



Office of Audit Services,
Region I
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November 30, 2010

Report Number: A-01-10-00504

Ms. Karen Murray
Chief Compliance Officer
Yale New Haven Health System
Office of Privacy and Corporate Compliance (Howe-2nd)
789 Howard Avenue
New Haven, CT 06510

Dear Ms. Murray:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Yale New Haven Hospital's Claims for Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2007 and 2008*. 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 David Lamir, Audit Manager, at (617) 565-2704 or through email at David.Lamir@oig.hhs.gov. Please refer to report number A-01-10-00504 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, Missouri 64106

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF YALE NEW HAVEN
HOSPITAL'S CLAIMS FOR
OUTPATIENT PROCEDURES THAT
INCLUDED THE REPLACEMENT
OF MEDICAL DEVICES FOR
CALENDAR YEARS
2007 AND 2008**



Daniel R. Levinson
Inspector General

November 2010
A-01-10-00504

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

The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, pays for hospital outpatient services under a prospective payment system.

Medical Device Replacement

Common medical devices implanted during outpatient procedures include pacemakers, cardioverter defibrillators, and neurostimulators. 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 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.

Yale-New Haven Hospital

Yale New-Haven Hospital (the Hospital) is a 667-bed acute-care hospital located in New Haven, Connecticut. National Government Services (NGS) processes and pays the Hospital’s Medicare claims for outpatient services. NGS paid the Hospital a total of \$2.3 million for 160 claims for outpatient procedures that included the replacement of medical devices during calendar years 2007 and 2008.

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 modifier 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 for replaced medical devices and for reporting the appropriate modifier and charges to reflect the credits received. For 33 of 36 sampled claims for calendar years 2007 and 2008, 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 replacement devices and therefore were not reportable. For the three remaining sampled claims, medical device credits were available from manufacturers and reportable; however:

- For one claim, the Hospital did not obtain a credit that was available under the terms of a manufacturer's warranty.
- For two claims, the Hospital obtained full credits but did not report the "FB" modifier or reduced charges on the claims to alert NGS that payment adjustments were needed.

For the three claims that we identified, the Hospital was overpaid \$27,030. Moreover, for these claims, beneficiaries incurred \$1,848 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not have controls to (1) obtain credits available under the terms of manufacturers' warranties or (2) report the appropriate modifiers and charges to reflect credits received from manufacturers.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NGS the 3 erroneous claims to correct overpayments totaling \$27,030 and overstated copayment costs totaling \$1,848,
- determine whether it should have obtained credits for the remaining 124 claims that we did not review and resubmit the claims as appropriate, and
- establish procedures to obtain credits available from manufacturers and report to NGS the credits obtained for replaced devices in accordance with Medicare requirements.

YALE NEW HAVEN HOSPITAL COMMENTS

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

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YALE NEW HAVEN HOSPITAL COMMENTS

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 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 hospital outpatient departments.¹

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

Credits for Replaced Medical Devices

Common medical devices implanted during outpatient procedures include pacemakers, cardioverter defibrillators, and neurostimulators. 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 outpatient procedures, Medicare generally requires payment adjustments. Specifically, for 31 types of

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.

devices that fall within 21 APCs, Medicare reduces the payment for the replacement of the 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 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 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.

Yale-New Haven Hospital

Yale-New Haven Hospital (the Hospital) is a 667-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 outpatient services.³

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 modifier and charges to reflect the credits received.

Scope

Our audit covered \$2.3 million in Medicare payments to the Hospital for 160 claims for outpatient procedures that included the replacement of any of the 31 specified types of medical devices. The 160 claims had dates of service during calendar years (CY) 2007 and 2008.

² The provider’s failure to report reduced charges on a claim with the “FB” modifier could result in excessive or unwarranted outlier payments.

³ NGS became a MAC in March 2008.

During this period, the Hospital did not submit any outpatient claims with “FB” or “FC” modifiers.⁴

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 February through June 2010. We also contacted NGS.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital’s outpatient paid claim data from CMS’s National Claims History file for CYs 2007 and 2008;
- developed a computer application to identify outpatient claims that included procedures for the replacement of any of the 31 specified types of medical devices and identified 160 claims;
- selected a judgmental sample of 36 of the 160 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 modifier 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;
- 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

⁴ CMS did not require providers to report the “FC” modifier on claims until January 1, 2008.

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

The Hospital did not fully comply with Medicare requirements for obtaining credits available from manufacturers for replaced medical devices and for reporting the appropriate modifier and charges to reflect the credits received. For 33 of the 36 sampled claims for CYs 2007 and 2008, 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 replacement devices and therefore were not reportable. For the three remaining sampled claims, credits were available from manufacturers and reportable; however:

- For one claim, the Hospital did not obtain a credit that was available under the terms of a manufacturer's warranty.
- For two claims, the Hospital obtained full credits but did not report the "FB" modifier or reduced charges on the claims to alert NGS that payment adjustments were needed.

For the three claims that we identified, the Hospital was overpaid \$27,030. Moreover, for these claims, beneficiaries incurred \$1,848 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not have controls to (1) obtain credits available under the terms of manufacturers' warranties or (2) report the appropriate modifiers and charges to reflect credits received 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

Federal regulations (42 CFR § 419.45) require a reduction in the OPPS payment 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.

NONCOMPLIANCE WITH MEDICARE REQUIREMENTS

Hospital Did Not Obtain Available Credit

For 1 of the 36 claims that we reviewed, the Hospital did not obtain a credit for a replaced device that was available under the terms of the manufacturer’s warranty. According to the beneficiary’s medical records for this claim, the device needed to be removed because the battery was depleted. This device was replaced less than 3 years after insertion and thus was eligible for a full credit. The Hospital should have obtained the credit, used the appropriate modifier and charges on its claim, and received a reduced payment.

An overpayment of \$15,776 for this claim occurred because the Hospital did not have controls to obtain credits available under the terms of the manufacturer’s warranty. Specifically, the Hospital did not follow the manufacturer’s procedures, such as returning the devices within a specified number of days after their removal, to obtain the available credits.

Hospital Did Not Report That It Received Credits

For 2 of the 36 claims that we reviewed, the Hospital received full credits for replaced devices but did not report the “FB” modifier or reduced charges on its claims. According to the beneficiaries’ medical records, these devices needed to be removed because the batteries were depleted. Under the terms of the warranty, the manufacturer provided full credits for the cost of the replaced devices. Therefore, these claims should have been submitted with the “FB” modifier and reduced charges to alert NGS that payment reductions were needed.

Overpayments of \$11,254 for the 2 claims occurred because the Hospital did not have controls for reporting medical device credits received from manufacturers. Specifically, the Hospital did not have procedures for coordinating functions among the various departments (i.e., accounts payable, reimbursement, coding, billing and clinical departments) 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 the three claims that we identified, the Hospital was overpaid \$27,030. Moreover, for these claims, beneficiaries incurred \$1,848 in additional copayment costs.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NGS the 3 erroneous claims to correct overpayments totaling \$27,030 and overstated copayment costs totaling \$1,848,
- determine whether it should have obtained credits for the 124 claims that we did not review and resubmit the claims as appropriate, and
- establish procedures to obtain credits available from manufacturers and report to NGS the credits obtained for replaced devices in accordance with Medicare requirements.

YALE NEW HAVEN HOSPITAL COMMENTS

In written comments to the draft report, the Hospital concurred with our recommendations. The Hospital’s comments are included in their entirety as the Appendix.

APPENDIX



VIA FEDERAL EXPRESS

November 11, 2010

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

RE: Yale New Haven Hospital
Report No. A-01-10-00504
Response to Draft Report

Dear Mr. Armstrong:

I am writing on behalf of Yale-New Haven Hospital (the "Hospital") to respond to the U.S. Department of Health & Human Services, Office of Inspector General's ("OIG's") draft report entitled "*Yale New Haven Hospital's Claims for Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2007 and 2008.*" The draft report makes three Recommendations and asks the Hospital to indicate its "concurrence" or "nonconcurrence" with each, along with an explanation for its position. Below, as requested, we address each of these Recommendations.¹

Recommendation: adjust and resubmit to NGS the 3 erroneous claims to correct overpayments totaling \$27,030 and overstated copayment costs totaling \$1,848.

Response: Concur. The Hospital is working with NGS regarding the resubmission and adjustment of these three claims. The Hospital notes that copayments for these three claims were made by third party payers, not beneficiaries. Accordingly, the Hospital will make necessary overpayment adjustments relating to these three claims with the appropriate payer.

Recommendation: determine whether [the Hospital] should have obtained credit for the 124 claims that [the OIG] did not review and resubmit the claims as appropriate.

Response: Concur. The Hospital is reviewing the 124 Medicare claims to determine whether they have or will receive any credits that may be due from manufacturers for replaced medical devices related to them and will resubmit them as appropriate.

¹ In addition, the Hospital notes its position that the "Prudent Buyer" principle does not apply to the type of claims addressed in the draft report.

Recommendation: establish procedures to obtain credits available from manufacturers and report to NGS the credits obtained for replaced devices in accordance with Medicare requirements.

Response: Concur. The Hospital's policies and procedures that address returning explanted devices to the manufacturer for warranty credit consideration and reporting credits obtained for replaced devices in accordance with Medicare requirements are as follows: Each Hospital clinical department involved with device implants/explants has implemented a written procedure to track the devices sent to Pathology, and subsequently to the manufacturer, after they have been evaluated and a determination made that a credit may be available. A committee has been formed that will meet regularly to ensure that appropriate credits are received and to provide the necessary information to the Hospital's Health Information Management (HIM) Department. The HIM Department will recode the procedures with the appropriate modifier and the corrected claim will be submitted to National Government Services for re-adjudication. The new policy requires an annual audit of these procedures to assure compliance with the Medicare requirements.

Thank you for giving us an opportunity to respond. As requested in the draft report, the Hospital is also submitting an electronic copy in PDF format. Please contact me at 203-688-3369 if you have any questions or any problems with the electronic copy.

Sincerely,

Karen Murray

Karen Murray, MBA, CHC, FACHE
Chief Compliance Officer

cc: Marna Borgstrom, President & CEO
James Staten, Executive Vice President, Corporate & Financial Services