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

Office of Audit Services,
Region I
John F. Kennedy Federal Building
Boston, MA 02203
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May 3, 2011

Report Number: A-01-10-00512

Ms. Janeanne C. Lubin-Szafranski
Vice President/General Counsel
Saint Raphael Healthcare System, Inc.
659 George Street
New Haven, CT 06511

Dear Ms. Lubin-Szafranski:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of the Hospital of Saint Raphael's Claims for Inpatient and Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2008 and 2009*. 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.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact David Lamir, Audit Manager, at (617) 565-2704 or through email at David.Lamir@oig.hhs.gov. Please refer to report number A-01-10-00512 on all correspondence.

Sincerely,

/Michael J. Armstrong/
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 and Medicaid Services
601 East 12th Street, Room 235
Kansas City, MO 64106

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE HOSPITAL OF SAINT RAPHAEL'S CLAIMS FOR INPATIENT & OUTPATIENT PROCEDURES THAT INCLUDED THE REPLACEMENT OF MEDICAL DEVICES FOR CALENDAR YEARS 2008 AND 2009

Daniel R. Levinson
Inspector General

May 2011
A-01-10-00512

Office of Inspector General

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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

The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, pays for hospital inpatient and outpatient services under distinct prospective payment systems.

Medical Device Replacement

Common medical devices implanted during outpatient procedures include pacemakers, cardioverter defibrillators, and their associated leads. Occasionally, devices need to be replaced. Providers may receive full or partial credit from manufacturers for devices that are covered under warranty or replaced because of recalls. To offset these credits, Medicare reduces the payment for the replacement of a device if (1) the device is replaced without cost to the provider, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device.

For outpatient services furnished on or after January 1, 2007, CMS established reporting requirements for a provider that incurs no cost or that receives full credit for a replaced device. In such circumstances, CMS requires the provider to report the modifier "FB" and to report reduced charges on a claim that includes a procedure code for the insertion of a replacement device. For services furnished on or after January 1, 2008, CMS also requires the provider to report the modifier "FC" on a claim that includes a procedure code for the insertion of a replacement device if the provider receives a credit from the manufacturer of 50 percent or more of the cost of the replacement device. Similarly, for inpatient discharges on or after October 1, 2008, CMS established reporting requirements for a provider that incurs no cost, receives full credit, or receives a credit for a replaced device that is 50 percent or greater than the cost of the device. In such circumstances, CMS requires the provider to report the value code "FD" and to bill the amount of the credit in the amount portion for that value code. CMS further requires the provider to report appropriate condition codes to indicate a medical device replacement.

Hospital of Saint Raphael

The Hospital of Saint Raphael (the Hospital) is a 511-bed acute-care hospital located in New Haven, Connecticut. National Government Services (NGS) processes and pays the Hospital's Medicare claims. NGS paid the Hospital a total of $6.5 million for 437 outpatient procedures that included the replacement of medical devices for the 2-year period ending December 31, 2009, and $9.6 million for 367 claims for inpatient claims covering the 15-month period ending December 31, 2009.

OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for obtaining credits available from manufacturers for replaced medical devices and for reporting the appropriate billing codes and charges to reflect the credits received.

SUMMARY OF FINDINGS

The Hospital did not fully comply with Medicare requirements for obtaining credits available from manufacturers and for reporting the appropriate billing codes and charges to reflect the credits it received. For 425 outpatient claims and 354 inpatient claims for the audit periods, there were no available credits or the credits were partial credits received from manufacturers that did not represent at least 50 percent of the cost of the devices and therefore were not reportable. For the 25 remaining claims, credits were available from manufacturers and reportable; however:

- For two inpatient claims, the Hospital did not obtain credits that were available under the terms of the manufacturers' warranties.

- For 12 outpatient claims and 11 inpatient claims, the Hospital obtained full credit but did not report the "FB" modifier and reduced charges (outpatient) or the "FD" value code and appropriate condition code (inpatient) on the claims to alert NGS that payment adjustments were needed.

For the 25 claims, the Hospital was overpaid $231,378 ($171,029 outpatient and $60,349 inpatient). Moreover, for these claims, beneficiaries incurred $6,778 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not (1) follow its established procedures to obtain credits available under the terms of manufacturers' warranties or (2) have controls to report the appropriate billing codes and charges to reflect credits due from manufacturers.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NGS the 25 erroneous claims to correct any outstanding portion of overpayments totaling $231,378 ($171,029 outpatient and $60,349 inpatient claims) and overstated copayment costs totaling $6,778, and

- strengthen its procedures to obtain credits available from manufacturers and establish procedures to report to NGS the credits that the Hospital was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

HOSPITAL OF SAINT RAPHAEL COMMENTS

In its written comments to our draft report, the Hospital concurred with our findings and recommendations. The Hospital's comments are included in their entirety as Appendix B.

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INTRODUCTION

BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act (the Act), provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Part A of Title XVIII provides inpatient hospital insurance while Part B of Title XVIII provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals.[1]

Hospital Prospective Payment Systems

Outpatient Prospective Payment System

As mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, together with the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, P.L. No. 106-113, CMS implemented an outpatient prospective payment system (OPPS) for hospital outpatient services. The OPPS was effective for services furnished on or after August 1, 2000. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned. CMS uses Healthcare Common Procedure Coding System codes and descriptors to identify and group the services within each APC group. All services and items within an APC group are comparable clinically and require comparable resources.

Inpatient Prospective Payment System

The Social Security Act Amendments of 1983, Public Law 98-21, enacted on April 20, 1983, established a prospective payment system for Medicare reimbursement to hospitals. Section 1886(d) of the Act set forth a system of payments for the costs of acute care hospital inpatient stays based on prospectively set rates effective for services furnished on or after October 1, 1983. Under the inpatient prospective payment system (IPPS), each case is categorized into a diagnosis-related group (DRG). Each DRG has a payment weight assigned to it based on the average resources used to treat Medicare patients in that DRG.

Under both the OPPS and the IPPS, outlier payments are available when exceptionally costly services exceed established thresholds.

[1]Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, requires CMS to transfer the functions of fiscal intermediaries to Medicare administrative contractors (MAC) between October 2005 and October 2011. Most, but not all, of the MACs are fully operational. For jurisdictions where the MACs are not fully operational, fiscal intermediaries continue to process Part B outpatient claims. For purposes of this report, the term "Medicare contractor" means the fiscal intermediary or MAC, whichever is applicable.

Credits for Replaced Medical Devices

Common medical devices implanted during inpatient and outpatient procedures include pacemakers, cardioverter defibrillators, and their associated leads. Occasionally, devices need to be replaced. Providers may receive full or partial credit from manufacturers for devices that are covered under warranty or replaced because of recalls. Warranties vary among manufacturers and product lines but commonly cover replaced devices on a pro rata basis depending on the age of the device. Providers generally must send replaced devices back to the manufacturers within a specified time after the replacement procedures to obtain credits.

Reimbursement for Medical Device Replacement

To offset the credits that a provider receives for costly devices replaced during inpatient and outpatient procedures, Medicare generally requires payment adjustments. Specifically, for 43 inpatient DRGs and 31 types of devices that fall within 21 outpatient APCs, Medicare reduces the payment for the replacement of the device if the provider is entitled to full or partial credits from the manufacturer.

Outpatient Reimbursement

For outpatient services furnished on or after January 1, 2007, CMS established reporting requirements for a provider that incurs no cost or that receives full credit for a replaced device. In such circumstances, CMS requires the provider to report the modifier "FB" and to report reduced charges on a claim that includes a procedure code for the insertion of a replacement device.[2] For outpatient services furnished on or after January 1, 2008, CMS also requires the provider to report the modifier "FC" on a claim that includes a procedure code for the insertion of a replacement device if the provider receives a credit from the manufacturer of 50 percent or more of the cost of the replacement device. Providers must use these modifiers as required to ensure that Medicare makes the appropriate payment adjustments.

In the preamble to the regulation implementing the billing requirements for device replacement credits (71 Fed. Reg. 68072 (Nov. 24, 2006)), CMS stated that payment adjustments were consistent with section 1862(a)(2) of the Act, which excludes from Medicare coverage an item or service that neither the beneficiary nor anyone on his or her behalf has an obligation to pay. According to CMS, payment of the full APC payment rate when a device was replaced under warranty or when there was a full credit for the price of the replaced device effectively results in Medicare payment for a noncovered item.

[2]The provider's failure to report reduced charges on a claim with the "FB" modifier could result in excessive or unwarranted outlier payments.

Inpatient Reimbursement

For inpatient discharges on or after October 1, 2008, CMS established reporting requirements for a provider that incurs no cost, receives full credit, or receives a credit for a replaced device that is 50 percent or greater than the cost of the device. In such circumstances, CMS requires the provider to report the value code "FD" on its claim and to bill the amount of the credit in the amount portion for that value code. CMS further requires the provider to report condition codes 49 or 50 to indicate a medical device replacement.[3]

Hospital of Saint Raphael

The Hospital of Saint Raphael (the Hospital) is a 511-bed acute-care hospital located in New Haven, Connecticut. As the Medicare contractor for hospitals in Connecticut, National Government Services (NGS) processes and pays the Hospital's claims for Medicare services.[4]

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Hospital complied with Medicare requirements for obtaining credits available from manufacturers for replaced medical devices and for reporting the appropriate billing codes and charges to reflect the credits received.

Scope

Our audit covered $16.1 million in Medicare payments to the Hospital for procedures involving the possible replacement of medical devices. Our audit population consisted of 804 claims: 437 outpatient claims, totaling $6.5 million, with dates of service during the 2-year period ending December 31, 2009; and 367 inpatient claims, totaling $9.6 million, with dates of services during the 15-month period ending December 31, 2009.[5] We limited our audit to claims that involved the replacement of pacemakers, cardioverter defibrillators, and their associated leads.[6] The listings of the corresponding 7 outpatient APCs and 14 inpatient DRGs applied in this audit are included in Appendix A. During the audit periods, the Hospital did not submit any outpatient claims with "FB" or "FC" modifiers, and it did not submit any inpatient claims with the "FD" value code or the appropriate condition code.[7]

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[3]Effective April 1, 2006, CMS required the use of two new condition codes to track devices provided without cost to providers. Condition code 49 refers to the replacement of a device which is not functioning properly and condition code 50 refers to devices subject to recalls. Medicare payment edits require the presence of both value and condition codes for inpatient claims involving a medical device replacement. *Medicare Claims Processing Manual*, Pub. 100-04, CR 4058, Transmittal 741.

[4]NGS became a MAC in March 2008.

[5]Requirements for use of the FD code for inpatient medical device credits did not commence until October 1, 2008. *Medicare Claims Processing Manual*, Pub. 100-04, CR 5860, Transmittal 1509.

[6]Our prior audits of replaced medical device credits disclosed that these types of devices presented the greatest risk of non-compliance with Medicare requirements.

[7]During our audit, the Hospital self-initiated a review to determine those claims that needed to be adjusted and resubmitted to NGS to reflect reportable credits received from manufacturers.

We limited our internal control review to the Hospital's controls related to (1) preparing and submitting Medicare claims for procedures that included the replacement of medical devices and (2) identifying and obtaining credits and reporting that manufacturers provided credits for medical devices that were either covered under warranty or recalled.

We conducted our fieldwork at the Hospital in New Haven, Connecticut, and at three medical device manufacturers in St. Paul, Minnesota, from May through September 2010. We also contacted NGS.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- extracted from CMS's National Claims History file the Hospital's outpatient paid claim data for the 2-year period ending December 31, 2009, and inpatient paid claim data for the 15-month period ending December 31, 2009;

- developed computer applications to identify (1) 437 outpatient claims that included procedures for the replacement of any of the 7 specified types of APCs and 14 medical devices and (2) 367 inpatient claims that included the 14 specific DRGs;

- selected judgmental samples of 30 outpatient claims and 25 inpatient claims and reviewed the beneficiaries' medical records, accounts payable invoices, and manufacturers' warranties to determine whether the Hospital should have submitted the claims with the applicable billing codes and reduced charges;

- reviewed the Hospital's procedures for identifying and obtaining credits and reporting on its Medicare claims that the manufacturers provided credits for replaced devices;

- interviewed officials from selected device manufacturers that conducted business with the Hospital to identify their requirements for issuing credits and obtained lists of credits issued to the Hospital to determine whether Medicare payment adjustments were needed;

- verified the results of the Hospital's self-initiated review of its inpatient and outpatient claims;

- reviewed adjusted claims that the Hospital resubmitted to NGS;

- calculated the correct payments for those claims for which payment adjustments were needed; and

- discussed the results of our review with Hospital 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

The Hospital did not fully comply with Medicare requirements for obtaining credits available from manufacturers and for reporting the appropriate billing codes and charges to reflect the credits it received. For 425 outpatient claims and 354 inpatient claims for the audit periods, there were no available credits or the credits were partial credits received from manufacturers that did not represent at least 50 percent of the cost of the devices and therefore were not reportable. For the 25 remaining claims, credits were available from manufacturers and reportable; however:

- For two inpatient claims, the Hospital did not obtain credits that were available under the terms of the manufacturers' warranties.

- For 12 outpatient claims and 11 inpatient claims, the Hospital obtained full credit but did not report the "FB" modifier and reduced charges (outpatient) or the "FD" value code and appropriate condition code (inpatient) on the claims to alert NGS that payment adjustments were needed.

For 25 claims the Hospital was overpaid $231,378 ($171,029 outpatient and $60,349 inpatient). Moreover, for these claims, beneficiaries incurred $6,778 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not (1) follow its established procedures to obtain credits available under the terms of manufacturers' warranties or (2) have controls to report the appropriate billing codes and charges to reflect credits due from manufacturers.

MEDICARE REQUIREMENTS

Prudent Buyer Principle

Under 42 CFR § 413.9, "All payments to providers of services must be based on the reasonable cost of services. . . ." CMS's *Provider Reimbursement Manual*, part 1, section 2102.1, states: "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program."

Section 2103 of the *Provider Reimbursement Manual* states that Medicare providers are expected to pursue free replacements or reduced charges under warranties. Section 2103(C)(4) provides the following example: "Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for

full or partial credits available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment."

Coding Requirements for Medical Device Credits

Outpatient Coding Requirements

Federal regulations (42 CFR § 419.45) require reductions in the OPPS payments for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device.

CMS guidance in Transmittal 1103, dated November 3, 2006, and in its *Medicare Claims Processing Manual* (the Manual) explains how a provider should report no-cost and reduced-cost devices under the OPPS. For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier "FB" and reduced charges on a claim that includes a procedure code for the insertion of a replacement device if the provider incurs no cost or receives full credit for the replaced device. If the provider receives a replacement device without cost from the manufacturer, the provider must report a charge of no more than $1 for the device (the Manual, chapter 4, § 61.3.1). If the provider receives full credit from the manufacturer for a replaced device that is less expensive than the replacement device, the provider must report a charge that represents the difference between its usual charge for the device being implanted and its usual charge for the device for which it received credit (the Manual, chapter 4, § 61.3.2).

For services furnished on or after January 1, 2008, CMS requires the provider to report the modifier "FC" on a claim that includes a procedure code for the insertion of a replacement device if the provider receives a credit from the manufacturer of 50 percent or more of the cost of the replacement device. Partial credits for less than 50 percent of the cost of a replacement device need not be reported with any modifier.

Inpatient Coding Requirements

Federal regulations (42 CFR § 412.89) require reductions in the IPPS payments for the replacement of an implanted device if (1) the device is replaced without cost to the provider, (2) the provider receives full credit for the cost of a device, or (3) the provider receives a credit equal to 50 percent or more of the cost of the device.

CMS guidance in Transmittal 1509, dated May16, 2008, explains how a provider should report no-cost and reduced-cost devices under the IPPS. For services furnished on or after October 1, 2008, CMS requires providers to bill the amount of the credit in the amount portion for value code "FD" when the provider receives a credit for a replaced device that is 50 percent or greater than the cost of the device. Partial credits for less than 50 percent of the cost of the device need

not be reported with the "FD" value code.[8] In addition, CMS Transmittal 741, dated November 4, 2005, and effective April 1, 2006, requires the use of two condition codes to track devices provided without cost to providers. Condition code 49 refers to the replacement of a device which is not functioning properly, and condition code 50 refers to devices subject to recalls. NGS prepayment edits require the presence of both value and condition codes for inpatient claims involving a medical device replacement.

NONCOMPLIANCE WITH MEDICARE REQUIREMENTS

Hospital Did Not Obtain Available Credits

For two inpatient claims, the Hospital did not obtain credits for replaced leads that were available under the terms of the manufacturers' warranties. For example, according to the Hospital's records for one claim, the defibrillator lead was subject to recall. The lead was replaced and the Hospital was due a credit from the manufacturer. The Hospital should have obtained the credit, used the "FD" value code and appropriate condition code on its claim, and received a reduced payment.

Overpayments of $4,568 for the two claims occurred because the Hospital did not follow its established procedures to obtain credits available under the terms of manufacturers' warranties.[9]

Hospital Did Not Report That It Received Credits

For 23 claims the Hospital received either full or partial credits for a replaced device, but did not report the appropriate billing codes and charges to reflect the credits it received. Specifically, for 12 outpatient claims, the Hospital received full or partial credits from manufacturers, but did not report the required "FB" or "FC" modifier and reduced charges on its claims. Similarly, for 11 inpatient claims, the Hospital received full credits, but did not report the "FD" value code and appropriate condition code on its claims. For instance, for one claim, according to the beneficiary's medical records, the replaced device needed to be removed because the battery was depleted. Under the terms of the warranty, the manufacturer provided full credit for the cost of the replaced device. Therefore, this claim should have been submitted with the appropriate billing codes and charges to alert NGS that a payment reduction was needed.

[8]We identified an ambiguity created by section 100.8 of Chapter 3 of the *Medicare Claims Processing Manual*, Pub. 100-04, as it currently reads. Whereas the regulation and Transmittal 1509 can be read to apply the "50 percent or greater" threshold to the cost of the *replaced* device, section 100.8, effective October 1, 2009, can be interpreted to apply the threshold to the cost of the *replacement* device. To remain consistent with the requirements of the outpatient regulation, we interpreted the inpatient requirements to apply the threshold to the cost of the *replacement* device, but note that for the inpatient claims identified below in which we determined that the hospital received a credit which was 50 percent or greater than the cost of the *replacement* device, that the credit would have also been 50 percent or greater than the cost of the *replaced* device. As such, our determination of overpayments remained the same under either interpretation.

[9]The Hospital subsequently received credits for the replaced leads from the manufacturers and adjusted its inpatient claims with the "FD" value code.

Overpayments of $171,029 for the 12 outpatient claims and $55,782 for the 11 inpatient claims occurred because the Hospital did not have controls for reporting medical device credits received from manufacturers.[10] Specifically, the Hospital did not have procedures for coordinating functions among the various departments (i.e., clinical, materials management, health information management, patient accounting, and accounts payable) to ensure that it submitted claims with the appropriate modifier and reduced charges to initiate reduced payments for credits received from manufacturers.

MEDICARE OVERPAYMENTS

For 25 claims the Hospital was overpaid $231,378 ($171,029 outpatient and $60,349 inpatient). Moreover, for these claims, beneficiaries incurred $6,778 in additional copayment costs associated with the outpatient claims.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NGS the 25 erroneous claims to correct any outstanding portion of overpayments totaling $231,378 ($171,029 outpatient claims and $60,349 inpatient) and overstated copayment costs totaling $6,778, and

- strengthen its procedures to obtain credits available from manufacturers and establish procedures to report to NGS the credits that the Hospital was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

HOSPITAL OF SAINT RAPHAEL COMMENTS

In its written comments to our draft report, the Hospital concurred with our findings and recommendations. The Hospital's comments are included in their entirety as Appendix B.

[10]During our review, the Hospital adjusted and resubmitted the 12 outpatient claims to NGS. Although the Hospital correctly reported the "FB" modifier on eight of the adjusted claims, it did not report reduced charges. The Hospital incorrectly reported the "FC" modifier on three of the four remaining adjusted claims. As a result, the adjusted claims did not fully resolve the overpayments.

APPENDIXES

APPENDIX A: CORRESPONDING AMBULATORY PAYMENT CLASSIFICATIONS AND DIAGNOSIS RELATED GROUPS

Outpatient Ambulatory Payment Classifications (APCs)

APC	APC Description
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	Insertion/Replacement of Pacemaker Pulse Generator
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	Insertion of Cardioverter-Defibrillator
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads
0654	Insertion/Replacement of a Permanent Dual Chamber Pacemaker
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker

Inpatient Diagnosis Related Groups (DRGs)

DRG	DRG Description
222	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with Major Complication/Comorbidity (MCC)
223	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock without MCC
224	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock with MCC
225	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock without MCC
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
242	Permanent Cardiac Pacemaker Implant with MCC
243	Permanent Cardiac Pacemaker Implant with Complication/Comorbidity (CC)
244	Permanent Cardiac Pacemaker Implant without CC/MCC
258	Cardiac Pacemaker Device Replacement with MCC
259	Cardiac Pacemaker Device Replacement without MCC
260	Cardiac Pacemaker Revision Except Device Replacement with MCC
261	Cardiac Pacemaker Revision Except Device Replacement with CC
262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC

Saint Raphael Healthcare System

659 George Street New Haven, Connecticut 06511 www.srhs.org

April 18, 2011

Mr. Michael J. Armstrong
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
John F. Kennedy Federal Building/Room 2425
Boston, MA 02203

Report Number: A-01-10-00512

Dear Mr. Armstrong:

I am responding on behalf of the Hospital of Saint Raphael to the above referenced report entitled *Review of the Hospital of Saint Raphael's Claims for Inpatient & Outpatient Procedures that Included the Replacement of Medical Devices for Calendar years 2008 and 2009.*

The Office of Inspector General has made two recommendations:

Recommendation #1: Adjust and resubmit to NGS the 25 erroneous claims to correct any outstanding portion of the overpayments totaling $231,378 ($171,029 outpatient and $60,349 inpatient claims) and overstated copayment costs totaling $6,778.

Response:

The Hospital of Saint Raphael has reviewed the identified claims and has adjusted the claims as appropriate in accordance with the Medicare billing regulations.

- For the two inpatient claims we have determined that each patient received both an AICD and leads. The AICDs were not eligible for manufacturer credits since they were replaced for clinical reasons and were not subject to recall or warranty. The credits received for the leads were processed on adjusted claims through the Medicare Fiscal Intermediary Shared System (FISS).
- The 12 outpatient claims and 11 inpatient claims were reviewed based on our understanding of the Medicare billing requirements. Adjusted bills were submitted through the Medicare FISS with a modifier "**FD**" value code and a modifier "**FB**" for those devices replaced by the manufacturer at no cost or, for which a full credit was received. In those instances where a partial credit equal to 50 percent or more of the cost of the replacement device was received, the adjusted bill was submitted using modifier "**FC**." The billing for co-payments was also adjusted as appropriate.

Recommendation #2: Strengthen...procedures to obtain credits available from manufacturers and establish procedures to report to NGS the credits that the hospital was entitled to receive.

In order to comply with the Medicare requirements for obtaining credits available from manufacturers for replaced medical devices the Saint Raphael Healthcare System and Hospital of Saint Raphael have adopted billing policies: Policy HSR M-130 Medical Device Implant and Explant Policy and Policy SRHS M-10 Medical Device Tracking Policy and Policy SRHS C-40 Accounting for Credits for Implantable Devices (see **Attachment A**). The Hospital has developed a reporting system involving our Operating Rooms and Catheterization Labs, Materials Management, and Patient Accounts. The Hospital is diligent in making good faith efforts to identify and receive all available credits for any replaced device and has submitted adjusted bills in accordance with CMS regulations. Quarterly internal audits of these procedures are conducted to ensure compliance. Based on the internal audits performed the Hospital has developed a reliable process to track explanted devices, to pursue available credits, and to submit adjusted bills to CMS for adjudication under the prospective payment system.

We appreciate the assistance provided to us during this review by the representatives of the Office of the Inspector General. We will continue to monitor the process for explanted devices and thank you for the opportunity to respond to your findings.

If I can be of any further assistance, please don't hesitate to contact me.

Thank you.

Yours,

J.C. Lubin-Szafranski

Vice President/General Counsel