

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF BETH ISRAEL  
DEACONESS MEDICAL CENTER  
CLAIMS THAT INCLUDED  
MEDICAL DEVICE  
REPLACEMENTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



David Lamir  
Regional Inspector General for  
Audit Services

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# *Office of Inspector General*

<http://oig.hhs.gov>

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## EXECUTIVE SUMMARY

***Beth Israel Deaconess Medical Center did not fully comply with Medicare requirements for billing inpatient and outpatient claims for replaced medical devices, resulting in overpayments of approximately \$483,000 over 4 years.***

### WHY WE DID THIS REVIEW

For calendar year (CY) 2012, Medicare paid hospitals \$148 billion, which represented 43 percent of all fee-for-service payments; therefore, the Office of Inspector General must provide continual and adequate oversight of Medicare payments to hospitals. Using data analysis techniques, we identified hospital claims for the replacement of defective medical devices that were at risk for noncompliance with Medicare billing requirements.

The objective of this review was to determine whether Beth Israel Deaconess Medical Center (BIDMC) complied with Medicare requirements for billing inpatient and outpatient services for replaced medical devices on selected claims.

### BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

BIDMC, located in Boston, Massachusetts, is a fully integrated medical center with 649 beds.

Our audit covered \$706,581 in Medicare payments to BIDMC for 23 claims for replaced medical devices, consisting of 14 inpatient and 9 outpatient claims. These claims had dates of service in CY 2010, CY 2011, CY 2012, or CY 2013.

### WHAT WE FOUND

BIDMC complied with Medicare billing requirements for 3 of the 23 inpatient and outpatient claims we reviewed. However, BIDMC did not fully comply with Medicare requirements for the remaining 20 claims, resulting in overpayments of \$483,104 for CYs 2010 through 2013. Specifically, 11 inpatient claims had errors, resulting in overpayments of \$339,384, and 9 outpatient claims had errors, resulting in overpayments of \$143,720. These errors occurred primarily because (1) BIDMC staff had inadequate education on inpatient level-of-care criteria, (2) case management and utilization review for inpatient short stays did not always occur, and (3) BIDMC did not always report the appropriate information to reflect the credits it received for replaced medical devices.

## **WHAT WE RECOMMEND**

We recommend that BIDMC:

- refund to the Medicare contractor \$483,104, consisting of \$339,384 in overpayments for 11 incorrectly billed inpatient claims and \$143,720 in overpayments for 9 incorrectly billed outpatient claims, and
- strengthen controls to ensure full compliance with Medicare requirements.

## **BETH ISRAEL DEACONESS MEDICAL CENTER COMMENTS AND OUR RESPONSE**

In written comments on our draft report, BIDMC generally concurred with our findings and recommendations.

However, BIDMC stated that it was inaccurate to suggest that its controls and staff education were inadequate throughout the entire review period relative to level of care medical necessity determinations. BIDMC stated that it made enhancements over the past few years to the staffing and internal controls that affect case management and the determination of the appropriate level of care.

We acknowledge BIDMC's concerns regarding our assertion that controls and staff education were inadequate throughout the entire review period. BIDMC's updated enhancements to staff education and internal controls most likely had an impact for 2013, the last year of our review, for which we did not identify medical necessity errors. We have updated the final report accordingly. We acknowledge BIDMC's efforts to strengthen its compliance with Medicare requirements.

BIDMC stated that it would process the necessary adjustments through its Medicare contractor and resubmit certain claims, as appropriate, to Part B. BIDMC stated that it will also continue to monitor and strengthen existing internal controls and educate staff to minimize the risk of errors.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

For calendar year (CY) 2012, Medicare paid hospitals \$148 billion, which represented 43 percent of all fee-for-service payments; therefore, the Office of Inspector General must provide continual and adequate oversight of Medicare payments to hospitals. Using data analysis techniques, we identified hospital claims for the replacement of defective medical devices that were at risk for noncompliance with Medicare billing requirements.

### OBJECTIVE

Our objective was to determine whether Beth Israel Deaconess Medical Center (BIDMC) complied with Medicare requirements for billing inpatient and outpatient services for replaced medical devices on selected claims.

### BACKGROUND

#### **The Medicare Program**

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

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

#### **Hospital Inpatient Prospective Payment System**

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system (IPPS). The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay.

#### **Hospital Outpatient Prospective Payment System**

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services

within each APC group.<sup>1</sup> All services and items within an APC group are comparable clinically and require comparable resources.

### **Medicare Requirements for Hospital Claims and Payments**

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Social Security Act (the Act), § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).

### **Beth Israel Deaconess Medical Center**

BIDMC, located in Boston, Massachusetts, is a fully integrated medical center with 649 beds.

### **HOW WE CONDUCTED THIS REVIEW**

We matched the warranty credits that medical device companies issued to BIDMC for devices that were covered under warranty or replaced because of recalls during CYs 2010 through 2013 and identified claims that are at risk for noncompliance with Medicare billing requirements. Our audit covered \$706,581 in Medicare payments to BIDMC for 23 claims for replaced medical devices, consisting of 14 inpatient and 9 outpatient claims. These claims had dates of service in CY 2010, CY 2011, CY 2012, or CY 2013.

We limited our review to 23 claims the hospital billed for replaced medical devices. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary. This report focuses on a selected risk area and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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 objectives.

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<sup>1</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

Appendix A contains the details of our scope and methodology.

## FINDINGS

BIDMC complied with Medicare billing requirements for 3 of the 23 inpatient and outpatient claims we reviewed. However, BIDMC did not fully comply with Medicare requirements for the remaining 20 claims, resulting in overpayments of \$483,104 for CYs 2010 through 2013. Specifically, 11 inpatient claims had errors, resulting in overpayments of \$339,384, and 9 outpatient claims had errors, resulting in overpayments of \$143,720. These errors occurred primarily because (1) BIDMC staff had inadequate education on inpatient level of care criteria, (2) case management and utilization review for inpatient short stays did not always occur, and (3) BIDMC did not always report the appropriate information to reflect the credits it received for replaced medical devices.

### **BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS**

BIDMC incorrectly billed Medicare for 11 of 14 selected inpatient claims, which resulted in overpayments of \$339,384.

#### **Medical Device Claims Incorrectly Billed as Inpatient**

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act, §1862(a)(1)(A)).

For 8 of the 14 selected claims, BIDMC incorrectly billed Medicare Part A for beneficiary stays that should have been billed as outpatient or outpatient with observation.<sup>2</sup> BIDMC officials attributed the patient admission errors to inadequate staff education on inpatient level of care criteria and case management and utilization review for inpatient short stays that did not always occur during most of our review. As a result of these errors, BIDMC received overpayments of \$318,934.<sup>3</sup>

#### **Manufacturer Credits for Replaced Medical Devices Not Reported**

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

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<sup>2</sup> Two of the eight claims incorrectly billed as inpatient also had a second type of error for a manufacturer credit for a replaced medical device not reported for CYs 2010 and 2012.

<sup>3</sup> BIDMC may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. We were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because these services had not been billed or adjudicated by the Medicare administrative contractor prior to the issuance of our draft report.

that was provided with a credit, hospitals must code Medicare claims with a combination of condition code 49 or 50, along with value code “FD” (chapter 3, § 100.8).

For 3 of the 14 selected claims, BIDMC received reportable medical device credits from manufacturers but did not adjust its inpatient claims with the appropriate value and condition codes to reduce payment as required. (One claim had a date of service CY 2010, and 2 claims had dates of services in CY 2013.) BIDMC officials stated that the errors occurred because BIDMC did not have appropriate internal control procedures to coordinate functions among various departments to ensure that BIDMC reported the appropriate information to reflect the credits it received for replaced medical devices. As a result of these errors, BIDMC received overpayments of \$20,450.

## **BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS**

BIDMC incorrectly billed Medicare for all nine of the selected outpatient claims, which resulted in overpayments of \$143,720.

### **Manufacturer Credit for Replaced Medical Device Not Reported**

Federal regulations require a reduction in the OPSS 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 (42 CFR § 419.45). 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.<sup>4</sup>

For all nine claims that we reviewed, BIDMC incorrectly billed Medicare for replaced devices:

- For four of the nine selected claims, BIDMC received full credit for a replaced device but did not report the “FB” modifier or reduce charges on its claim.
- For three of the nine selected claims, BIDMC appended the “FB” modifier to the wrong HCPCS code and did not reduce the charges on two of those claims.
- For two of the nine selected claims, BIDMC used the modifier “FC” when the “FB” modifier should have been used.

BIDMC officials stated that the errors occurred because BIDMC did not have appropriate internal control procedures to coordinate functions among various departments to ensure that BIDMC reported the appropriate information to reflect the credits it received for replaced medical devices. As a result of these errors, BIDMC received overpayments of \$143,720.

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<sup>4</sup> CMS provides guidance on how a provider should report no-cost and reduced-cost devices under the OPSS (CMS Transmittal 1103, dated November 3, 2006, and the Manual, chapter 4, § 61.3).

## RECOMMENDATIONS

We recommend that BIDMC:

- refund to the Medicare contractor \$483,104, consisting of \$339,384 in overpayments for 11 incorrectly billed inpatient claims and \$143,720 in overpayments for 9 incorrectly billed outpatient claims, and
- strengthen controls to ensure full compliance with Medicare requirements.

### **BETH ISRAEL DEACONESS MEDICAL CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, BIDMC generally concurred with our findings and recommendations.

However, BIDMC stated that it was inaccurate to suggest that its controls and staff education were inadequate throughout the entire review period relative to level of care medical necessity determinations. BIDMC stated that it made enhancements over the past few years to the staffing and internal controls that affect case management and the determination of the appropriate level of care.

We acknowledge BIDMC's concerns regarding our assertion that controls and staff education were inadequate throughout the entire review period. BIDMC's updated enhancements to staff education and internal controls most likely had an impact for 2013, the last year of our review, for which we did not identify medical necessity errors. We have updated the final report accordingly. We acknowledge BIDMC's efforts to strengthen its compliance with Medicare requirements.

BIDMC stated that it would process the necessary adjustments through its Medicare contractor and resubmit certain claims, as appropriate, to Part B. BIDMC stated that it will also continue to monitor and strengthen existing internal controls and educate staff to minimize the risk of errors.

BIDMC's comments are included in their entirety as Appendix B.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$706,581 in Medicare payments to BIDMC for 23 claims for replaced medical devices consisting of 14 inpatient and 9 outpatient claims. These claims had dates of service in CY 2010, CY 2011, CY 2012, or CY 2013.

We limited our review of BIDMC's internal controls to those applicable to the inpatient and outpatient area of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. This report focuses on the selected risk area and does not represent an overall assessment of all claims submitted by BIDMC for Medicare reimbursement.

We conducted our fieldwork at BIDMC during the month of May 2014.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- requested and received from three cardiac device manufacturers a listing of warranty credits issued to BIDMC to identify recipients of devices that prematurely failed;
- matched those recipients to the Medicare enrollment database to identify Medicare recipients;
- selected 23 claims (14 inpatient and 9 outpatient) for detailed review;
- reviewed available data from CMS's Common Working File for the selected claims to determine whether the claims had been cancelled or adjusted;
- reviewed the itemized bills and medical record documentation provided by BIDMC to support the selected claims;
- reviewed BIDMC medical records to determine whether inpatient claims should have been billed as outpatient claims;
- requested that BIDMC conduct its own review of the selected claims to determine whether the services were billed correctly;
- discussed the incorrectly billed claims with BIDMC personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments; and

- discussed the results of our review with BIDMC 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 objectives.



Beth Israel Deaconess  
Medical Center



A teaching hospital of  
Harvard Medical School

December 19, 2014

Office of Audit Services, Region 1  
JFK Federal Building  
15 New Sudbury Street, Room 2425  
Boston, MA 02203

Re: Report Number: A-01-14-00502

Entity Name: Beth Israel Deaconess Medical Center  
Address: 330 Brookline Avenue  
Boston, MA 02215

Provider #: 220086  
NPI #: 1548202641  
Tax ID#: 042103881

Contact Person: John A. Goulart, Jr.  
Address: Beth Israel Deaconess Medical Center  
Office of Compliance and Business Conduct  
109 Brookline Avenue, Suite 200  
Boston, MA 02215

Phone #: (617) 667-7259  
[jgoulart@bidmc.harvard.edu](mailto:jgoulart@bidmc.harvard.edu)

Dear Mr. Lamir,

Thank you for contacting the Beth Israel Deaconess Medical Center Office of Compliance and Business Conduct seeking our comments on report A-01-14-00502. Because this report addresses both the reporting and billing of medical device credits and the associated level of care provided at the time the patient's medical device was replaced, we have broken down your office's findings by issue. The following table summarizes the information in the report dated November 21, 2014, which covers 23 targeted services billed to Medicare over four calendar years.

Issue	Part A		Part B	
	#	\$	#	\$
Device Credits	3/14	20,450.00	9/9	143,720.00
Medical Necessity for Level of Care	8/14	318,934.00	N/A	N/A
<b>Total:</b>	<b>11/14</b>	<b>339,384.00</b>	<b>9/9</b>	<b>143,720.00</b>

On a general level, we concur with your findings and have initiated the process to submit refunds to our Medicare contractor and to re-submit certain claims, as appropriate, to Part B where the level of care provided supports ancillary charges to the Medicare program. We have also taken numerous steps to strengthen our internal controls to ensure full compliance with Medicare requirements, including the steps described below.

#### **Device Credits (Part A and Part B):**

Prior to the initiation of this review, the Medical Center undertook steps to develop more robust communications processes about medical device credits and a better understanding of the coding intricacies involved in these claims specific to the FB and FC modifiers, the FD value code, and the reduction of charges on the claim. The Medical Center also has instituted ongoing monitoring / auditing



processes in this area. More specifically, the Medical Center has developed the following key internal controls:

1. Created internal forms / spreadsheets to track / report known device credits.
2. In late 2012, we reviewed this topic as a part of our Compliance Audit Work Plan.
3. Following the 2012 compliance audit we:
  - a. Secured the involvement and engagement of stakeholders from the following areas: Cardiology, Revenue Cycle Operations, Compliance and all Outside Vendors.
  - b. Instituted a requirement that Cardiology request monthly activity reports directly from all vendors and review these against internal forms / spreadsheets.
  - c. Revised internal forms / spreadsheets to track / report known and possible device credits.
  - d. Implemented a requirement that individual departments monitor device credit issues.
  - e. Instituted a practice of sharing, reviewing and discussing OIG device warrantee audit reports and industry publications to improve stakeholder awareness and knowledge.

#### **Level of Care Medical Necessity Determinations:**

While we generally concur with the government's findings in this area, it is inaccurate to suggest that the Medical Center's controls and staff education were inadequate throughout the entire review period. Notably, over the course of the past three years, the following enhancements have been made to our staffing and internal controls surrounding case management and the determination of the appropriate level of care:

1. Routine internal review and periodic external validation of the Program for Evaluating Payment Patterns Electronic Report (PEPPER).
2. Admitting providers have received training in what qualifies for inpatient admission and the certification of medical necessity.
3. Case Management coverage has been enhanced to ensure that patients are assessed for medical necessity and appropriately classified as inpatients or outpatients with / without observation.
4. Controls within the Medical Center's information system have been established so that patient status assessments made by Case Management are appropriately communicated to the attending physician to allow any disagreements about patient status to be discussed and resolved in a timely manner.
5. Changes to certain internal administrative processes and information systems have been made to ensure that all physician orders for hospitalizations are appropriately documented in the medical record.



6. New processes have been established across the Medical Center's clinical and financial operations to more effectively communicate initial hospitalization determinations, and any changes in, patient status (*e.g.*, outpatient or inpatient status) as well as to accurately calculate start, stop, and carve out times for observation services.
7. Internal and external monitoring resources have been deployed to validate medical necessity for hospitalizations, to verify the presence of physician orders, and to appropriately calculate all units of observation services prior to billing.
8. Expanded training and education regarding Medicare requirements for billing hospitalizations has been provided to Case Management, members of the Medical Center's Medical Staff, and relevant support staff.
9. Staffing in the Office of Compliance and Business Conduct has been enhanced to provide additional resources for training, education, monitoring, and auditing regarding Medicare compliance requirements.
10. Outside consultants were engaged to verify the accuracy of the Medical Center's coding and billing practices for hospitalizations and to make any further recommendations for improvements.

Thank you for reaching out to us and seeking our comments on this report. If you have any questions in this regard, or need any additional information, please do not hesitate to contact me at (617) 667-7259 or [jgoulart@bidmc.harvard.edu](mailto:jgoulart@bidmc.harvard.edu).

Sincerely,

John A. Goulart, Jr.

Beth Israel Deaconess Medical Center | Office of Compliance and Business Conduct  
Director of Compliance Audit and Billing Compliance