Office of Audit Services
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John F. Kennedy Federal Building
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November 19, 2010

Report Number: A-01-10-00503

Ms. Marjorie Beal
Senior Director, Hospital Billing Compliance
UMass Memorial Healthcare, Hahnemann Campus
22 Shattuck Street
Worcester, MA 01605

Dear Ms. Beal:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of UMass Memorial Medical Center 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-01-10-00503 in 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 (CFMFFSO)
Centers for Medicare & Medicaid Services
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Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF UMASS MEMORIAL MEDICAL CENTER 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-01-10-00503

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.

UMass Memorial Medical Center

UMass Memorial Medical Center (the Hospital) is a 632 bed acute-care hospital located in Worcester, Massachusetts. National Heritage Insurance Company (NHIC) processes and pays the hospital's claims for outpatient services. NHIC paid the Hospital a total of $2.4 million for 181 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

Although the Hospital complied with Medicare requirements for obtaining credits available from manufacturers for replaced medical devices, it did not fully comply with requirements for reporting the appropriate modifier and charges to reflect the credits received. For 31 of 32

sampled claims for calendar years 2007 and 2008, there were no available credits or the credits were partial credits received from the manufacturer that did not represent at least 50 percent of the cost of the replacement device and therefore were not reportable. For the one remaining sampled claim, a credit was available from the manufacturer and reportable. For this claim, the Hospital obtained full credit but did not report the "FB" modifier on the claim to alert NHIC that a payment adjustment was needed.

Our limited review of the 149 remaining claims for the audit period found that the Hospital had received full credits for the replaced devices on 2 claims. However, the Hospital did not report the "FB" modifier or reduced charges on these claims to alert NHIC that payment adjustments were needed.

As a result, for the 3 claims the Hospital was overpaid $33,762. Moreover, for these claims, beneficiaries incurred $1,440 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not have controls to report the appropriate modifiers and charges to reflect credits received from manufacturers.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NHIC the 3 erroneous claims to correct overpayments totaling $33,762 and overstated copayment costs totaling $1,440; and

- establish procedures to report to NHIC the credits obtained for replaced devices in accordance with Medicare requirements.

UMASS MEMORIAL MEDICAL CENTER COMMENTS

In comments on our draft report, UMass Memorial Medical Center agreed with our findings and recommendations. UMass Memorial Medical Center's comments are included in their entirety in the appendix.

TABLE OF CONTENTS

Page

INTRODUCTION 1

BACKGROUND 1
Hospital Outpatient Prospective Payment System 1
Credits for Replaced Medical Devices 1
Reimbursement for Medical Device Replacement 1
UMass Memorial Medical Center 2

OBJECTIVE, SCOPE, AND METHODOLOGY 2
Objective 2
Scope 2
Methodology 3

FINDINGS AND RECOMMENDATIONS 4

MEDICARE REQUIREMENTS 4
Coding Requirements for Medical Device Credits 4

NONCOMPLIANCE WITH MEDICARE REQUIREMENTS 5
Hospital Did Not Report That It Received Credits 5

MEDICARE OVERPAYMENTS 5

RECOMMENDATIONS 6

UMASS MEMORIAL MEDICAL CENTER COMMENTS 6

APPENDIX

UMASS MEMORIAL MEDICAL CENTER 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.

UMass Memorial Medical Center

UMass Memorial Medical Center (the Hospital) is a 632 bed acute-care hospital located in Worcester, Massachusetts. As the Medicare contractor for hospitals in Massachusetts, National Heritage Insurance Company (NHIC) 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 $2.4 million in Medicare payments to the Hospital for 181 claims for outpatient procedures that included the replacement of any of the 31 specified types of medical

[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] NHIC became a MAC on May 18, 2009.

devices. The 181 claims had dates of service during calendar years (CY) 2007 and 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 Worcester, Massachusetts, and at three medical device manufacturers in St. Paul, Minnesota, from February through June 2010. We also contacted NHIC.

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 181 claims;
- selected a judgmental sample of 32 of the 181 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;
- requested information from the Hospital on the 149 remaining claims in the population and performed a limited review to identify those claims for which the Hospital received reportable credits from the device manufacturers;
- calculated the correct payments for those claims for which payment adjustments were needed; and

[4] CMS did not require providers to report the "FC" modifier on claims until January 1, 2008.

- 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Although the Hospital complied with Medicare requirements for obtaining credits available from manufacturers for replaced medical devices, it did not fully comply with requirements for reporting the appropriate modifier and charges to reflect the credits received. For 31 of 32 sampled claims for calendar years 2007 and 2008, there were no available credits or the credits were partial credits received from the manufacturer that did not represent at least 50 percent of the cost of the replacement device and therefore were not reportable. For the one remaining sampled claim, a credit was available from the manufacturer and reportable because the Hospital obtained full credit but did not report the "FB" modifier on the claim to alert NHIC that a payment adjustment was needed.

Our limited review of the 149 remaining claims for the audit period found that the Hospital had received full credits for the replaced devices on 2 claims. However, the Hospital did not report the "FB" modifier or reduced charges on these claims to alert NHIC that payment adjustments were needed.

As a result, for the 3 claims that we identified the Hospital was overpaid $33,762. Moreover, for these claims, beneficiaries incurred $1,440 in additional copayment costs. These overpayments and additional copayment costs occurred because the Hospital did not have controls to report the appropriate modifiers and charges to reflect credits received from manufacturers.

MEDICARE REQUIREMENTS

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 Report That It Received Credits

For 1 of the 32 claims that we reviewed, the Hospital received full credit for a replaced device but did not report the "FB" modifier on its claim (although the Hospital did report reduced device charges). According to the beneficiary's medical records, the manufacturer recalled the device just over 6 months after its insertion. Under the terms of the recall, the manufacturer provided full credit for the cost of the replaced device. Therefore, this claim should have been submitted with the "FB" modifier to alert NHIC that a payment reduction was needed.

Our limited review of information provided to us by the medical device manufacturers found that the Hospital had received full credits for replaced devices for 2 of the remaining 149 claims but had not reported the credits in accordance with Medicare requirements. These claims should have been submitted with the "FB" modifier and reduced charges to alert NHIC that a payment reduction was needed.

Overpayments of $33,762 for the three 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, patient accounts, and Medicare billing) 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 $33,762. Moreover, for these claims, beneficiaries incurred $1,440 in additional copayment costs.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NHIC the 3 erroneous claims to correct overpayments totaling $33,762 and overstated copayment costs totaling $1,440; and

- establish procedures to report to NHIC the credits obtained for replaced devices in accordance with Medicare requirements.

UMASS MEMORIAL MEDICAL CENTER COMMENTS

In comments on our draft report, UMass Memorial Medical Center agreed with our findings and recommendations. UMass Memorial Medical Center's comments are included in their entirety in the appendix.

APPENDIX

UMassMemorial

Compliance Office

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November 09, 2010

Mr. Michael Armstrong
Regional Inspector General for Audit Services,
Office of the Inspector General, Audit Services, Region 1
John F. Kennedy Federal Building, Room 2425
Boston, MA 02203

Re: Draft Report Number A-01-10-00503 titled *Review of UMass Memorial Medical Center Claims for Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2007 and 2008.*

Dear Mr. Armstrong,

In accordance with your letter dated October 14, 2010, I am responding to your request for written comments related to the validity of facts contained in the draft report, the reasonableness of the recommendations offered by the Office of the Inspector General and the nature of corrective actions taken or planned.

Overall, we are in agreement with the information contained in this draft report. Specifically, we are pleased that the OIG auditors recognized the fact that UMass Memorial Medical Center generally complied with requirements for obtaining credits available from manufacturers.

In response to the specific recommendations contained in the OIG's draft report, we offer the following response.

- "Adjust and resubmit to NHIC the 3 erroneous claims to correct overpayments totaling $33,762 and overstated co-payment costs totaling $1,440."

  - We agree with the auditor's findings related to the above claims and have adjusted these claims in the Medicare Fiscal Intermediary Shared System (FISS). In all three instances, co-payments were paid by secondary insurance and adjustments will be submitted to those insurers when the Medicare adjusted payments have been processed.

- "Establish procedures to report to NHIC the credits obtained for replacement devices in accordance with Medicare requirements."

- Education regarding Medicare replacement device billing requirements has been provided. Policies and procedures have been developed to ensure appropriate coding and billing to Medicare when credits for replacement devices have been received.

Additionally, UMass Memorial Medical Center will perform a retrospective review of Medicare claims involving credits for devices replaced under warranty for the time period January 1, 2007 to present. Claim adjustments will be submitted to NHIC and secondary payors (including Medicare beneficiaries) for claims where modifier FB or FC had not been reported.

Please feel free to contact me at 508-334-5593 if you have any questions.

Sincerely,

Marjorie A. Beal

Marjorie A. Beal
Senior Director, Hospital Billing Compliance
UMass Memorial Health Care
508-334-5593

C: John Randolph
Todd Keating
John Salzberg