapy sources, with special emphasis on Yttrium-90 disposal requirements.

## **LAKEWOOD COMMENTS**

In its comments on our draft report, Lakewood did not fully agree with our recommendations. Because Lakewood could find no specific prohibition against billing multiple times for a single vial of Yttrium-90 SIR-Spheres, it will continue to do so. In addition, Lakewood stated that the physical inventory requirements in the Florida Administrative Codes (F.A.C.) governing the use and handling of Yttrium-90 and Medicare billing requirements are not applicable to SIR-Spheres because they are not traditional brachytherapy sources. After removing personal patient information, we included Lakewood's comments as the Appendix.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

We maintain that our findings and recommendations are valid. Because Lakewood administered one vial of SIR-Spheres to two different patients and billed Medicare (or other insurance) for two vials, Medicare paid twice for the same vial. In addition, Lakewood has not adhered to the F.A.C.s regarding decay in storage, which they cited in their response. Therefore, Lakewood did not meet the Medicare requirements for payment of unused microspheres.

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LAKWOOD RANCH MEDICAL CENTER COMMENTS

# 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 the seeds, or “sources,” remain inside the body. Two types of permanent sources are radioactive seeds and Yttrium-90 microspheres.

### 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.

### 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. Lakewood Ranch Medical Center (Lakewood) uses only Sirtex Yttrium-90 microspheres (SIR-Spheres). The therapeutic radiologist calculates the dose, and the oncologist delivers the microspheres using a catheter. Each therapeutic treatment order<sup>1</sup> (vial) of SIR-Spheres is intended for a single patient.

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<sup>1</sup> A standard therapeutic treatment order from the manufacturer is three GigaBecquels of Yttrium-90 microspheres in a vial of 5 cubic centimeters (cc) of water solution.

## **Yttrium-90 Usage**

Yttrium-90 microspheres have a physical half-life of 64.1 hours, which means that after approximately 64 hours, they lose 50 percent of their potency.<sup>2</sup> Therefore, timing of implantation into the patient is crucial for positive treatment outcomes.

## **Medicare Payments for Brachytherapy Sources**

The brachytherapy catheter is reimbursed using Healthcare Common Procedure Coding System (HCPCS) code 55875, and the seeds and microspheres are reimbursed using HCPCS codes C1716 through C1719, C2616, and C2632 through C2699. Section 1833(t)(16)(C) of the Act states that the payment basis for the device or therapeutic radiopharmaceutical under this subsection must be equal to the hospital's charges for each device or radiopharmaceutical furnished, adjusted to cost.<sup>3</sup> 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.

## **Lakewood Ranch Medical Center**

Lakewood is a 120-bed acute care hospital located in Bradenton, Florida. Lakewood is a member of the Manatee Healthcare System and a subsidiary of Universal Health Services, Inc. In calendar years (CY) 2008 and 2009, Lakewood billed Medicare for 108 brachytherapy treatments: 65 for SIR-Spheres, 30 for catheter insertion, 12 for Iodine-125 seeds, and 1 for Technetium-99m liquid source.

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

### **Objective**

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

### **Scope**

We reviewed all 108 Medicare outpatient brachytherapy paid claims, totaling \$1,655,080, for Lakewood's cost reporting periods from January 1, 2008, through December 31, 2009 (CYs 2008 and 2009).

We limited our review of Lakewood'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

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<sup>2</sup> PerkinElmer, Inc., "Yttrium-90 Handling Precautions." Available online at [http://www.perkinelmer.com/CMSResources/Images/44-74001tch\\_yttrium90.pdf](http://www.perkinelmer.com/CMSResources/Images/44-74001tch_yttrium90.pdf). Accessed on June 28, 2011.

<sup>3</sup> The Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 142 amended § 1833(t)(16)(C) of the Act to extend this payment methodology through December 31, 2009.

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 September through October 2010 at Lakewood in Bradenton, Florida.

## **Methodology**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed Florida State 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 108 outpatient Medicare claims containing brachytherapy HCPCS codes for Lakewood for CYs 2008 and 2009;
- reviewed Medicare claim forms, patient medical records, and Lakewood's additional supporting documentation for the identified claims;
- reviewed required logs, inventories, and additional documentation supporting that Lakewood met all 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 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 RECOMMENDATIONS**

Lakewood met applicable Medicare payment requirements for all 43 claims for catheter insertion, Iodine-125 seeds, and a Technetium-99m source. However, none of the 65 SIR-Sphere claims met applicable Medicare payment requirements, resulting in overpayments of \$761,534.<sup>4</sup> These 65 claims were in error for the following reasons:

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<sup>4</sup> In each instance, we allowed payments proportionate to the amount of sources actually implanted in the patients.

- Lakewood used a single vial of SIR-Spheres to treat 2 separate patients on 43 claims, which resulted in overpayments of \$483,137.
- Lakewood lacked required Medicare documentation showing proper handling and disposal of unused brachytherapy sources on 19 claims, which resulted in overpayments of \$223,202.
- Lakewood billed for undelivered brachytherapy on two claims, which resulted in overpayments of \$38,138.
- Lakewood billed for an unsupported service on one claim, which resulted in an overpayment of \$17,057.

Lakewood improperly billed these claims because it did not have policies and procedures to account for partial vial usage or handling, tracking, or proper disposition of the unused portion of a vial, and it did not follow its procedures for ordering brachytherapy sources.

## **FEDERAL AND STATE REQUIREMENTS**

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

Section 1861(v)(1)(A) of the Act defines “reasonable cost” as “the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services ....” Pursuant to 42 CFR § 413.9(a), “All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.” Furthermore, pursuant to 42 CFR § 413.9(c), “It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.”

The *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 4, section 61.4.3, states:

CMS will consider the relatively few brachytherapy sources that were ordered but not implanted due to specific clinical considerations to be ... billable to Medicare under the following circumstances. The hospital may charge for all sources if they were specifically acquired by the hospital for the particular patient according to a physician’s prescription for the sources ... in order to ensure that the clinically appropriate number of sources was available for the implantation procedure, and they were not implanted in any other patient. Those sources that were not implanted must have been disposed of in accordance with all appropriate requirements for their handling. In general, the number of sources used in the care of the patient but not implanted would not be expected to constitute more than a small fraction of the sources actually implanted in the patient.

## **Nuclear Regulatory Commission Requirements**

The U.S. Nuclear Regulatory Commission (NRC) regulates uses of nuclear materials, such as in nuclear medicine. 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 byproduct 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. Florida signed such an agreement with NRC. In Florida, the Department of Health, Bureau of Radiation Control, is responsible for maintaining the NRC requirements under its agreement with NRC.

## **Florida Administrative Code**

Pursuant to the Florida Administrative Code (F.A.C.) § 64E-5.633(1) and (2), a licensee must maintain accountability at all times of brachytherapy sources in storage or use and must record the following for brachytherapy use: the number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and the number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

Pursuant to F.A.C. §§ 64E-5.624 (2)(a) through (g), when brachytherapy sources are held for decay in storage, a licensee must retain a record of each disposal for 3 years. The record must include the date of the disposal, the date the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the radiation survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

## **MEDICARE OVERPAYMENTS**

### **Overpayments Resulting From Billing for Multiple Patients Treated From a Single Vial**

Sirtex package inserts state that each vial of radioactive SIR-Spheres is manufactured as one therapeutic treatment and meant for use by a single patient.<sup>5</sup> For 43 claims, Lakewood billed Medicare for an entire vial of SIR-Spheres (including sources that were not implanted), used the remaining sources that had not been implanted to treat a different patient, and billed the other patient's insurance (i.e., Medicare or private insurance) for an entire vial. Federal law defines reasonable costs as costs actually incurred. Lakewood incurred costs for one vial, used one vial to treat two patients, and billed for two vials (i.e., one vial for each patient). Lakewood is not

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<sup>5</sup> Sirtex's package insert states that the vials are for single-patient use. See <http://www.sirtex.com/files/US20Package20Insert1.pdf>.

entitled to Medicare reimbursement for costs that it did not incur. Because Lakewood received payments based on costs that exceeded the costs actually incurred, the 43 claims resulted in \$483,137 in identified Medicare overpayments to Lakewood.

In 22 of these 43 claims, Lakewood treated 2 Medicare patients from the same vial of SIR-Spheres, billed Medicare twice for the entire contents of each vial, and received 2 Medicare payments for each vial. These 22 claims resulted in 11 Medicare overpayments to Lakewood totaling \$237,127.

For the remaining 21 claims, 1 patient was covered by Medicare and the other patient was covered by private insurance. These 21 improper claims resulted in an overpayment of \$246,010.

### **Lack of Accountability for the Use of SIR-Spheres**

For 19 claims, Lakewood billed for sources not implanted; however, Lakewood did not meet the Medicare billing requirements for unused sources.<sup>6</sup> According to Federal requirements, unused sources that are not disposed of in accordance with all appropriate requirements are not billable to Medicare. Pursuant to F.A.C. § 64E-5.633, Lakewood must maintain accountability at all times for all brachytherapy sources in storage or use, including a record of the number and activity of sources returned to storage, and maintain its records for 3 years.

Pursuant to F.A.C. § 64E-5.624(2), all sources placed in storage for decay must be documented to ensure proper disposal. The records must be kept for 3 years and must indicate the date of the disposal, the date the radioactive material was placed into storage, the radionuclides disposed, the model and serial number of the radiation survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. Lakewood provided us with logs of wipe/leak tests that it conducted to determine the amount of radiation outside the sources' containers. However, Lakewood did not provide a record documenting when it placed the SIR-Spheres into storage for decay or when it disposed of the vials.

Furthermore, to be billable under Medicare, sources not implanted in the Medicare beneficiary must have been specifically acquired by the hospital for that particular patient. However, at Lakewood, the purchase orders and invoices did not always match, and some invoices did not contain an identifier for the specific patient who was to receive the treatment or the date the treatment was to be administered. In cases in which patient identifiers and treatment dates did not match, Lakewood could not document the specific patient for whom the SIR-Spheres were ordered. Without this information, Lakewood could not have appropriately billed for any unused sources. The lack of accountability for the unused SIR-Spheres in these 19 claims resulted in Medicare overpayments totaling \$223,202.

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<sup>6</sup> For the provider to receive payment for unused sources, the sources must be ordered for a particular patient, the unused sources must not be implanted in any other patient, and the unused sources must have been handled and disposed of in accordance with all appropriate requirements for their handling (CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 4, section 61.4.3).

## **Billing for Canceled Procedures and Unsupported Services**

For two claims, Medicare patients were scheduled for SIR-Spheres injections, but the procedures were canceled before injection, and the medical records indicated that the procedures were never performed. Nevertheless, Lakewood billed Medicare for both vials of SIR-Spheres that had been ordered for the procedures. These improper claims resulted in Medicare overpayments to Lakewood totaling \$38,138.

For one claim, Lakewood billed Medicare for a vial of SIR-Spheres for a Medicare patient who, according to medical records, not only did not receive the SIR-Spheres injection but also was never scheduled to receive it. This improper claim resulted in a Medicare overpayment of \$17,057.

## **CAUSES OF MEDICARE OVERPAYMENTS**

### **Billing for Multiple Patients Treated From a Single Vial**

Lakewood did not ensure that prescriptions matched purchase orders and purchase orders matched invoices for the patients receiving SIR-Spheres. In each of the 43 claims discussed above, the attending physician prescribed 1 vial for each patient, but Lakewood ordered only 1 vial that was later split to treat 2 patients. When Lakewood treated the second patient, it billed a second time for the entire vial, even though it had already been reimbursed for the entire contents of that vial in treating the first patient.

Lakewood officials disagreed that treating multiple patients from a single vial and billing Medicare for the entire vial for each patient is prohibited under Medicare. Consequently, Lakewood did not have policies and procedures to accurately address the Medicare billing requirements relating to them.

### **Lack of Accountability for the Use of SIR-Spheres and Canceled Procedures**

Lakewood stated that it was unaware of the Medicare conditions of payment for unused brachytherapy sources and unaware of the Florida regulatory requirements for tracking unused radioactive sources. Lack of proper recordkeeping systems prevented Lakewood from accurately tracking whether the unused SIR-Spheres were disposed of, implanted in another patient, or placed into storage for decay.

### **Billing for Canceled Procedures and Unsupported Services**

The canceled and unsupported services were improperly billed because Lakewood did not follow the manufacturer's procedures for ordering SIR-Spheres, and the medical records section was not communicating with the billing department. The policies and procedures at Lakewood did not require the billing department to examine the medical records and verify that the services had occurred before billing.

## TOTAL MEDICARE OVERPAYMENTS

In each of the instances above, we allowed payments proportionate to the amount of sources actually implanted in the Medicare patients. During CYs 2008 and 2009, Medicare overpaid Lakewood a total of \$761,534 for unused SIR-Spheres for 65 brachytherapy claims.

## RECOMMENDATIONS

We recommend that Lakewood:

- refund to the Medicare program \$761,534 in overpayments for improper brachytherapy claims;
- develop and implement procedures to ensure that all brachytherapy sources are billed correctly; and
- develop and implement procedures for handling, tracking, and disposing of all radioactive brachytherapy sources, with special emphasis on Yttrium-90 disposal requirements.

## LAKWOOD COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, Lakewood did not fully agree with our recommendations. Because Lakewood could find no specific prohibition against billing multiple times for a single vial of SIR-Spheres, it will continue to do so. In addition, Lakewood stated that the physical inventory requirements in the F.A.C. governing the use and handling of Yttrium-90 and Medicare billing requirements are not applicable to SIR-Spheres because they are not traditional brachytherapy sources.

Lakewood's comments, excluding personally identifiable information, are included as the Appendix.

We maintain that our findings are valid. We summarize Lakewood's comments and our response to those comments in more detail below.

### Recommendation 1 (Lakewood Comments)

- A. Multiple Patients Treated From a Single Vial. Lakewood stated that the Medicare HCPCS code C2616 for SIR-Spheres (Yttrium-90) did not specify a quantity of SIR-Spheres but indicated that the quantity of the isotope is "per source." Lakewood further stated that it consistently charged for one unit of the code for each administration of SIR-Spheres, and it is not permitted to charge less than one unit for HCPCS code C2616.
- B. Documentation of Handling and Disposal of Brachytherapy Sources. Lakewood stated that SIR-Spheres differ from traditional brachytherapy seeds in several important

respects. Based on these differences, in some instances, compliance with the handling, tracking, and disposal rules applicable to traditional brachytherapy sources is “physically impossible.” Lakewood stated that each vial of SIR-Spheres must be used the day it is received. The remaining SIR-Spheres are not returned to storage but are, instead, sent to a decay cabinet until safe for disposal. Lakewood further stated that F.A.C. §§ 64E-5.618 and 64E-5.633 are not applicable to SIR-Spheres; instead, SIR-Spheres are more appropriately regulated under F.A.C. § 64E-5.624, governing decay in storage, because that criterion does not require inventory, initial estimate of activity, location, dates, or radiation safety officer signature. Lakewood stated that its decay storage is in compliance with F.A.C. § 64E-5.624.

- C. Undelivered Brachytherapy on Two Claims. Lakewood concurs with our findings.
- D. Unsupported Service. Lakewood disagrees with the finding for Sample #80, dated August 12, 2008, in which the patient did not receive brachytherapy SIR-Spheres. Lakewood claimed that the Medicare payment should be allowed because it administered the brachytherapy SIR-Spheres on a subsequent date, August 21, 2008.

#### **Recommendation 1 (Office of Inspector General Response)**

- A. Multiple Patients Treated From a Single Vial. We continue to assert that these claims were inappropriate because each charge for HCPCS code C2616 should have covered the cost to treat one patient with one unit (one vial) of Yttrium-90 microspheres (HCPCS C2616). Instead, Lakewood split one unit (one vial) between two patients. Lakewood correctly states that it “consistently charged for one unit of the code for each administration of SIR-Spheres....” However, when Lakewood split a vial, administered that vial to two different patients, and billed Medicare (or other insurance) for two HCPCS C2616 units, Lakewood was paid twice for the same vial of SIR-Spheres.
- B. Documentation of Handling and Disposal of Brachytherapy Sources. Lakewood cited F.A.C. § 64E-5.624 as the appropriate regulation governing decay in storage. This F.A.C. section requires the licensee to maintain disposal records to track the disposal of radioactive materials placed in storage for decay. Because Lakewood could not identify when it placed the vials into storage, it did not comply with the criteria that it cited in its response (F.A.C. §§ 64E-5.624 (2)(a) through (g)).
- D. Unsupported Service. The patient in sample #80 received insertion of brachytherapy SIR-Spheres on a later date, August 21, 2008, as Lakewood claims. However, Lakewood also received a separate Medicare payment for the insertion of brachytherapy SIR-Spheres into the same patient on August 21, 2008. Thus the Medicare payment for the brachytherapy SIR-Spheres insertion procedure that never took place on August 12, 2008, should be disallowed because the procedure was not performed.

## **Recommendation 2 (Lakewood Comments)**

- A. Policies and Procedures for Billing for Multiple Patients Treated From a Single Vial. Lakewood stated that the reimbursement guidelines for brachytherapy had changed since our audit period. In the 2010 Medicare Outpatient Prospective Payment System Final Rule (Final Rule), CMS changed the criteria regulating reimbursement from “cost based” to Ambulatory Payment Classification prospective reimbursement. Lakewood stated that the preamble to the Final Rule does not address the split dosage issue, and the code descriptor for C2616 has not changed. “Therefore, under the prospective payment rate, ‘per source’ appears to mean ‘per vial.’” Absent regulatory or subregulatory guidance to the contrary, Lakewood stated that it would continue to bill for one unit of SIR-Spheres under HCPCS code C2616, including those circumstances in which portions of a single vial are administered to two patients, and its charges will reflect the cost of a single vial.
- B. Policies and Procedures for Canceled Procedures. Lakewood concurred with our recommendation and will strengthen its internal controls to prevent billing for canceled brachytherapy procedures.

## **Recommendation 2 (Office of Inspector General Response)**

- A. Policies and Procedures for Billing for Multiple Patients Treated From a Single Vial. Our audit covered CYs 2008 and 2009 (before CMS revised the criteria), when SIR-Spheres were reimbursed based on “reasonable costs.” The issue that Lakewood brings up concerning the lack of Medicare’s definition of a unit is not valid. The manufacturer, Sirtex, states that a vial is for single-patient use. The real issue is that Lakewood’s practice of double billing for a single vial caused Medicare to overpay for each vial of SIR-Spheres that Lakewood split and administered to two patients. Because Lakewood overstated its costs, the Medicare payment for each patient was substantially greater than the cost of a single vial. Therefore, Medicare reimbursed Lakewood more than the reasonable costs for SIR-Spheres brachytherapy sources because it paid Lakewood twice for a single unit of the sources.

## **Recommendation 3 (Lakewood Comments)**

Development and Implementation of Procedures for Handling, Tracking, and Disposing of All Radioactive Brachytherapy Sources With Special Emphasis on Yttrium-90 Tracking and Disposal Requirements. Lakewood disagreed with this recommendation because SIR-Spheres are not a traditional brachytherapy source, and, therefore, it is not appropriate or physically possible for Lakewood to apply to SIR-Spheres handling, tracking, and disposal requirements that are applicable to traditional brachytherapy sealed sources. Lakewood stated that it is in compliance with all applicable Florida laws regarding the handling, tracking, and disposing of unused SIR-Spheres.

**Recommendation 3 (Office of Inspector General Response)**

Development and Implementation of Procedures for Handling, Tracking, and Disposing of All Radioactive Brachytherapy Sources With Special Emphasis on Yttrium-90 Tracking and Disposal Requirements. As noted in OIG Recommendation 1B above, SIR-Spheres are a radioactive brachytherapy source and, as such, are subject to NRC regulations and the F.A.C. for decay-in-storage requirements.

# **APPENDIX**

APPENDIX: LAKEWOOD RANCH MEDICAL CENTER COMMENTS



December 1, 2011

**VIA FEDERAL EXPRESS AND ELECTRONIC MAIL ([Andrew.funtal@oig.hhs.gov](mailto:Andrew.funtal@oig.hhs.gov))**

Mr. Andrew Funtal, Audit Manager  
United States Department of Health and Human Services  
Office of Inspector General  
61 Forsyth Street SW, Suite 3T41  
Atlanta, Georgia 30303

**RE: Report Number A-04-10-06131 Review of Outpatient Brachytherapy Medicare Payments to Lakewood Ranch Medical Center**

Dear Mr. Funtal:

This letter responds on behalf of Lakewood Ranch Medical Center (“Lakewood”) to the draft report entitled “Review of Outpatient Brachytherapy Medicare Payments to Lakewood Ranch Medical Center” (the “Report”). During and following the review by the Office of Inspector General (“OIG”) audit team, Lakewood staff reviewed the practices of Lakewood related to the handling, tracking, use, disposal and billing of brachytherapy sources. As detailed below, Lakewood concurs with the OIG findings regarding brachytherapy-related catheter insertion, the use of Iodine-125 seed, and the use of Technetium-125m liquid sources, but respectfully disagrees with certain of the OIG recommendations regarding the use and storage of Yttrium-90 microspheres (“SIR Spheres”). SIR Spheres are not a traditional brachytherapy product and the OIG recommendations related to handling and storage of SIR Spheres are inconsistent with the necessary use and storage requirements of the SIR Spheres product and Florida regulators’ interpretation of applicable Florida law. Lakewood appreciates this opportunity to respond to the draft OIG recommendations as set forth in the Report.

**OIG Recommendation 1: The OIG recommends that Lakewood refund to the Medicare program \$761,534 in overpayments for improper brachytherapy claims, which includes: (A) \$483,137 for Lakewood’s use of a single vial of SIR Spheres to treat two separate patients on 43 claims; (B) \$223,202 for lack of certain documentation showing handling and disposal of unused brachytherapy sources on 19 claims; (C) \$38,138 for undelivered brachytherapy on two claims; and (D) \$17,057 for an unsupported service on one claim.**

Lakewood responds to items A – D in turn below.

A. Multiple Patients Treated From a Single Vial. The OIG recommends that Lakewood refund \$483,137 for Lakewood’s use of a single vial of SIR Spheres to treat two separate patients on 43 claims. We disagree with this recommendation. SIR Spheres are described by HCPCS

Code C2616. The code does not specify a quantity of SIR Spheres and instead indicates that the quantity of the isotope is “per source.” In this case, the sole manufacturer of the source (*i.e.*, SIR Spheres) distributes the source in a single size vial. Each vile contains hundreds of thousands of the SIR Spheres per milliliter in a liquid suspension. Since the SIR Spheres are only distributed in a single size vile and the source material in each vile numbers in the hundreds of thousands, one unit of HCPCS C2616 is the vile. Lakewood consistently charged for one unit of the code for each administration of SIR Spheres and is not permitted to charge less than one unit of HCPCS C2616.

B. Documentation of Handling and Disposal of Brachytherapy Sources. The OIG recommends that Lakewood refund \$223,202 for lack of certain documentation showing handling and disposal of unused brachytherapy sources on 19 claims.

Lakewood respectfully disagrees with the identified overpayment amount of \$223,202 associated with 19 claims for which the OIG states Lakewood did not properly dispose of unused amounts of SIR Spheres because Lakewood did appropriately dispose of the unused amounts of SIR Spheres in accordance with applicable Florida law. Lakewood has been inspected by the Florida Bureau of Radiation control several times and the Bureau has found no deficiencies in this area. The basis for Lakewood’s disagreement is explained further below.

Radiation for brachytherapy is generated by tiny pieces of radioactive material, typically in a form called “seeds” or “pellets.” Radiation oncologists use these seeds, also called the “source,” to deliver a dose of radiation to a tumor or the surgical cavity left after a tumor has been removed. Brachytherapy seeds may be permanently left in the body, or placed temporarily for short periods of time. A brachytherapy seed may be the size of a dried rice grain or a bit of lead from a mechanical pencil.

SIR Spheres differ from traditional brachytherapy seeds in several important respects: (1) Yttrium-90 microspheres are suspended in liquid form and are microscopic as opposed to seeds which are readily quantifiable; (2) Yttrium-90 microspheres have a radioactive shelf-life of 64 hours whereas traditional seeds require storage, tracking and proper disposal because seeds remain radioactive for a longer period of time; (3) the dosage of Yttrium-90 microspheres to patients is in measured liquid form as opposed to one traditional seed. See Exhibit A to this letter for a side-by-side comparison of the procurement and handling of brachytherapy seeds as opposed to Yttrium-90 microspheres.

Traditional brachytherapy seeds are encapsulated in a shell and are therefore labeled a “sealed source.” Florida regulation 64E-5.101(133) defines “sealed source” as “radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.”<sup>1</sup> This contrasts greatly to a SIR Sphere, which is held in a liquid medium as a suspension. The individual SIR Spheres contained in each vial of liquid contain the Yttrium-90 radioactive material. The SIR Spheres are virtually invisible to the naked eye and

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<sup>1</sup> F.A.C. 64E-5.101(133) as defined above was effective 12/18/2001-2/27/2008. Effective 2/28/2008, F.A.C. 64E-5.101(133) was revised to define “sealed source” as “radioactive material that is encased in a capsule designed to prevent release or escape of the radioactive material” and state that the definition was “substantially similar” to the previous definition. Effective 2/11/2010, F.A.C. 64E-5.101(133) was renumbered as F.A.C. 64E-5.101(129).

hundreds of thousands or more of SIR Spheres exist in a milliliter of liquid. Therefore, although SIR Spheres are technically brachytherapy sources, they are suspended in liquid and are not a sealed source as are most brachytherapy sources.

Though there are many regulatory requirements governing the use of sealed brachytherapy sources, the liquid suspension style of SIR Spheres creates instances where compliance with the handling, tracking and disposal rules applicable to traditional brachytherapy sources is physically impossible. For example, the requirements of F.A.C. 64E-5.618 and 64EE-5.633, which regulate storage of brachytherapy sources, are not applicable to SIR Spheres because SIR Spheres are not returned to inventory storage following administration. Because the half-life of SIR Spheres is approximately 64 hours, the doses are never in storage for future use. Each ordered vial of SIR Spheres must be used on the same day it is received. For this reason, they are not returned to storage but sent to a decay cabinet to decay until safe for disposal. Therefore, SIR Spheres are more appropriately regulated under F.A.C. 64E-5.624, governing decay in storage. Unlike the requirements for returning radioactive materials to storage under F.A.C. 64E-5.618, there are no requirements regarding inventory, or initial estimate of activity, location, dates, nor radiation safety officer signature under the F.A.C. 64E-5.624. Lakewood's decay storage is therefore in compliance with F.A.C. 64E-5.624.

C. Undelivered Brachytherapy on Two Claims. The OIG recommends that Lakewood refund to the Medicare program \$38,138 for undelivered brachytherapy on two claims (Sample #1 and Sample #102). Lakewood concurs with this recommendation and will make payment to Highmark Medicare Services within 30 days of the issuance of the Final OIG Report.

D. Unsupported Service. The OIG recommends that Lakewood refund to the Medicare program \$17,057 for an unsupported service on one claim to the patient in Sample # 80. Lakewood respectfully disagrees with the identified overpayment amount. The OIG mistakenly determined that Lakewood provided Phase I of the brachytherapy procedure to the patient, but billed for Phase II of the procedure. As documented in the August 2008 medical record entries attached as Exhibit B to this letter, Lakewood provided Phase I of the procedure to the patient on August 12, 2008 and Phase II of the procedure to the patient on August 21, 2008. Under Phase I, the adequacy of the vasculature for reception of the Sir Spheres is evaluated. The Sir Spheres are administered on a subsequent date as Phase II.

**OIG Recommendation 2: The OIG recommends that Lakewood develop and implement procedures to ensure that all brachytherapy sources are billed correctly.**

A. Policies and Procedures for Billing for Multiple Patients Treated From a Single Vial.

Since the audit period dates in 2008 and 2009, the reimbursement methodology for brachytherapy has changed. The 2010 Medicare Outpatient Prospective Payment System Final Rule (the "Final Rule") published in the Federal Register on November 20, 2009, changed the reimbursement methodology from "cost based" reimbursement to APC prospective reimbursement for brachytherapy sources, effective January 1, 2010. (See 74 F.R. 60316, 60532-60537) The preamble to the Final Rule does not address the split dosage issue related to SIR Spheres. SIR Spheres remain under HCPCS C2616 and the code descriptor did not change. The units for C2616 remain described as "per source," with an APC rate that approximates the costs

associated with one vial of SIR Spheres. Therefore, under the prospective payment rate, "per source" appears to mean "per vial." As discussed above in response to Recommendation 1.A, it is not possible to bill for less than one unit of C2616 when less than a full vial of SIR Spheres is administered to a patient. Absent regulatory or sub-regulatory guidance to the contrary, when a partial vial of SIR Spheres is administered to a patient, Lakewood will bill for one unit of C2616, including in those circumstances where portions of a single vial are administered to two patients and its charges will reflect the cost of a single vial.

Lakewood will assure that it (1) only accounts for the costs of one vial of SIR Spheres on its Medicare cost report when it uses one vial for treatments provided to two Medicare patients, (2) allocates the cost of a single vial of SIR Spheres proportionately between payors when a single vial is used for treatments provided to a Medicare and a private insurance patient and (3) will include the entire cost of one vial on the cost report in the event that Lakewood does not have a second patient to use the remaining SIR Spheres within the shelf life of the SIR Spheres.

B. Policies and Procedures for Cancelled Procedures

Lakewood will strengthen its internal controls for verification of medical records to prevent billing for cancelled brachytherapy procedures.

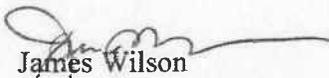
**OIG Recommendation 3: Development and implementation of procedures for handling, tracking and disposing of all radioactive brachytherapy sources with special emphasis on Yttrium-90 tracking and inventory requirements.**

Lakewood respectfully disagrees with OIG Recommendation 3. As discussed above in response to Recommendation 1, the SIR Spheres product is not a traditional brachytherapy source and, therefore, it is not appropriate, or physically possible, for Lakewood to apply the handling, tracking and disposal that are applicable to traditional brachytherapy sealed sources to SIR Spheres. Lakewood is in compliance with all applicable Florida laws regarding the handling, tracking and disposal of unused SIR Spheres.

\* \* \*

We thank you for the opportunity to respond to the draft OIG recommendations. Please do not hesitate to contact me if you have any questions regarding our responses.

Sincerely,

  
James Wilson  
Chief Executive Officer

**Exhibit A**  
**Comparison of Procurement and Handling of Traditional Brachytherapy Seeds and Yttrium-90 Microspheres (“SIR Spheres”)**

Action	SIR Spheres	Traditional Brachytherapy Seeds
Ordering	Candidacy is determined by pre-screening arteriogram, liver scan and lab testing. After candidacy is determined dose is ordered by Radiology personnel.	Candidacy is determined by Urologist. Dose is ordered by treating Oncologist directly from vendor, 21 <sup>st</sup> Century Oncology.
Dose	Dose is delivered in a pre calibrated standard dose vial. Spheres are held in a liquid suspension naked to the invisible eye. <b>Therefore, they can not be counted individually.</b> Assay and wipe test is performed in the Nuclear Hot Lab. Spheres are held in the Hot Lab until prepared and delivered to the Interventional/Cath Lab by the Nuclear Technologist.	Seeds are delivered to the Nuclear Hot Lab. Assay and wipe test is performed. <b>Seeds are individual encapsulated doses and are counted individually.</b> After assay and wipe test is performed, the seeds are picked up and transported to the OR suite by the Oncology RN.
Location of Procedure	Delivery of SIR Spheres is performed in the Interventional/Cath Lab suite. The patient is admitted for observation overnight.	Delivery of the Brachytherapy seeds is performed in the OR suite. The patient is discharged home after recovery.
Method of Delivery to Patient	SIR Spheres are delivered via intra arterial catheter directly into the designated vessel identified by Interventional Radiologist. This is performed with the patient under moderate sedation.	Seeds are loaded into thin, hollow needles and injected directly into the prostate. This is performed with the patient under general anesthesia.
Disposal	Due to the short half life of 64 hours, the dose is calibrated for day of administration. Any remaining dose cannot be reused and is placed in the Nuclear Hot Lab for decay.	The half life of the seed is approximately 17-59 days depending on source of Radiation. Unused seeds can be reused. All unused seeds are returned from the OR and placed in the Nuclear Hot Lab for pick up by the Nuclear Pharmacy (21 <sup>st</sup> Century).
Treatment/Target Area	SIR Spheres are used to treat liver cancer.	Seeds are used to treat prostate cancer.
Treatment Phases	There are 2 phases of treatment for SIR Sphere therapy.	Prostate seed therapy is single visit.

**Exhibit B**  
**Medical Record Documentation Supporting Claim**

Please see attached.

Not included for report purposes as Exhibit contains personally identifiable information (PII) not meant for public consumption.