DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Office of Audit Services
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203

December 6, 2010

Report Number: A-01-10-00501

Mr. John B. Belknap
Director, Corporate Compliance
Massachusetts General Hospital
Bulfinch 360
55 Fruit Street
Boston, MA 02114

Dear Mr. Belknap:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Massachusetts General 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-01-10-00501 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
601 East 12th Street, Room 235
Kansas City, Missouri 64106

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MASSACHUSETTS GENERAL HOSPITAL'S CLAIMS FOR OUTPATIENT PROCEDURES THAT INCLUDED THE REPLACEMENT OF MEDICAL DEVICES FOR CALENDAR YEARS 2007 AND 2008

Daniel R. Levinson
Inspector General

December 2010
A-01-10-00501

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 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.

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.

Massachusetts General Hospital

Massachusetts General Hospital (the Hospital) is a 900-bed medical center located in Boston, Massachusetts. National Heritage Insurance Company (NHIC) processes and pays the Hospital's Medicare claims for outpatient services. NHIC paid the Hospital a total of $2.8 million for 212 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 29 of 34 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 five remaining sampled claims, medical device credits were available from manufacturers and reportable.

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

- For three claims, the Hospital obtained full credits but did not report the "FB" modifier or reduced charges on the claims to alert NHIC that a payment adjustment was needed.

Our limited review of the 178 remaining claims for the audit period found that the Hospital had received full credits for the replaced devices on 5 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 10 claims, the Hospital was overpaid $62,653. Moreover, for these claims, beneficiaries incurred $6,210 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 NHIC the 10 erroneous claims to correct overpayments totaling $62,653 and overstated copayment costs totaling $6,210,

- determine whether it should have obtained credits for the remaining 173 claims (the 178 claims for which we performed a limited review less the 5 claims for which the Hospital had received full credits) and resubmit the claims as appropriate, and

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

MASSACHUSETTS GENERAL HOSPITAL'S COMMENTS

In written comments to the draft report, the Hospital generally concurred with our recommendations. The Hospital concurred with our recommendation to re-adjudicate through the Medicare Fiscal Intermediary Shared System eight of the ten claims identified by the OIG as overpayments. The Hospital does not believe the regulation cited in the report applies to the two remaining claims where warranty credits were not received. The Hospital will continue to pursue warranty credits for the remaining two claims and will adjust and resubmit those claims if it obtains credits for the replaced devices. The Hospital's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

As stated in Section 2103 of CMS's *Provider Reimbursement Manual*, Medicare providers are expected to pursue free replacements or reduced charges for devices that fail while covered under a manufacturer warranty. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment. For two claims the Hospital did not obtain credits for the replaced devices that were available under the terms of the manufacturers' warranties. Therefore, the Hospital should adjust and resubmit to NHIC the two claims to reflect credits that could have been obtained.

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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 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. 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 inserted 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 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.

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.

Massachusetts General Hospital

Massachusetts General Hospital (the Hospital), is a 900 bed medical center located in Boston, 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 $2.8 million in Medicare payments to the Hospital for 212 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 device charges on a claim with the modifier "FB" could result in excessive or unwarranted outlier payments.

[3] NHIC became a MAC effective May 18, 2009.

devices. The 212 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 Boston, 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 212 claims;

- selected a judgmental sample of 34 of the 212 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 178 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;

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

- 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 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 29 of the 34 sampled claims for CYs 2007 and 2008, there were no available credits or the credits were partial credits received from manufacturers but did not represent at least 50 percent of the cost of the replacement devices and therefore were not reportable. For the five remaining sampled claims, medical device credits were available from manufacturers and reportable; however:

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

- For three claims, the Hospital obtained full credits but did not report the "FB" modifier or reduced charges on the claims to alert NHIC that a payment adjustment was needed.

Our limited review of the 178 remaining claims for the audit period found that the Hospital had received full credits for the replaced devices on 5 claims. However, the Hospital did not report the "FB" modifier or reduced charges on these claims to alert NHIC that payment adjustments were needed.

For the ten claims that we identified, the Hospital was overpaid $62,653. Moreover, for these claims, beneficiaries incurred $6,210 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 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 Credits

For 2 of the 34 claims that we reviewed, the Hospital did not obtain credits for replaced devices that were available under the terms of the manufacturers' warranties. For example, according to the beneficiary's medical records for one claim, the device needed to be removed because the battery was depleted. This device was replaced less than 5 years after insertion and thus was

eligible for full credit. The Hospital should have obtained the credit, used the appropriate modifier and charges on its claim, and received a reduced payment.

Overpayments of $6,934 for the two claims occurred because the Hospital did not have controls to obtain credits available under the terms of manufacturers' warranties. Specifically, the Hospital did not follow the manufacturers' 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 3 of the 34 claims that we reviewed, the Hospital received full credits for the 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 replaced because the batteries were depleted. Under the terms of the warranty, the manufacturer provided full credits for the three devices. Therefore, these claims should have been submitted with the "FB" modifier and reduced charges to alert NHIC that payment reductions were needed.

Our limited review of information provided to us by the medical device manufacturers and confirmed by the Hospital found that the Hospital had received full credits for replaced devices for 5 of the remaining 178 claims but had not reported the credits in accordance with Medicare requirements.[5] These five claims should have been submitted with the "FB" modifier and reduced charges to alert NHIC that payment reductions were needed.

Overpayments of $55,719 for the eight 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., cardiology, vendor management, accounts payable, and patient accounts) 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 ten claims that we identified, the Hospital was overpaid $62,653. Moreover, for these claims, beneficiaries incurred $6,210 in additional copayment costs.

RECOMMENDATIONS

We recommend that the Hospital:

- adjust and resubmit to NHIC the 10 erroneous claims to correct overpayments totaling $62,653 and overstated copayment costs totaling $6,210,

- determine whether it should have obtained credits for the remaining 173 claims (the 178 claims for which we performed a limited review less the 5 claims for which the Hospital had received full credits) and resubmit the claims as appropriate, and

[5] We did not determine whether the Hospital should have obtained available credits.

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

MASSACHUSETTS GENERAL HOSPITAL'S COMMENTS

In written comments to the draft report, the Hospital generally concurred with our recommendations. The Hospital concurred with our recommendation to re-adjudicate through the Medicare Fiscal Intermediary Shared System eight of the ten claims identified by the OIG as overpayments. The Hospital does not believe the regulation cited in the report applies to the two remaining claims where warranty credits were not received. The Hospital will continue to pursue warranty credits for the remaining two claims and will adjust and resubmit those claims if it obtains credits for the replaced devices. The Hospital's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

As stated in Section 2103 of CMS's *Provider Reimbursement Manual*, Medicare providers are expected to pursue free replacements or reduced charges for devices that fail while covered under a manufacturer warranty. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment. For two claims the Hospital did not obtain credits for the replaced devices that were available under the terms of the manufacturers' warranties. Therefore, the Hospital should adjust and resubmit to NHIC the two claims to reflect credits that could have been obtained.

APPENDIX

MASSACHUSETTS GENERAL HOSPITAL
MASSACHUSETTS GENERAL PHYSICIANS ORGANIZATION

Corporate Compliance Office
55 Fruit Street, Bulfinch 360
Boston, Massachusetts 02114

November 5, 2010

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

Provider Number: 220071
Report Number: A-01-10-00501

Dear Mr. Armstrong:

The purpose of this letter is to provide the comments of the Massachusetts General Hospital (MGH) relating to the above referenced Report, which relates to claims paid under Medicare's Hospital Outpatient Prospective Payment System (HOPPS).

MGH concurs with the Office of Inspector General (OIG) that, of the 212 explantations reviewed, in eight instances related to outpatient services rendered to Medicare beneficiaries between January 1, 2007 and December 31, 2008, warranty credits were received from device vendors that justified modification of claims previously submitted to Medicare in accordance with Federal Regulations 42 CFR 419.45. MGH has re-adjudicated these claims through the Medicare Fiscal Intermediary Shared System (FISS). These actions will result in a voluntary refund of approximately $55,718. Related refunds to Medicare beneficiaries and secondary payers are also being processed.

Federal Regulations 42 CFR 419.45 require a reduction in the HOPPS payment for the replacement of an implanted device only 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. While MGH has successfully obtained credits in eight of the ten claims identified by the OIG, MGH does not believe the regulation has been triggered for the remaining two claims since MGH has not received

warranty credits related to the two replaced devices. However, MGH continues to pursue warranty credits for the remaining two cases identified by the OIG and will re-adjudicate the previously submitted claims if warranty credits are received requiring such actions. MGH will also conduct reasonable inquiry into whether warranty credits are available for the remaining 173 devices explanted from Medicare beneficiaries during 2007 and 2008 and will re-adjudicate related previously submitted claims if warranty credits are received requiring such actions.

MGH believes it had and continues to have a reliable process to return explanted devices to the device manufacturer for warranty credit consideration. MGH acknowledges it did not have sufficient processes to coordinate the re-adjudication of claims if credits were received that warranted such actions. MGH has provided the OIG with an overview of interim and long term solutions designed to enable MGH to track requests for warranty credits, identify credits received and report to Medicare instances where such credits obligate MGH to re-adjudicate claims.

Please let us know if you have any questions or need any additional information.

Sincerely,

John Belknap
Corporate Compliance Officer
Massachusetts General Hospital

cc: Stephen Gillis
Director of Billing Compliance