DEPARTMENT OF HEALTH AND HUMAN SERVICES **OFFICE OF INSPECTOR GENERAL**

Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

February 29, 2012

Report Number: A-04-11-03065

Mr. Leslie A. Donahue
President and CEO
Piedmont Hospital
1968 Peachtree Road North West
Atlanta, GA 30309

Dear Mr. Donahue:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Piedmont Hospital Did Not Fully Comply With Medicare Requirements for Obtaining and Reporting Credits for Replacement Cardiac Medical Devices.* 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 John Drake, Audit Manager, at (404) 562-7755 or through email at John.Drake@oig.hhs.gov. Please refer to report number A-04-11-03065 in all correspondence.

Sincerely,

/Lori S. Pilcher/
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
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, MO 64106

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PIEDMONT HOSPITAL DID NOT FULLY COMPLY WITH MEDICARE REQUIREMENTS FOR OBTAINING AND REPORTING CREDITS FOR REPLACEMENT CARDIAC MEDICAL DEVICES

Daniel R. Levinson
Inspector General

February 2012
A-04-11-03065

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 neurostimulators. Occasionally, devices need to be replaced. Providers may receive full or partial credit from manufacturers for devices that are covered under warranty or replaced because of recalls. To offset these credits, Medicare reduces the payment for the replacement of a device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device.

For 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 a provider to report the modifier "FC" on a claim that includes a procedure code for the insertion of a replacement device if the provider received 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. Condition codes are codes entered on the CMS-1450 (UB-04) form that describe conditions or events that apply to a billing period.

Piedmont Hospital

Piedmont Hospital (Piedmont) is a 481-bed acute tertiary care facility located in Atlanta, Georgia. Cahaba Government Benefit Administrators, LLC (Cahaba) has responsibility for the administration and processing of all Part A (inpatient) and Part B (outpatient) claims in Georgia. Cahaba paid Piedmont a total of $7.9 million for 574 claims for outpatient procedures that included the replacement of medical devices for the 2-year period ending December 31, 2009 and $11.5 million for 562 inpatient claims covering the 15-month period ending December 31, 2009.

OBJECTIVE

Our objective was to determine whether Piedmont 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

Piedmont did not fully comply with Medicare requirements for obtaining credits available from manufacturers or for reporting the appropriate billing codes and charges to reflect the credits it received. For 76 of our sampled 79 claims (46 outpatient and 30 inpatient), 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 three remaining claims, credits were available from manufacturers and reportable; however:

- For one inpatient claim, Piedmont did not pursue a credit that was available under the terms of the manufacturer's warranty.

- For one inpatient claim, Piedmont obtained a full credit but did not report the "FD" value code and appropriate condition code on the claim to alert Cahaba that a payment adjustment was needed.

- For one outpatient claim, Piedmont obtained full credit but did not report the "FB" modifier to alert Cahaba that a payment adjustment was needed. However, Piedmont rebilled Medicare at a reduced rate of $1, which prevented Piedmont from being overpaid for the claim.

Piedmont was overpaid $7,625 for two inpatient claims. However, Piedmont received no overpayment for the third claim. These overpayments occurred because Piedmont did not (1) have a written policy on how to obtain credits available under the terms of manufacturers' warranties or (2) have controls to report the appropriate billing codes and charges to reflect credits due from manufacturers.

RECOMMENDATIONS

We recommend that Piedmont:

- adjust and resubmit to Cahaba the two erroneous claims to correct any outstanding portion of overpayments totaling $7,625;

- review the 530 inpatient claims and consider reviewing the 527 outpatient claims that were not included in our sample, and resubmit the claims to Cahaba as appropriate; and

- strengthen its procedures to obtain credits available from manufacturers and establish procedures to report to Cahaba the credits that Piedmont was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

PIEDMONT HOSPITAL COMMENTS

In its comments on our draft report, Piedmont agreed with our third recommendation to adopt additional policies and procedures that would strengthen its ongoing programs to document that it appropriately requested manufacturer credits for devices under warranty. Piedmont, however, neither agreed that the claims we identified were in error nor agreed that it should review the remaining claims in our audit population.

After removing the personally identifiable information, we included Piedmont's comments as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on Piedmont's comments, we modified our second recommendation. However, nothing in Piedmont's comments caused us to change our first recommendation.

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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.[1]

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 (HCPCS) 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 sets 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 patient in that DRG.

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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.

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

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.[2] 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.

[2] 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.[3]

Piedmont Hospital

Piedmont Hospital (Piedmont) is a 481-bed acute tertiary care facility located in Atlanta, Georgia. As the Medicare contractor for hospitals in Georgia, Cahaba Government Benefit Administrators (Cahaba) administers and processes Piedmont's claims for Medicare services.[4]

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Piedmont 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 $19.3 million in Medicare payments to Piedmont for procedures involving the possible replacement of medical devices. Our audit population consisted of 1,136 claims: 574 outpatient claims, totaling $7.9 million, with dates of service during the 2-year period ending December 31, 2009; and 562 inpatient claims, totaling $11.5 million, with dates of services during the 15-month period ending December 31, 2009.[5] We limited our audit to claims that involved the replacement of pacemakers, cardioverter defibrillators, and their associated leads[6] The listing of the corresponding 6 outpatient HCPCS codes and 12 inpatient DRGs applied in this audit is included as Appendix A. During the audit periods, Piedmont did not submit any

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[3] 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 that 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.

[4] Cahaba has been a Medicare contractor since the inception of the program in 1966.

[5] 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.

[6] Prior Office of Inspector General (OIG) 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 for items selected in our sample.

We limited our internal control review to Piedmont'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 Piedmont in Atlanta, Georgia, from March through April 2011. We also met with Cahaba officials in Birmingham, Alabama.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- extracted from CMS's National Claims History file Piedmont's outpatient paid claim data for the 2-year period ending December 31, 2009, and inpatient paid claim data for the 15-month period ending December 31, 2009;

- filtered the paid claims data to identify (1) 574 outpatient claims that included procedures for the replacement of any of the six specified HCPCS and (2) 562 inpatient claims that included the 12 specific DRGs (Appendix A);

- selected judgmental samples of 47 outpatient claims and 32 inpatient claims and reviewed the beneficiaries' medical records, remittance advices, and manufacturers' warranties, to determine whether Piedmont should have submitted the claims with the applicable billing codes and reduced charges;

- reviewed Piedmont's *Medical Device Credit Questionnaire* on their procedures for identifying and obtaining credits and reporting on its Medicare claims that the manufacturers provided credits for replaced devices;

- interviewed officials from select device manufacturers that conducted business with Piedmont to identify their requirements for issuing credits and obtained lists of credits issued to Piedmont to determine whether Medicare payment adjustments were needed;

- obtained and reviewed medical device warranties issued by the manufacturers for select cardiac devices;

- reviewed adjusted claims that Piedmont resubmitted to Cahaba;

- had Cahaba calculate the correct payments for those claims for which payment adjustments were needed; and

- discussed the results of our review with Piedmont 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

Piedmont did not fully comply with Medicare requirements for obtaining credits available from manufacturers or for reporting the appropriate billing codes and charges to reflect the credits it received. For 76 of our 79 sampled claims (46 outpatient and 30 inpatient), 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 three remaining claims, credits were available from manufacturers and reportable; however:

- For one inpatient claim, Piedmont did not pursue a credit that was available under the terms of the manufacturer's warranty.

- For one inpatient claim, Piedmont obtained a full credit but did not report the "FD" value code and appropriate condition code on the claim to alert Cahaba that a payment adjustment was needed.

- For one outpatient claim, Piedmont obtained full credit but did not report the "FB" modifier to alert Cahaba that a payment adjustment was needed. However, Piedmont rebilled Medicare at a reduced rate of $1, which prevented Piedmont from being overpaid for the claim.

Piedmont was overpaid $7,625 for two inpatient claims. However, Piedmont received no overpayment for the third claim. These overpayments occurred because Piedmont did not (1) have a written policy on how to obtain credits available under the terms of manufacturers' warranties or (2) 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…." Furthermore, 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 supplied."

Coding Requirements for Medical Device Credits

Outpatient Coding Requirements

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* 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.

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 May16, 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 portion 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.[7] 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. Cahaba prepayment edits require the presence of both value and condition codes for inpatient claims involving a medical device replacement.

NONCOMPLIANCE WITH MEDICARE REQUIREMENTS

Piedmont Did Not Obtain Available Credits

For one inpatient claim, Piedmont did not obtain a credit for a replaced lead that was available under the terms of the manufacturer's warranty. Specifically, according to Piedmont's records for the one claim, the lead was subject to recall. Although, the original lead was capped and left inside the patient and replaced, Piedmont still qualified for the recall credit. Piedmont should have obtained the credit, used the "FD" value code and appropriate condition code on its claim, and received a reduced payment.

An overpayment of $4,000 for this claim occurred because Piedmont did not have established procedures to obtain credits available under the terms of manufacturers' warranties.[8]

Piedmont Did Not Report That It Received Credits

For two claims Piedmont received full credits for a replaced device but did not report the appropriate billing codes and charges to reflect the credits it received. Specifically, for one outpatient claim, Piedmont received a full credit from the manufacturer but did not report the required "FB" or "FC" modifier. However, the hospital rebilled Medicare at a reduced rate of $1 to reflect the credit received for the no-charge replaced device. For one inpatient claim, Piedmont received a full credit but did not report the "FD" value code and appropriate condition code on its claim.

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[7] We identified an ambiguity created by section 100.8 of Chapter 3 of the *Medicare Claims Processing Manual*, Pub. 100-04, as it currently reads. Whereas the regulation and Transmittal 1509 can be read to apply the "50 percent or greater" threshold to the cost of the *replaced* device, section 100.8, effective October 1, 2009, can be interpreted to apply the threshold to the cost of the *replacement* device. To remain consistent with the requirements of the outpatient regulation, we interpreted the inpatient requirements to apply the threshold to the cost of the *replacement* device, but note that for the inpatient claims identified below in which we determined that the hospital received a credit which was 50 percent or greater than the cost of the *replacement* device, that the credit would have also been 50 percent or greater than the cost of the *replaced* device. As such, our determination of overpayments remained the same under either interpretation.

[8] Piedmont subsequently received credits for the replaced cardiac device.

An overpayment of $3,625 for the one inpatient claim occurred because Piedmont did not have controls for reporting medical device credits received from manufacturers. Specifically, Piedmont did not have procedures for coordinating functions among the billing department to ensure that it submitted claims with the appropriate modifier and reduced charges to initiate reduced payments for credits received from manufacturers.

MEDICARE OVERPAYMENTS

Piedmont was overpaid $7,625 for two inpatient claims.

RECOMMENDATIONS

We recommend that Piedmont:

- adjust and resubmit to Cahaba the two erroneous claims to correct any outstanding portion of overpayments totaling $7,625;

- review the 530 inpatient claims and consider reviewing the 527 outpatient claims that were not included in our sample, and resubmit the claims to Cahaba as appropriate; and

- strengthen its procedures to obtain credits available from manufacturers and establish procedures to report to Cahaba the credits that Piedmont was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

PIEDMONT HOSPITAL COMMENTS

In its comments on our draft report, Piedmont agreed with our third recommendation to adopt additional policies and procedures to strengthen its ongoing programs that would document that it appropriately requests manufacturer credits for devices under warranty. Piedmont, however, neither agreed that the claims we identified were in error nor agreed that it should review the remaining claims in our audit population.

With respect to the claims that we found in error, Piedmont said that in one instance, the amount of a credit it received was less than the cost of the device. Piedmont said that it considered the device to be a combination of the warranted device (cardiac leads) plus an additional device (cardiac generator) that the leads attach to. Using this reasoning, Piedmont concluded that the credit amount was less than 50 percent of the combination of the leads and generator and therefore not reportable.

Regarding the instance in which an available credit was not obtained, Piedmont said that there was no requirement in the regulations that hospitals affirmatively pursue replacement device credits. Piedmont also said that there was no billing error in this instance because it had not received a credit when the claim was billed.

Piedmont said that it was too burdensome for it to review the remaining claims that were not sampled given the small number of errors that the OIG found.

In regard to our recommendation to strengthen its procedures for obtaining and reporting credits, Piedmont stated that it was adopting additional policies and procedures to document that it appropriately requested manufacturers' credits for devices under warranty.

After removing the personally identifiable information, we included Piedmont's comments as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on Piedmont's comments, we modified our second recommendation. However, nothing in Piedmont's comments caused us to change our first recommendation.

In regard to our first recommendation, we do not agree with Piedmont's contention that cardiac leads should be combined with a cardiac generator for the purpose of determining the 50 percent threshold amount applicable to warranty credits. The manufacturer separately warrants leads and generators as separate devices. No manufacturer's warranty covers the device combination Piedmont described. Therefore, we continue to recommend that Piedmont adjust and resubmit this claim to Cahaba for adjudication of the overpayment.

In regard to our finding that Piedmont did not obtain a credit for a replaced lead that was available under the terms of the manufacturer's warranty, Piedmont qualified for a recall credit, but did not pursue it. Piedmont should report to Cahaba the credits that it was entitled to, irrespective of whether the credits were obtained, for replaced devices in accordance with Medicare requirements.

We also do not agree with Piedmont's assertion that it was not required to pursue replacement device credits. Federal regulations (42 CFR § 413.9) state that costs should be reasonable. In addition, section 2102.1 of the *Provider Reimbursement Manual* states that there: "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." Furthermore, section 2103 of the *Provider Reimbursement Manual* specifically states that, even if the provider fails to pursue credits for devices, the credit amounts must still be reduced from the costs the provider claimed. Therefore, based on guidance provided in the CFR and the *Provider Reimbursement Manual*, Piedmont should pursue replacement device credits.

We continue to recommend that Piedmont review the 530 inpatient claims and, consider reviewing the 527 outpatient claims that were not included in our sample, and resubmit the claims as appropriate.

APPENDIXES

APPENDIX A: CORRESPONDING HEALTHCARE COMMON PROCEDURE CODING SYSTEM AND DIAGNOSIS-RELATED GROUPS

Healthcare Common Procedure Coding System (HCPCS)

HCPC	Description
33233	Removal of permanent pacemaker pulse generator
33234	Removal of transvenous pacemaker electrodes; single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33241	Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
33244	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s) by transvenous extraction
33284	Removal of an implantable, patient-activated cardiac event recorder

Inpatient Diagnosis-Related Groups (DRG)

DRG	DRG Description
222	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with Complication/Comorbidity (MCC) Major
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
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

PIEDMONT HEALTHCARE

December 23, 2011

VIA Overnight Delivery

Ms. Lori S. Pilcher
Regional Inspector General
For Audit Services
Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, Georgia 30303

Re: Piedmont Hospital
DRAFT Report No.: A-04-11-03065

Dear Ms. Pilcher:

We have received the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled *Review of Piedmont Hospital's Claims for Inpatient and Outpatient Procedures That Included the Replacement of Cardiac Medical Devices for Calendar Years 2008 and 2009* (the "Report"). Piedmont Hospital ("Piedmont" or the "Hospital") offers the following comments on the Report and the OIG's recommendations.

The Report makes three recommendations, each of which is addressed below:

- **Recommendation 1:** Adjust and resubmit to Cahaba the two erroneous claims to correct any outstanding portion of overpayment totaling $4,625.

Piedmont respectfully disagrees with this recommendation. Both claims identified as erroneous were inpatient claims that were billed in accordance with CMS guidelines, as understood by the Hospital at the time:

[redacted]: The warranty credit for Patient PJK did not represent at least 50% of the cost of the device, and accordingly no refund was owed. As documented in Exhibit A, Patient PJK was admitted for inpatient services at Piedmont on December 28, 2009 because the lead device to this patient's cardiac defibrillator had failed. Patient PJK's records document that the interventional cardiologist capped the defective leads and inserted new leads. Importantly, because the ICD generator (Medtronic Model #7288, Serial # PUB112715H) was at late mid-life (original implant date 5/02/05), a new Medtronic ICD (D154AWG) was implanted. Although Piedmont received a device credit for the lead of $3,625, there was no warranty

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credit for the ICD generator device, which cost $13,750, together with $500 for an additional lead that the patient required. Therefore, the total cost for the implanted device was $17,875, and so the warranty credit of $3,625 came to only 20% of the total cost. There is no error in the claim submitted, no overpayment resulted from the claim, and Piedmont is not obligated to make a refund.

[redacted]: Patient BH had a complex medical condition that necessitated inpatient admission for multiple complications and cardiac issues, including the need for lead replacement. The lead had been originally implanted on March 8, 2005 and was the subject of a recall. Notably, 42 C.F.R. § 419.45 requires a reduction in the payment to the hospital only if the device is replaced without cost to the provider or beneficiary; the provider receives full credit for the cost of a replaced device; or the provider receives a partial credit of 50% or more of the total costs of the replaced device. Notwithstanding the OIG's present position, there is no requirement in the regulations that hospitals affirmatively pursue replacement device credits. Thus, based on the plain language of the regulation, there was no error in Piedmont's billing, as no credit had been received when the claim was billed. (It bears emphasizing, however, that notwithstanding the language in the regulation, Piedmont is, in fact, affirmatively pursuing replacement device credits).

- **Recommendation 2:** Review the remaining 1,057 claims (1,136 claims minus the 79 claims we reviewed), focusing on inpatient claims, and resubmit the claims to Cahaba as appropriate.

This recommendation seems unduly burdensome given the results of the OIG audit. In its Report, the OIG notes that the scope of the audit was limited to claims involving the replacement of pacemakers, cardiac defibrillators, and their associated leads. Prior OIG audits indicated that these types of devices presented the greatest risk of noncompliance with Medicare requirements. For Piedmont, the OIG reported that it filtered paid claims data to identify: 1) 574 outpatient claims, and 2) 562 inpatient claims. It is our understanding that from this universe, the OIG auditors selected a "judgmental" sample of 47 outpatient claims and 32 inpatient claims which were most likely to identify errors.

As to the 47 outpatient claims, the OIG audit revealed only one outpatient claim that should have included an FB or FC modifier. Yet for that claim, Piedmont billed only $1 and did so specifically to ensure that it did not receive reimbursement for the replacement device. Indeed, the Report notes that this "prevented Piedmont from being overpaid for the claim." Accordingly, while Piedmont did not include the modifier code, the end result was the same – the Hospital received no reimbursement for the replacement. Since there were no overpayments identified in the audit, there is no basis for any further review of the remaining 527 outpatient claims.

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With respect to the 32 inpatient claims, taking into the account the discussion above regarding Patients PJK and BH, the OIG audit yielded, *at most,* only a single claim (for patient BH) that should have included a replacement device modifier code.

Moreover, the recommendation that Piedmont audit a universe of 1,057 claims seems unfair in view of OIG recommendations with respect to other hospitals undergoing comparable audits. Based on the published information concerning those audits, the OIG recommended that those hospitals audit much smaller numbers of claims. Even if the claim for patient BH should have included a modifier code, Piedmont's error rate is less than one-half of one percent. Thus, the more onerous recommendation with respect to Piedmont seems unduly burdensome.

- **Recommendation 3:** Strengthen its procedures to obtain credits available from manufacturers and establish procedures to report to Cahaba the credits that Piedmont was entitled to, irrespective of whether the credits were obtained for replaced devices in accordance with Medicare requirements.

Piedmont had procedures in place to report credits using appropriate modifiers. Moreover, as acknowledged in the OIG Report, shortly after receiving a credit for the identified outpatient claim and long before this audit, Piedmont re-billed the claim to ensure the reimbursement was appropriate.

Nevertheless, Piedmont is adopting additional policies and procedures to strengthen its ongoing programs to document that it appropriately requests manufacturer credits for devices under warranty.

We look forward to continuing to work cooperatively with your office in resolving these remaining issues.

Sincerely,

Tracy M. Field
Executive Vice President, Compliance
Piedmont Healthcare, Inc.

Enclosure