



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region V  
233 North Michigan Avenue  
Suite 1360  
Chicago, IL 60601

October 24, 2011

Report Number: A-05-11-00012

Delos Cosgrove, M.D.  
Chief Executive Officer and President  
Cleveland Clinic Main Campus  
Mail Code H18  
9500 Euclid Avenue  
Cleveland, OH 44195

Dear Dr. Cosgrove:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Cleveland Clinic's Claims for Procedures That Included the Replacement of Medical Devices During 2008 and 2009*. 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 Stephen Slamar, Audit Manager, at (312) 353-7905 or through email at [Stephen.Slamar@oig.hhs.gov](mailto:Stephen.Slamar@oig.hhs.gov). Please refer to report number A-05-11-00012 in all correspondence.

Sincerely,

/Sheri L. Fulcher/  
Regional Inspector General  
for Audit Services

Enclosure

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Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF CLEVELAND CLINIC'S  
CLAIMS FOR PROCEDURES THAT  
INCLUDED THE REPLACEMENT  
OF MEDICAL DEVICES DURING  
2008 AND 2009**



Daniel R. Levinson  
Inspector General

October 2011  
A-05-11-00012

# *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 inpatient and outpatient services under distinct prospective payment systems.

#### **Medical Device Replacement**

Common medical devices implanted during outpatient procedures include pacemakers, cardioverter defibrillators, and their associated leads. 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 outpatient 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. Similarly, for inpatient discharges on or after October 1, 2008, CMS established reporting requirements for a provider that incurs no cost, receives full credit, or receives a credit for a replaced device that is 50 percent or greater than the cost of the device. In such circumstances, CMS requires the provider to report the value code “FD” and to bill the amount of the credit in the amount portion for that value code. CMS further requires the provider to report appropriate condition codes to indicate a medical device replacement.

#### **Cleveland Clinic**

The Cleveland Clinic (the Clinic) is a 1,300-bed acute-care hospital located in Cleveland, Ohio. National Government Services (NGS) processes and pays the Clinic’s Medicare claims. NGS paid the Clinic a total of \$11.2 million for 1,261 outpatient procedures that included the replacement of medical devices for the two-year period ending December 31, 2009, and \$10 million for 407 claims for inpatient claims covering the one year period ending September 30, 2009.

### **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 billing codes 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 and for reporting the appropriate billing codes and charges to reflect the credits it received. For 1,247 outpatient claims and 397 inpatient claims for the audit periods, 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 devices and therefore were not reportable. For the 24 remaining claims, credits were available from manufacturers and reportable. However, regarding the credits:

- For five outpatient and one inpatient claims, the Clinic did not obtain credits that were available under the terms of the manufacturers' warranties.
- For six outpatient and nine inpatient claims, the Clinic obtained full credit but did not report the "FB" modifier and reduced charges (outpatient) or the "FD" value code and appropriate condition code (inpatient) on the claims to alert NGS that payment adjustments were needed.
- For three outpatient claims, the Clinic obtained partial credit but did not report the "FC" modifier and reduced charges.

The Clinic was overpaid \$253,593 for the 24 claims (\$184,568 outpatient and \$69,025 inpatient). Moreover, for these claims, beneficiaries incurred \$5,615 in additional copayment costs. The overpayments and additional copayment costs occurred because the Clinic did not have controls to report the appropriate billing codes and charges to reflect credits due from manufacturers.

## **RECOMMENDATIONS**

We recommend that the Clinic:

- adjust the 24 erroneous claims and resubmit them to NGS to correct the overpayments totaling \$253,593 and overstated copayment costs totaling \$5,615,
- strengthen its procedures for identifying and obtaining the credits available from manufacturers, and
- establish procedures in accordance with Medicare requirements for reporting to NGS the credits for replaced devices that the Clinic is entitled to, regardless of whether it received the credits.

## **CLEVELAND CLINIC COMMENTS**

In its comments on our draft report, the Clinic disagreed with the amount of eleven overpayments in our first recommendation. The Clinic stated that the credit for three claims was not reportable, because the amount of credit received from the manufacturer was less than 50 percent. For one claim, it was only entitled to a partial credit but the OIG calculated a full credit.

The Clinic believes that CMS' methodology for calculating the outlier payments for four claims should allow underpayments to be netted against the credit. It also noted that three claims involved the insertion of two devices, but because Medicare policy allows only one credit, the Clinic was actually underpaid on the claims.

The Clinic agreed with our second and third recommendations and has implemented new procedures for processing credits from device manufacturers.

#### **OFFICE OF INSPECTOR GENERAL RESPONSE**

After reviewing the Clinic's comments, we adjusted the findings in our report by removing three claims where the Clinic received less than a 50 percent credit and by reducing the credit amount on one claim.

The Clinic's opinions regarding revising CMS' methodology for calculating outlier payments relating to four claims and Medicare's policy of allowing only one credit when two devices are inserted relating to three claims, is beyond the scope of our review. We calculated the Medicare overpayment on these seven claims in accordance with current Medicare policies and procedures.



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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 A of Title XVIII provides inpatient hospital insurance while 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 hospitals.<sup>1</sup>

### Hospital Prospective Payment Systems

#### *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.

#### *Inpatient Prospective Payment System*

The Social Security Act Amendments of 1983, Public Law 98-21, enacted on April 20, 1983, established a prospective payment system for Medicare reimbursement to hospitals. Section 1886(d) of the Act set forth a system of payments for the costs of acute care hospital inpatient stays based on prospectively set rates effective for services furnished on or after October 1, 1983. Under the inpatient prospective payment system (IPPS), each case is categorized into a diagnosis-related group (DRG). Each DRG has a payment weight assigned to it based on the average resources used to treat Medicare patients in that DRG.

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

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<sup>1</sup> 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.

## **Credits for Replaced Medical Devices**

Common medical devices implanted during inpatient and outpatient procedures include pacemakers, cardioverter defibrillators, and their associated leads. 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 inpatient and outpatient procedures, Medicare generally requires payment adjustments. Specifically, for 43 inpatient DRGs and 31 types of devices that fall within 21 outpatient APCs, Medicare reduces the payment for the replacement of the device if the provider is entitled to full or partial credits from the manufacturer.

### *Outpatient Reimbursement*

For outpatient 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.<sup>2</sup> For outpatient 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.

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

## *Inpatient Reimbursement*

For inpatient discharges on or after October 1, 2008, CMS established reporting requirements for a provider that incurs no cost, receives full credit, or receives a credit for a replaced device that is 50 percent or greater than the cost of the device. In such circumstances, CMS requires the provider to report the value code “FD” on its claim and to bill the amount of the credit in the amount portion for that value code. CMS further requires the provider to report condition codes 49 or 50 to indicate a medical device replacement.<sup>3</sup>

### **Cleveland Clinic**

The Cleveland Clinic (the Clinic) is a 1,300-bed acute-care hospital located in Cleveland, Ohio. As the Medicare contractor for hospitals in Ohio, National Government Services (NGS) processes and pays the Clinic’s claims for Medicare services.<sup>4</sup>

## **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 billing codes and charges to reflect the credits received.

### **Scope**

Our audit covered \$21.2 million in Medicare payments to the Clinic for procedures involving the possible replacement of medical devices. Our audit population consisted of 1,668 claims: 1,261 outpatient claims, totaling \$11.2 million, with dates of service during the two-year period ending December 31, 2009; and 407 inpatient claims, totaling \$10 million, with dates of services during the one year period ending September 30, 2009.<sup>5</sup> We limited our audit to claims that involved the replacement of pacemakers, cardioverter defibrillators, and their associated leads.<sup>6</sup>

The listings of the corresponding seven outpatient APCs and 14 inpatient DRGs applied in this audit are included in Appendix A. During the audit periods, the Clinic did not submit any

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<sup>3</sup> Effective April 1, 2006, CMS required the use of two new condition codes to track devices provided without cost to providers. Condition code 49 refers to the replacement of a device which is not functioning properly and condition code 50 refers to devices subject to recalls. Medicare payment edits require the presence of both value and condition codes for inpatient claims involving a medical device replacement. *Medicare Claims Processing Manual*, Pub. 100-04, CR 4058, Transmittal 741.

<sup>4</sup> NGS became a MAC in March 2008.

<sup>5</sup> Requirements for use of the FD code for inpatient medical device credits did not commence until October 1, 2008. *Medicare Claims Processing Manual*, Pub. 100-04, CR 5860, Transmittal 1509.

<sup>6</sup> Our prior audits of replaced medical device credits disclosed that these types of devices presented the greatest risk of non-compliance with Medicare requirements.

outpatient claims with “FB” or “FC” modifiers, and it did not submit any inpatient claims with the “FD” value code or the appropriate condition code.<sup>7</sup>

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 Cleveland, Ohio from December 2010 through January 2011.

## **Methodology**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted from CMS’s National Claims History file the Clinic’s outpatient paid claim data for the two-year period ending December 31, 2009, and inpatient paid claim data for the 1 year period ending September 30, 2009;
- developed computer queries to identify (1) 1,261 outpatient claims that included procedures for the replacement of any of the seven specified types of APCs and 14 medical devices and (2) 407 inpatient claims that included the 14 specific DRGs;
- selected judgmental samples of 22 outpatient claims and 23 inpatient claims and reviewed the beneficiaries’ medical records and manufacturers’ warranties to determine whether the Clinic should have submitted the claims with the applicable billing codes 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;
- relied on Region I auditors to interview 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;
- reviewed six outpatient and seven inpatient claims that the Clinic, through its self-initiated claims review, identified as having received a credit;
- reviewed adjusted claims that the Clinic resubmitted to NGS;

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<sup>7</sup> During our audit, the Clinic self-initiated a review to determine those claims that needed to be adjusted and resubmitted to NGS to reflect reportable credits received from manufacturers.

- calculated the correct payments for those claims for which payment adjustments were needed; and
- 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 objective. 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 and for reporting the appropriate billing codes and charges to reflect the credits it received. For 1,247 outpatient claims and 397 inpatient claims for the audit periods, 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 devices and therefore were not reportable. For the 24 remaining claims, credits were available from manufacturers and reportable. However, regarding the credits:

- For five outpatient and one inpatient claims, the Clinic did not obtain credits that were available under the terms of the manufacturers' warranties.
- For six outpatient and nine inpatient claims, the Clinic obtained full credit but did not report the "FB" modifier and reduced charges (outpatient) or the "FD" value code and appropriate condition code (inpatient) on the claims to alert NGS that payment adjustments were needed.
- For three outpatient claims, the Clinic obtained partial credit but did not report the "FC" modifier and reduced charges.

Medicare overpaid the Clinic \$253,593 for the 24 claims (\$184,568 outpatient and \$69,025 inpatient). Moreover, for these claims, beneficiaries incurred \$5,615 in additional copayment costs. The overpayments and additional copayment costs occurred because the Clinic did not have controls to report the appropriate billing codes 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**

### *Outpatient Coding Requirements*

Federal regulations (42 CFR § 419.45) require reductions in the OPPS payments 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 (chapter 4, section 61.3.1 of the Manual). 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 (chapter 4, section 61.3.2 of the Manual).

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.

### *Inpatient Coding Requirements*

Federal regulations (42 CFR § 412.89) 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 cost of a device, or (3) the provider receives a credit equal to 50 percent or more of the cost of the device.

CMS guidance in Transmittal 1509, dated May 16, 2008, explains how a provider should report no-cost and reduced-cost devices under the IPPS. For services furnished on or after October 1, 2008, CMS requires providers to bill the amount of the credit in the amount section for value code “FD” when the provider receives a credit for a replaced device that is 50 percent or greater than the cost of the device. Partial credits for less than 50 percent of the cost of the device need not be reported with the “FD” value code. In addition, CMS Transmittal 741, dated November 4, 2005, and effective April 1, 2006, requires the use of two condition codes to track devices provided without cost to providers. Condition code 49 refers to the replacement of a device which is not functioning properly, and condition code 50 refers to devices subject to recalls. NGS prepayment edits require the presence of both value and condition codes for inpatient claims involving a medical device replacement.

## **NONCOMPLIANCE WITH MEDICARE REQUIREMENTS**

### **Clinic Did Not Obtain Available Credits**

For five outpatient claims and one inpatient claim, the Clinic did not obtain credits for replaced devices that were available under the terms of the manufacturers’ warranties. For example, according to the Clinic’s records for one claim, the defibrillator lead was subject to recall. The lead was replaced and the Clinic was due a credit from the manufacturer. The Clinic should have obtained the credit, used the “FD” value code and appropriate condition code on its claim, and received a reduced payment.

Overpayments of \$75,161 for the five outpatient claims and \$20,000 for the one inpatient claim occurred because the Clinic did not follow established procedures to obtain credits available under the terms of manufacturers’ warranties.

### **Clinic Did Not Report Credits It Received**

For 18 claims the Clinic received either full or partial credits for a replaced device, but did not report the appropriate billing codes and charges to reflect the credits it received. Specifically, for nine outpatient claims, the Clinic received full or partial credits from manufacturers, but did not report the required “FB” or “FC” modifier and reduced charges on its claims. Similarly, for nine inpatient claims, the Clinic received full credits, but did not report the “FD” value code and appropriate condition code on its claims. For one of the 18 claims, according to the beneficiary’s medical records, the replaced device needed to be removed because the battery was depleted. Under the terms of the warranty, the manufacturer provided full credit for the cost of the



replaced device. Therefore, this claim should have been submitted with the appropriate billing codes and charges to alert NGS that a payment reduction was needed.

Overpayments of \$109,407 for the nine outpatient claims and \$49,025 for the nine inpatient claims occurred because the Clinic did not have controls for reporting medical device credits received from manufacturers. Specifically, the Clinic did not have procedures for coordinating functions among the various departments (i.e., clinical, materials management, health information management, patient accounting, and accounts payable) to ensure that it submitted claims with the appropriate modifier and reduced charges to initiate reduced payments for credits received from manufacturers.

## **MEDICARE OVERPAYMENTS**

Medicare overpaid the Clinic \$253,593 (\$184,568 outpatient and \$69,025 inpatient) for 24 claims for which available medical device credits were either not obtained or obtained but not properly reported. In addition, the overpayments on these claims caused the beneficiaries to incur \$5,615 in additional copayment costs.

## **RECOMMENDATIONS**

We recommend that the Clinic:

- adjust the 24 erroneous claims and resubmit them to NGS to correct the overpayments totaling \$253,593 and overstated copayment costs totaling \$5,615,
- strengthen its procedures for identifying and obtaining the credits available from manufacturers, and
- establish procedures in accordance with Medicare requirements for reporting to NGS the credits for replaced devices that the Clinic is entitled to, regardless of whether it received the credits.

## **CLEVELAND CLINIC COMMENTS**

In its comments on our draft report, the Clinic disagreed with the amount of eleven overpayments in our first recommendation. The Clinic stated that the credit for three claims was not reportable, because the amount of credit received from the manufacturer was less than 50 percent. For one claim, it was only entitled to a partial credit but the OIG calculated a full credit. The Clinic believes that CMS' methodology for calculating the outlier payments for four claims should allow underpayments to be netted against the credit. It also noted that three claims involved the insertion of two devices, but because Medicare policy allows only one credit, the Clinic was actually underpaid on the claims.

The Clinic agreed with our second and third recommendations and has implemented new procedures for processing credits from device manufacturers.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

After reviewing the Clinic's comments, we adjusted the findings in our report by removing three claims where the Clinic received less than a 50 percent credit and by reducing the credit amount on one claim.

The Clinic's opinions regarding revising CMS' methodology for calculating outlier payments relative to four claims and Medicare's policy of allowing only one credit when two devices are inserted relative to three claims, is beyond the scope of our review. We calculated the Medicare overpayment on these seven claims in accordance with current Medicare policies and procedures.

# **APPENDIXES**

**APPENDIX A: CORRESPONDING AMBULATORY PAYMENT CLASSIFICATIONS  
AND DIAGNOSIS RELATED GROUPS**

**Outpatient Ambulatory Payment Classifications (APCs)**

<b>APC</b>	<b>APC Description</b>
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	Insertion/Replacement of Pacemaker Pulse Generator
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	Insertion of Cardioverter-Defibrillator
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads
0654	Insertion/Replacement of a Permanent Dual Chamber Pacemaker
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker

**Inpatient Diagnosis Related Groups (DRGs)**

<b>DRG</b>	<b>DRG Description</b>
222	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with Major Complication/Comorbidity (MCC)
223	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock without MCC
224	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock with MCC
225	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock without MCC
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
242	Permanent Cardiac Pacemaker Implant with MCC
243	Permanent Cardiac Pacemaker Implant with Complication/Comorbidity (CC)
244	Permanent Cardiac Pacemaker Implant without CC/MCC
258	Cardiac Pacemaker Device Replacement with MCC
259	Cardiac Pacemaker Device Replacement without MCC
260	Cardiac Pacemaker Revision Except Device Replacement with MCC
261	Cardiac Pacemaker Revision Except Device Replacement with CC
262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC

APPENDIX B: CLEVELAND CLINIC COMMENTS



Donald A. Sinko, CPA  
Chief Integrity Officer

August 12, 2011

James M. Barton  
Acting Regional Inspector General for Audit Services  
Office of Inspector General  
Office of Audit Services, Region V  
233 North Michigan Avenue  
Suite 1360  
Chicago, IL 60601

**Re: Response to Draft Report  
Report Number A-05-11-00012**

Dear Mr. Barton:

I am responding on behalf of The Cleveland Clinic ("CC") to the draft report entitled "*Review of Cleveland Clinic's Claims for Procedures that Included the Replacement of Medical Devices During 2008 and 2009*," sent with your letter dated July 18, 2011. During the time of the OIG audit, CC conducted its own retrospective review of all Medicare claims for cardiac explant devices from 2008 through 2010 in order to determine if CC received any cardiac device warranty credits in addition to the credits identified in the OIG sample audit. All claim amounts identified by CC to be refunded were rebilled prior to the completion of the OIG audit. Improvements to the warranty credit process were also implemented at that time. The draft report notes that the credits identified by CC are included in the OIG's report. We appreciate this opportunity to review the OIG's draft findings on all credits and to include our responses for the final report.

The OIG has asked for CC's response on three recommendations:

**Recommendation #1:** Adjust the 27 erroneous claims and resubmit them to NGS to correct the overpayments totaling \$313,886 and overstated copayment costs totaling \$7,977.

**Response:** This recommendation focuses on findings for 10 inpatient and 17 outpatient claims out of a total of 1,641 claims filed during the audit period. While the OIG has reported a total overpayment on 27 claims totaling \$313,886, as explained in more detail below, CC's audit has determined that there is a difference on only 24 claims totaling \$246,878.

CC concurs with the OIG with regard to its findings on the 10 inpatient claims. CC has taken the necessary steps to readjudicate these inpatient claims through NGS, resulting in a refund to Medicare of approximately \$69,025.

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Of the 17 outpatient claims, there are 3 claims (Sample #4, 18 and 27) for which CC does not concur that any overpayment is owed to Medicare. The credit that CC received from the manufacturer on these 3 claims was less than 50% of the cost of the device. Therefore, there are no amounts due to be refunded to Medicare related to these claims, thus reducing the reported overpayment by \$52,587.

In addition, there are 4 claims (Sample #39, OM 1, OM 2 and OM 8), for which CC does not concur with the amount of the identified overpayment. While CC did receive a credit from the device manufacturer on each of these 4 claims, CC was actually underpaid on the original claims based on CMS' methodology for calculating outlier payments. The device credit on these 4 claims should be netted against the amount of the underpayments still owed to CC under the outlier methodology, thus reducing the reported overpayment by \$5,582.

In addition, on 1 claim (Sample #21), CC received a partial credit on the device, not a full credit as recommended by the OIG. Recalculating the refund based on the partial credit reduces the reported overpayment by \$8,819.

Finally, for 3 claims (Sample #31, 40 and OM 8), the medical procedures that were performed involved the implantation of two medical devices, only one of which was eligible for a credit. Medicare requires that the FC or FB modifier be placed on the entire procedure, which results in the hospital being underpaid for services rendered.

CC has taken the necessary steps to correctly readjudicate all pertinent outpatient claims through NGS, resulting in a refund to Medicare of approximately \$177,853.

**Recommendation #2:** Strengthen procedures for identifying and obtaining the credits available from manufacturers.

**Response:** CC implemented important process improvements to strengthen its existing procedures for identification and receipt of manufacturer credits on cardiac devices. First, for cardiac devices that may be entitled to a warranty credit, CC is not aware of the amount of the warranty credit, if any, that will be issued by the manufacturer at the time of the explant procedure. Instead, CCF submits a request to the manufacturer related to the potential warranty claim at the same time a claim is submitted to Medicare for reimbursement of the full amount for the procedure. Manufacturers may take a significant amount of time to determine credit amounts. In addition, because warranty credits are subsequently deducted on future invoices well after the explant procedure has occurred, a tracking process is necessary not only to ensure that proper credits are received from manufacturers, but also that subsequent claim adjustments are made to Medicare in accordance with the regulations.

CCF's new process requires the Heart and Vascular Institute to document and track at the outset that an explant is being evaluated by the manufacturer for credit, and a warranty credit may be received. The physician of record and vendor representative will identify devices qualifying for potential credit. The CC billing department will routinely compare a list of actual credits received with the Institute's list of potential outstanding credits, and create a variance report that is then provided to the Institute. If a manufacturer denies a credit request, appeals will be taken as appropriate. When the

manufacturer renders a positive determination on a warranty claim, and the amount is 50% or greater of the device cost, the amount granted will be utilized to adjust and rebill the claim to Medicare at that time.

**Recommendation #3:** Establish procedures in accordance with Medicare requirements for reporting to NGS the credits for replaced devices that the Clinic is entitled to, regardless of whether it received the credits.

**Response:** Federal law allows CMS to reduce the amount of payment for both inpatient and outpatient claims for an implanted device when a significant portion of the payment is attributable to the cost of the device and:

1. The service is replaced without cost; or
2. The provider receives full credit or credit that is greater than 50% of the new device.

42 C.F.R. 419.45; 42 C.F.R. 412.89

The reduction in payment is permitted when the provider actually receives the appropriate credit. While CC concurs that procedures must be in place to pursue and report all appropriate credits, CC does not concur that an obligation exists to report potential credits, regardless of whether the credit is ever received.

As noted above, CC's new process requires the Heart and Vascular Institute to document and track at the outset that an explant is being evaluated by the manufacturer for credit, and a warranty credit may be received. The physician of record and vendor representative will identify devices qualifying for a potential credit. The CC billing department will routinely compare a list of actual credits received with the Institute's list of potential outstanding credits, and create a variance report that is provided to the Institute. The credits will be actively pursued and when the manufacturer renders a favorable determination on a warranty claim that is 50% or greater than the cost of the new device, the amount granted will be utilized to adjust and rebill the claim to Medicare at that time. If a manufacturer denies a credit request, appeals will be taken as appropriate.

Thank you for your consideration and the opportunity to respond to these concerns. Please do not hesitate to contact me if you have any additional questions regarding CC's response.

Very truly yours,



Donald A. Sinko  
Chief Integrity Officer