Office of Audit Services
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203
(617) 565-2684

December 14, 2010

Report Number: A-01-10-00506

Mr. James J. Kenney
Director of Internal Audit
Lahey Clinic
41 Mall Road
Burlington, MA 01805

Dear Mr. Kenney:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Lahey Clinic'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) 565-4336 or through email at David.Lamir@oig.hhs.gov. Please refer to report number A-01-10-00506 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)
Center for Medicare & Medicaid Services
601 East 12th Street Room 235
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Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF LAHEY CLINIC'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-01-10-00506

Office of Inspector General

http://oig.hhs.gov

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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 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.

Lahey Clinic

Lahey Clinic (the Clinic) is a 317-bed acute-care hospital located in Burlington, Massachusetts. National Heritage Insurance Company (NHIC) processes and pays the Clinic's Medicare claims for outpatient services. NHIC paid the Clinic a total of $3.7 million for 210 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 Clinic 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 Clinic 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 27 of 30 sampled claims for calendar years 2007 and 2008, there were no available credits or the credit was a partial credit 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 three remaining sampled claims, credits were available from manufacturers and reportable; however:

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

- For one claim, the Clinic obtained full credit but did not report the "FB" modifier or reduced charges on the claim to alert NHIC that a payment adjustment was needed.

The Clinic's review (which we verified) of the 180 remaining claims for the audit period found that the Clinic had received full credits for the replaced devices on 7 claims. However, the Clinic did not report the "FB" modifier or reduced charges on these claims to alert NHIC that payment adjustments were needed.

For the three claims that we identified and the seven claims that the Clinic identified, the Clinic was overpaid $121,268. Moreover, for these claims, beneficiaries incurred $4,464 in additional copayment costs. These overpayments and additional copayment costs occurred because the Clinic 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 due from manufacturers.

RECOMMENDATIONS

We recommend that the Clinic:

- adjust and resubmit to NHIC the 10 erroneous claims to correct any outstanding portion of overpayments totaling $121,268 and overstated copayment costs totaling $4,464,

- determine whether it could have obtained credits for the remaining 173 claims (the 180 claims that we did not review less the 7 claims for which the Clinic found that it 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 that the Clinic was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

LAHEY CLINIC'S COMMENTS

In written comments to the draft report, the Clinic concurred in part and disagreed in part with our recommendations. Regarding our first recommendation, the Clinic stated that 8 of 10 erroneous claims were properly adjudicated by NHIC in late July 2010. For 2 of the 10 claims, the manufacturer did not issue a credit to the Clinic. The Clinic has requested credits on these 2 claims and, if credits are received, the claims will be re-processed. In addressing our second recommendation, the Clinic stated that it will perform a second review of the 173 claims to ensure that all credits received have been reflected although the Clinic believes it complied with

all applicable requirements regarding these claims. In response to our third recommendation, the Clinic stated that it has established procedures to ensure that it receives all applicable credits and that claims are processed correctly. The Clinic's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding the Clinic's comments on our first recommendation, as required by 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 Clinic did not obtain credits for the replaced devices that were available under the terms of the manufacturers' warranties. For these claims, the Clinic should adjust and resubmit to NHIC the two claims to reflect credits that could have been obtained. Regarding the Clinic's comments on our second recommendation, we did not recommend that the Clinic review the remaining 173 claims to ensure that all credits received have been reflected. Rather, we recommended the Clinic review the 173 claims to determine whether it *could have* obtained credits and, if so, resubmit the claims. Lastly, we clarified our third recommendation to emphasize that the Clinic should report to NHIC the credits that the Clinic was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

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LAHEY CLINIC'S 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

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[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.

Lahey Clinic

Lahey Clinic (the Clinic) is a 317-bed acute-care hospital located in Burlington, Massachusetts. As the Medicare contractor for hospitals in Massachusetts, National Heritage Insurance Company (NHIC) processes and pays the Clinic's claims for Medicare outpatient services.[3]

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Clinic 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 $3.7 million in Medicare payments to the Clinic for 210 claims for outpatient procedures that included the replacement of any of the 31 specified types of medical devices.

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[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.

The 210 claims had dates of service during calendar years (CY) 2007 and 2008.During this period, the Clinic submitted only two outpatient claims with "FB" modifiers.[4]

We limited our internal control review to the Clinic'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 Clinic in Burlington, 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 Clinic'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 210 claims;
- selected a judgmental sample of 30 of the 210 claims and reviewed the beneficiaries' medical records, accounts payable invoices, and manufacturers' warranties to determine whether the Clinic should have submitted the claims with the applicable modifier and reduced charges;
- reviewed the Clinic'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 Clinic to identify their requirements for issuing credits and obtained lists of credits issued to the Clinic to determine whether Medicare payment adjustments were needed;
- verified the results of the Clinic's self-initiated review of the 180 remaining claims in the population;
- reviewed adjusted claims that the Clinic resubmitted to NHIC;
- 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 Clinic 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 Clinic 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 27 of the 30 sampled claims for CYs 2007 and 2008, there were no available credits or the credit was a partial credit 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 two claims, the Clinic did not obtain credits that were available under the terms of the manufacturers' warranties.

- For one claim, the Clinic obtained full credit but did not report the "FB" modifier or reduced charges on the claim to alert NHIC that a payment adjustment was needed.

The Clinic's review (which we verified) of the 180 remaining claims for the audit period found that the Clinic had received full credits for the replaced devices on 7 claims. However, the Clinic did not report the "FB" modifier or reduced charges on these claims to alert NHIC that payment adjustments were needed.

For the three claims that we identified and the seven claims that the Clinic identified, the Clinic was overpaid $121,268. Moreover, for these claims, beneficiaries incurred $4,464 in additional copayment costs. These overpayments and additional copayment costs occurred because the Clinic 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 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

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

Clinic Did Not Obtain Available Credits

For 2 of the 30 claims that we reviewed, the Clinic 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 3 years after insertion and thus was

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

Overpayments of $42,333 for the two claims occurred because the Clinic did not have controls to obtain credits available under the terms of manufacturers' warranties. Specifically, the Clinic 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.

Clinic Did Not Report That It Received Credits

For 1 of the 30 claims that we reviewed, the Clinic received full credit for a replaced device but did not report the "FB" modifier or reduced charges on its claim. According to the beneficiary's medical records, the manufacturer recalled the device about 3 years 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 and reduced charges to alert NHIC that a payment reduction was needed.

After our initial contact, the Clinic initiated a review of the 180 claims that we did not review.[5] The Clinic found that it had received full credits for replaced devices for 7 of the 180 claims but had not reported the credits in accordance with Medicare requirements. Through information provided to us by the Clinic and selected medical device manufacturers, we verified the Clinic's results. These seven claims should have been submitted with the "FB" modifier and reduced charges to alert NHIC that payment reductions were needed.

Overpayments of $78,935 for the eight claims (one claim that we identified and seven claims that the Clinic identified) occurred because the Clinic did not have controls for reporting medical device credits received from manufacturers.[6] Specifically, the Clinic 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 and the seven claims that the Clinic identified, the Clinic was overpaid $121,268. Moreover, for these claims, beneficiaries incurred $4,464 in additional copayment costs.

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[5] The Clinic's review did not include determining whether it should have obtained available credits.

[6] During our review, the Clinic adjusted and resubmitted the eight claims to NHIC. Although the Clinic correctly reported the "FB" modifier on the adjusted claims, it did not report reduced charges. As a result, the adjusted claims did not fully resolve the overpayments that we identified.

RECOMMENDATIONS

We recommend that the Clinic:

- adjust and resubmit to NHIC the 10 erroneous claims to correct any outstanding portion of overpayments totaling $121,268 and overstated copayment costs totaling $4,464,

- determine whether it could have obtained credits for the remaining 173 claims (the 180 claims that we did not review less the 7 claims for which the Clinic found that it 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 that the Clinic was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

LAHEY CLINIC'S COMMENTS

In written comments to the draft report, the Clinic concurred in part and disagreed in part with our recommendations. Regarding our first recommendation, the Clinic stated that 8 of 10 erroneous claims were properly adjudicated by NHIC in late July 2010. For 2 of the 10 claims, the manufacturer did not issue a credit to the Clinic. The Clinic has requested credits on these 2 claims and, if credits are received, the claims will be re-processed. In addressing our second recommendation, the Clinic stated that it will perform a second review of the 173 claims to ensure that all credits received have been reflected although the Clinic believes it complied with all applicable requirements regarding these claims. In response to our third recommendation, the Clinic stated that it has established procedures to ensure that it receives all applicable credits and that claims are processed correctly. The Clinic's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding the Clinic's comments on our first recommendation, as required by 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 Clinic did not obtain credits for the replaced devices that were available under the terms of the manufacturers' warranties. For these claims, the Clinic should adjust and resubmit to NHIC the two claims to reflect credits that could have been obtained. Regarding the Clinic's comments on our second recommendation, we did not recommend that the Clinic review the remaining 173 claims to ensure that all credits received have been reflected. Rather, we recommended the Clinic review the 173 claims to determine whether it *could have* obtained credits and, if so, resubmit the claims. Lastly, we clarified our third recommendation to emphasize that the Clinic should report to NHIC the credits that the Clinic was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

APPENDIX

Lahey CLINIC

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A teaching hospital of Tufts University School of Medicine

November 24, 2010

Report Number: A-01-10-00506

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

Dear Mr. Armstrong:

Lahey Clinic Hospital, Inc. ("Lahey Clinic") is in receipt of the U.S. Department of Health & Human Services, Office of Inspector General ("OIG"), draft report entitled *Review of Lahey Clinic's Claims for Outpatient Procedures that Included the Replacement of Medical Devices for Calendar Years 2007 and 2008.* Lahey Clinic's response to the OIG's recommendations are set forth below, in a format that mirrors the format in your letter.

Recommendation #1: *Adjust and resubmit to NHIC the 10 erroneous claims to correct any outstanding portion of overpayments totaling $121,268 and overstated copayment costs totaling $4,464.*

Lahey Clinic followed Medicare's billing criteria in submitting claims based on information available at the time of billing. When Lahey Clinic determined that a returned device credit was received, claims were adjusted in accordance with Medicare regulations. Eight of these claims were properly adjudicated by NHIC in late July 2010.

For two of the 10 claims, the manufacturer did not issue a credit to Lahey Clinic. Lahey Clinic has requested any and all credits that may be owed on these two claims and once received, the claims will be re-processed as appropriate.

Recommendation #2: *Determine whether it should have obtained credits for the remaining 173 claims (the 180 claims that we did not review less the 7 claims for which the Clinic found it had received full credits) and resubmit the claims as appropriate.*

As is pointed out in the OIG draft report, Lahey Clinic had previously reviewed the 173 claims. As a result of receiving this recommendation, we have decided to perform a second review to ensure that all credits received have been reflected. Lahey Clinic will adjust all claims that received device credits as a result of this second review.

As the OIG is aware, during the time period covered by the 173 claims, Lahey Clinic's process for returning explanted medical devices to the manufacturers was to place the explanted medical devices in specifically identified and dedicated bins for the manufacturers' staff (sales/technician) to retrieve. Lahey Clinic and the manufacturers' representatives adhered to this process during this time period... The manufacturers evaluated explanted medical devices from Lahey Clinic to determine whether credits would be processed to Lahey Clinic. Therefore, Lahey Clinic believes it complied with all applicable requirements regarding the 173 claims. Lahey Clinic cannot explain why a manufacturer has stated that a number of medical devices were not received by the manufacturer.

Recommendation #3: *Establish procedures to obtain credits available from manufacturers and report to CMS the credits obtained for replaced devices in accordance with Medicare requirements.*

As is pointed out in the draft report, Lahey Clinic has established procedures to ensure that Lahey Clinic receives all applicable credits and that claims are processed correctly. It deserves noting that the device manufacturers have historically taken weeks and even months to determine and then issue a notice of a credit. Due to this great length of time, the hospital has been submitting initial claims without the benefit of knowledge of a future credit. Once the manufacture issues Lahey Clinic a credit, a corrected claims is generated to correct any overpayment. We would very much like to continue to work with manufacturers and CMS so that credits can be identified in time for a correct first claim.

NHIC Medicare is struggling with how to re-process these explant claims where credits have been received, especially, in the situation where two medical devices (for instance, pacemaker and lead) are involved, but only one of those devices receives a credit. Medicare is adjusting the entire claim since the CMS guidance indicates that the modifier needs to be placed on the procedure that includes both devices. This results in the hospital being underpaid for the services rendered.

In conclusion, as was conveyed to the OIG during the audit, Lahey Clinic has adjusted claims when a manufacturer credit was received. Lahey Clinic has also established procedures that ensure Lahey Clinic will continue to submit accurate claims when explanted device credits are received. Lahey Clinic will continue to work closely with the manufacturers that bear the burden of determining and issuing credit amounts for replaced devices that Lahey Clinic has returned. Lahey Clinic looks forward to working with manufactures and NHIC Medicare in efforts to improve the process, timeliness and accuracy of claims and payment for future explanted device cases. .

Sincerely,

James J. Kenney
Director of Internal Audit
Corporate Compliance Officer