

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE OVERPAYMENTS IN
JURISDICTION 15 FOR UNREPORTED
CARDIAC DEVICE CREDITS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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Regional Inspector General
for Audit Services

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Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

Medicare contractors for Jurisdiction 15 overpaid hospitals \$548,000 on selected inpatient and outpatient claims for replaced cardiac medical devices during calendar year 2011.

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor) in each Medicare jurisdiction. For calendar year 2011, Medicare contractors nationwide paid hospitals \$243.7 million for certain inpatient and outpatient cardiac medical device claims potentially eligible for a manufacturer's credit. Previous Office of Inspector General hospital compliance reviews of inpatient and outpatient manufacturers' credits for replaced cardiac medical devices found that Medicare contractors overpaid hospitals for selected claims.

The objective of this review was to determine whether payments that Medicare contractors for Jurisdiction 15 made to hospitals for selected inpatient and outpatient claims for replaced cardiac medical devices were in accordance with Medicare requirements.

BACKGROUND

Common cardiac medical devices used to treat beneficiaries include defibrillators, pacemakers, and their associated electrical leads. These devices are implanted during either an inpatient or outpatient procedure. Occasionally, devices may require replacement due to defects, recalls, battery depletions, or mechanical complications, which may be covered under the device manufacturer's warranty. Federal regulations generally require payment reductions for the replacement of an implanted device if the hospital receives a full or partial credit from manufacturers for medical devices that are covered under warranty or replaced because of defects or recalls.

During our audit period (January 1 through December 31, 2011), National Government Services, Inc. (NGS), began as the Medicare contractor for Jurisdiction 15 (Kentucky, Ohio, and West Virginia). Effective October 17, 2011, CGS Administrators, LLC (CGS), became the Medicare contractor for Jurisdiction 15. The Medicare contractors for Jurisdiction 15 paid hospitals \$15,100,833 for 770 inpatient and 1,089 outpatient cardiac medical device claims billed with principal diagnosis codes indicating there was a mechanical complication of an implantable cardiac device. We reviewed a total of 641 claims with total payments of \$9,717,370. These 641 claims had dates of service in CY 2011 and consisted of 309 inpatient and 332 outpatient claims.

Because CGS assumed responsibility for claims formerly paid by NGS for Jurisdiction 15, we have addressed our findings and recommendations to CGS for review and comment.

WHAT WE FOUND

Payments that the Medicare contractors for Jurisdiction 15 made to hospitals for 86 of the 641 inpatient and outpatient claims for replaced cardiac medical devices were not correct. These incorrect payments resulted in overpayments of \$547,553 that the hospitals had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, hospitals had refunded \$19,465 for another 5 claims. The remaining 550 claims were correct.

For 45 of the 309 inpatient claims, hospitals received a reportable medical device credit from a manufacturer for a replaced device but did not adjust its inpatient claim with the proper condition and value codes to reduce payment as required. For 16 of the 332 outpatient claims, hospitals received full credit for a replaced device but did not properly report the “FB” modifier and reduce charges on its claim. For an additional 25 of the 641 claims (21 inpatient claims and 4 outpatient claims), hospitals did not obtain a credit for a replaced device for which a credit was available under the terms of the manufacturer’s warranty.

Hospitals attributed the incorrect billings to inadequate policies and procedures for reporting manufacturer credits, lack of awareness of warranties and credit availability, and hospital misapplication of the credit amounts.

WHAT WE RECOMMEND

We recommend that CGS:

- recover the \$547,553 in identified overpayments, and
- use the results of this audit in its ongoing hospital education activities.

CGS’s COMMENTS

In written comments on our draft report, CGS concurred with our recommendations and provided information on actions that it had taken or planned to take to address our recommendations.

TABLE OF CONTENTS

INTRODUCTION 1

 Why We Did This Review 1

 Objective 1

 Background 1

 Manufacturer Credits for Replaced Cardiac Medical Devices 1

 Reduced Payments to Hospitals for the Replacement of
 Implantable Cardiac Devices 2

 National Government Services and CGS Administrators 2

 How We Conducted This Review 2

FINDINGS 3

 Federal Requirements 3

 Inpatient Manufacturer Credits for Replaced Medical Devices 3

 Outpatient Manufacturer Credits for Replaced Medical Devices 3

 Prudent Buyer Principle 4

 Replaced Medical Device Credits Not Reported or Obtained 4

 Inpatient Billing Errors 4

 Outpatient Billing Errors 5

 Causes of Incorrect Medicare Payments 5

RECOMMENDATIONS 5

CGS’S COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE 6

APPENDIXES

 A: Audit Scope and Methodology 7

 B: CGS’s Comments 9

INTRODUCTION

WHY WE DID THIS REVIEW

The Centers for Medicare & Medicaid Services (CMS) pays Medicare claims through the Medicare administrative contractor or fiscal intermediary (Medicare contractor) in each Medicare jurisdiction. For calendar year 2011, Medicare contractors nationwide paid hospitals \$243.7 million for certain inpatient and outpatient cardiac medical device claims¹ potentially eligible for a manufacturer's credit. Previous Office of Inspector General hospital compliance reviews of inpatient and outpatient manufacturers' credits for replaced medical devices found that Medicare contractors overpaid hospitals for selected claims.

OBJECTIVE

The objective of this review was to determine whether payments that Medicare contractors for Jurisdiction 15 made to hospitals for selected inpatient and outpatient claims for replaced cardiac medical devices were in accordance with Medicare requirements.

BACKGROUND

CMS contracts with Medicare contractors to, among other things, determine reimbursement amounts and pay claims, conduct reviews and audits, and safeguard against fraud and abuse. Medicare contractors must establish and maintain efficient and effective internal controls.² These controls include automatic data processing systems, which are intended to prevent increased program costs caused by incorrect or delayed payments.

Manufacturer Credits for Replaced Cardiac Medical Devices

Common cardiac medical devices used to treat beneficiaries include defibrillators, pacemakers, and their associated electrical leads. These devices are implanted during either an inpatient or outpatient procedure. Occasionally, devices may require replacement due to defects, recalls, battery depletions, and mechanical complications, which may be covered under the device manufacturer's warranty.

Device warranties vary among manufacturers but hospitals will generally receive full or partial credits from manufacturers for medical devices that are covered under warranty or replaced because of defects or recalls. Some manufacturers require that the hospital request the device credit. Other manufacturers automatically issue the credit if the device is returned and is under warranty or is determined to be defective. Hospitals, by and large, must send replaced devices back to the manufacturers within a specified time after the replacement procedures to obtain

¹ Using CMS's National Claims History file, we identified inpatient and outpatient claims nationwide billed with principal diagnosis codes indicating a mechanical complication of an implantable cardiac device for which Medicare payments were made during calendar year 2011.

² CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, section 10.

credits. Most electrical leads for devices have lifetime warranties and should qualify for a full credit should the manufacturer verify a lead malfunction.

Reduced Payments to Hospitals for the Replacement of Implantable Cardiac Devices

Federal regulations require reductions in both inpatient prospective payment system (IPPS) and outpatient prospective payment system (OPPS) payments for the replacement of an implanted device if (1) the device is replaced without cost to the hospital, (2) the hospital receives full credit for the device cost, or (3) the hospital receives a credit equal to 50 percent or more of the device cost (42 CFR § 412.89 and § 419.45). In addition, “All payments to hospitals of services must be based on the reasonable cost of services ...” (42 CFR § 413.9).

National Government Services and CGS Administrators

During January 1 through December 31, 2011 (audit period), National Government Services, Inc. (NGS), began as the Medicare contractor for Jurisdiction 15 (Kentucky, Ohio, and West Virginia). CGS Administrators, LLC (CGS), assumed full responsibility as the Medicare contractor for Jurisdiction 15 effective October 17, 2011. Accordingly, we have addressed our findings and recommendations to CGS for review and comment.

HOW WE CONDUCTED THIS REVIEW

During our audit period, the Medicare contractors for Jurisdiction 15 paid hospitals \$15,100,833 for 770 inpatient and 1,089 outpatient cardiac medical device claims billed with principal diagnosis codes of 996.01 and 996.04.³ We reviewed a total of 641 claims with total payments of \$9,717,370. These 641 claims had dates of service in CY 2011 and consisted of 309 inpatient and 332 outpatient claims. We used computer matching, data mining, and other analytical techniques to identify the claims potentially at risk for noncompliance with Medicare billing requirements. We evaluated compliance with selected billing requirements, but we did not use medical review to determine whether services were medically necessary.

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.

See Appendix A for the details of our scope and methodology.

³ Principle diagnosis codes 996.01 and 996.04 are used when a patient has an implantable cardiac device (specifically defibrillators, pacemakers, and associated leads) replaced due to a mechanical complication.

FINDINGS

Payments that the Medicare contractors for Jurisdiction 15 made to hospitals for 86 of the 641 inpatient and outpatient claims for replaced cardiac medical devices were not correct. These incorrect payments resulted in overpayments of \$547,553 that the hospitals had not identified, refunded, or adjusted by the beginning of our audit. Before our fieldwork, hospitals had refunded \$19,465 for another 5 claims. The remaining 550 claims were correct.

For 45 of the 309 inpatient claims, hospitals received reportable medical device credits from a manufacturer for replaced devices but did not adjust its inpatient claim with the proper condition and value codes to reduce payment as required. For 16 of the 332 outpatient claims, hospitals received full credits for replaced devices but did not properly report the “FB” modifier and reduced charges on its claim. For an additional 25 of the 641 claims (21 inpatient claims and 4 outpatient claims), hospitals did not obtain credits for replaced devices for which credits were available under the terms of the manufacturer’s warranty.

Hospitals attributed the incorrect billings to inadequate policies and procedures for reporting manufacturer credits, lack of awareness of warranties and credit availability, and hospital misapplication of the credit amounts.

FEDERAL REQUIREMENTS

Inpatient Manufacturer Credits for Replaced Medical Devices

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 *CMS Medicare Claims Processing Manual* (the Manual) states that to bill correctly for a replacement device that was provided with a credit, providers must code Medicare claims with a combination of condition code 49 or 50, along with value code “FD” (chapter 3, § 100.8).

Outpatient Manufacturer Credits for Replaced Medical Devices

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(a)). For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier “FB” and reduced charges on an outpatient 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.⁴

Prudent Buyer Principle

Federal regulations state, “All payments to providers of services must be based on the reasonable cost of services ...” (42 CFR § 413.9). The *CMS Provider Reimbursement Manual (PRM)* reinforces this requirement in additional detail. The PRM 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” (part I, § 2102.1).

The PRM further defines prudent buyer principles and states that Medicare providers are expected to pursue free replacements or reduced charges under warranties (part I, § 2103.A). The PRM provides the following example: “Hospital 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.” (part I, § 2103.C.4)

REPLACED MEDICAL DEVICE CREDITS NOT REPORTED OR OBTAINED

Inpatient Billing Errors

For 45 of the 309 inpatient claims, hospitals received reportable medical device credits from a manufacturer for replaced devices but did not adjust its inpatient claim with the proper condition and value codes to reduce payment as required. For an additional 21 of the 309 inpatient claims, hospitals did not obtain credits for replaced devices for which credits were available under the terms of the manufacturer’s warranty. The following illustrates an example of each type of error:

- One hospital received a credit for a recalled electrical lead, but did not report condition code 50 (indicating a recall) and value code “FD” (indicating a credit was received from the manufacturer for a replaced medical device) on the claim as required. As a result, the Medicare contractors paid the hospital \$30,872 when they should have paid \$25,202, resulting in an overpayment of \$5,670. The hospital attributed this error to inadequate internal policies and procedures for reporting manufacturers’ credits.
- One hospital failed to request a credit for a recalled electrical lead. As a result, the Medicare contractors paid the hospital \$32,537, when they should have paid \$30,133,

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

resulting in an overpayment of \$2,404. The hospital attributed this error to a lack of awareness of warranties and credit availability.

As a result of these errors, the Medicare contractors for Jurisdiction 15 paid hospitals \$1,547,058 for inpatient claims when they should have paid \$1,296,519, resulting in overpayments of \$250,539.

Outpatient Billing Errors

For 16 of the 332 outpatient claims, hospitals received full credits for replaced devices but did not properly report the “FB” modifier and reduce charges on its outpatient claim. For an additional 4 of the 332 outpatient claims, hospitals did not obtain credits for replaced devices for which credit was available under the terms of the manufacturer’s warranty. The following illustrates an example of each type of error:

- One hospital received a credit for a failed defibrillator, but did not report modifier “FB” and reduce charges on the claim as required. As a result, the Medicare contractors paid the hospital \$28,862 when they should have paid \$8,035, resulting in an overpayment of \$20,827. The hospital attributed this error to inadequate internal policies and procedures for reporting manufacturers’ credits.
- One hospital failed to request a credit for a recalled electrical lead. As a result, the Medicare contractors paid the hospital \$24,378, when they should have paid \$4,874, resulting in an overpayment of \$19,504. The hospital attributed this error to a lack of awareness of warranties and credit availability.

As a result of these errors, the Medicare contractors for Jurisdiction 15 paid hospitals \$382,176 for outpatient claims when they should have paid \$85,162, resulting in overpayments of \$297,014.

CAUSES OF INCORRECT MEDICARE PAYMENTS

Hospitals attributed the incorrect billings to inadequate policies and procedures for reporting manufacturer credits, lack of awareness of warranties and credit availability, and hospital misapplication of the credit amounts.

RECOMMENDATIONS

We recommend that CGS:

- recover the \$547,553 in identified overpayments, and
- use the results of this audit in its ongoing hospital education activities.

CGS'S COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CGS concurred with our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. However, CGS disagreed with our statement related to why the Medicare contractors overpaid hospitals. CGS stated that errors on claims were committed on the provider side and in their billing practices with Medicare contractors not able to prevent 100 percent of the errors in data submitted by providers. For that reason, CGS stated that CMS allows for clerical reopenings from providers when errors in the data are found. We agree with CGS's comment and have removed the statement.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period, the Medicare contractors for Jurisdiction 15 paid hospitals \$15,100,833 for 770 inpatient and 1,089 outpatient medical device claims billed with principal diagnosis codes 996.01 and 996.04, indicating a mechanical complication of an implantable cardiac device (specifically defibrillators, pacemakers, and associated electrical leads). We reviewed a total of 641 claims with total payments of \$9,717,370. These 641 claims had dates of service in CY 2011 and consisted of 309 inpatient and 332 outpatient claims.

We did not review the overall internal control structure of the Medicare contractors or the hospitals because our objective did not require us to do so. Rather, we limited our review to (1) the Medicare contractors' internal controls to prevent the overpayment of Medicare claims associated with the selected claims and (2) hospitals' internal controls to prevent incorrect billing for the selected claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

We conducted our audit from June 2013 through May 2014 and performed fieldwork by contacting CGS in Nashville, Tennessee, and 87 hospitals that received the selected Medicare payments during our audit period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify inpatient and outpatient claims billed with principal diagnosis codes 996.01 and 996.04 for which Medicare payments were made during our audit period;
- used computer matching, data mining, and other analytical techniques to identify claims at risk for noncompliance with Medicare billing requirements;
- selected 641 claims at risk of error, totaling \$9,717,370 that the Medicare contractors paid to the 87 hospitals;
- requested that the 87 hospitals furnish documentation including:
 - Device Manufacturer
 - Model
 - Model Number
 - Serial Number
 - Implant and Explant dates

- Warranty information for explanted device
- Invoices for implanted and explanted devices
- Itemized bill
- UB-04 Medicare Claim Form
- History and Physical
- Discharge Summary
- Operative Report/Procedure Notes supporting the surgical procedure for the device replacement
- Paperwork used to request a credit from the manufacturer;
- reviewed the documentation to determine whether:
 - the new device was provided at no cost,
 - the manufacturer issued a credit for the replaced device, or
 - a credit would have been available had the hospital pursued one;
- calculated overpayment amounts in accordance with Federal requirements and Medicare payment procedures; and
- discussed the results of our review with hospitals and CGS.

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.

APPENDIX B: CGS's COMMENTS

John Kimball
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October 09, 2014

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Regional Inspector General for Audit Services
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233 North Michigan Avenue, Suite 1360
Chicago, IL 60601

RE: CGS Response to Draft OIG Report entitled *Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits (A-05-13-00029)*

Dear Ms. Sheri Fulcher,

CGS Administrators, LLC, the Part A/B and Home Health and Hospice Medicare Administrative Contractor for Jurisdiction 15, appreciates the opportunity to comment on the Office of Inspector General's draft report entitled *Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits (A-05-13-00029)*. In addition to requesting comments on the report, you ask that CGS state concurrence or nonconcurrence with each of the two recommendations in the report.

The OIG makes two (2) recommendations in its report. Those recommendations are:

1. Recover the \$547,553 in identified overpayments.
2. Use the results of this audit in its ongoing provider education activities.

While CGS concurs with the recommendations in the report, CGS disagrees with the statement, "[t]he Medicare contractors overpaid these hospitals because there were insufficient edits in place to prevent or detect overpayments." The majority of claims found in error during this audit review were processed by NGS and not CGS. As with any claim, the MAC processes claims based on the data provided on the claim form submitted by the provider of services. It is not a reasonable expectation that every claim is suspended for validation/verification of the data being submitted by the provider. The MAC relies on the data presented on the claim form, and makes coverage determinations based on that data. CGS acknowledges that errors were made on claims, but those errors were committed on the provider side and in their billing practices, whether by mistake or intent. The MAC is not able to prevent errors in data that are submitted by providers in 100% of the cases (CMS acknowledges as much and allows for clerical reopenings from providers when errors in the data submitted are found).

CGS would not know, unless a provider reported it on the claim (by using the appropriate HCPCS modifier), that a device was subject to recall/warranty and therefore warranted no

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DME Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services



payment or reduced payment. It is incumbent on providers to identify these situations and ensure they have adequate controls, processes, etc. in place to ensure they are submitting claims accurately.

CGS agrees with the recommendation on educating providers. CR 8653 (and associated MLN Matters article MM8653) provides guidance on how to report devices that meet these criteria. We posted this article on our website to educate providers, and distributed notification to providers through our email distribution list to inform them about the article – details are:

- April 2014 monthly bulletin includes MM8653:
http://www.cgsmedicare.com/parta/pubs/bulletin/2014/04_14.pdf
- MM8653 is posted on our Part A Fees web page:
<http://www.cgsmedicare.com/parta/fees/>
- MM8653 was posted on our website (under News & Publications) and sent via email distribution list (a/k/a listserv) on 3/13/14.

Claims included in this audit were submitted and processed prior to publication of this article. At this time, we do not believe further steps are needed to educate providers.

In summary, CGS Administrators, LLC is fully aware of the overpayments in draft report A-05-13-00029 and, as demonstrated above, upon proper notification we will take aggressive and extensive steps to address those overpayments. Should you have any additional questions, please feel to contact Jacqueline Yarbrough at 615.782.4671 or Jacqueline.Yarbrough@cgsadmin.com.

Sincerely,

John Kimball

John Kimball
Vice President, Operations