

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**HOSPITALS DID NOT ALWAYS COMPLY  
WITH MEDICARE REQUIREMENTS FOR  
REPORTING COCHLEAR DEVICES  
REPLACED WITHOUT COST**

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Deputy Inspector General  
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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*Hospitals did not always comply with Medicare requirements for reporting cochlear devices replaced without cost to the hospital or beneficiary, resulting in overpayments of \$2.7 million over 3 years.*

### WHY WE DID THIS REVIEW

Prior Office of Inspector General (OIG) reviews have found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for replaced medical devices. Our compliance reviews at specific hospitals nationwide identified approximately \$10 million in Medicare overpayments due to hospitals that did not report to the Centers for Medicare & Medicaid Services (CMS) device manufacturer credits that they received or that were available under the terms of manufacturer warranties that they did not obtain.

Our reviews of claims for replaced medical devices have identified that the devices are at risk of noncompliance with Medicare billing requirements. Most of this work has focused on credits for defective cardiac devices. In this review, we have expanded our focus to Medicare claims for cochlear devices.

The objective of this review was to determine whether hospitals nationwide complied with Medicare requirements for reporting cochlear devices replaced without cost to the hospital or beneficiary.

### BACKGROUND

CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). Medicare does not cover items or services for which neither the beneficiary nor anyone on his or her behalf has an obligation to pay. Accordingly, payment of the full APC payment rate when a hospital replaces a device 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.

Federal regulations require a payment reduction in the outpatient prospective payment system 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)).

To identify devices replaced without cost, CMS requires hospitals to report the modifier -FB and reduced charges (services furnished prior to January 1, 2014), or value code FD along with condition code 49 or 50 (services furnished on or after January 1, 2014). Payment is reduced for specified procedure codes subject to the adjustment.

A cochlear device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers and part of which is worn or carried by the individual to capture, analyze, and code sound. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communications for persons who are moderately to profoundly hearing impaired.

Our audit covered \$4,298,959 in Medicare payments to 78 hospitals nationwide for 149 outpatient claims for replaced cochlear devices. We reviewed all claims that represented cochlear devices potentially replaced at no cost on the basis of data we obtained from the device manufacturers. These claims had dates of service in calendar years (CYs) 2012 through 2014.

## **WHAT WE FOUND**

Hospitals nationwide did not always comply with Medicare requirements for reporting cochlear devices replaced without cost to the hospital or beneficiary. Specifically, for 116 of the 149 claims we reviewed, hospitals did not report the appropriate modifiers and charges (for claims with dates of service in CYs 2012 and 2013) or a combination of the appropriate value code and condition codes (for claims with dates of service in CY 2014) to alert the Medicare contractors of the need for payment adjustments. For the remaining 33 claims, we confirmed that the hospital had paid for the device, or the medical records showed that the procedure performed was not a device replacement.

For the 116 incorrectly billed claims we identified, hospitals received \$2,685,588 in Medicare overpayments. These overpayments occurred because hospitals did not have controls to identify and report no-cost replacements they received from cochlear device manufacturers.

Hospitals agreed that they billed these claims incorrectly and returned \$1,446,179 of the \$2,685,588 in overpayments to the Medicare contractors during our audit. Hospitals stated that they attempted to return most of the remaining identified overpayments of \$1,239,409. However, for these claims, the hospitals either did not provide us with proof that the Medicare contractor adjusted the claim or stated that the Medicare contractor would not allow the adjustment to process or reopen the claim. This included \$553,374 in overpayments that were within the 4-year reopening period when the hospitals received our audit notice that identified the potential overpayments, but these overpayments are now outside of the 4-year reopening period.

## **WHAT WE RECOMMEND**

We recommend that CMS instruct the Medicare contractors to:

- verify the \$1,446,179 in identified overpayments for incorrectly billed claims that hospitals stated they refunded to Medicare during our review;
- recover \$686,035 in identified overpayments for CYs 2013 and 2014 that had not been refunded to Medicare by the conclusion of our audit;

- assist hospitals in returning the agreed-upon overpayments of \$553,374 for CY 2012 claims that are outside the Medicare 4-year reopening period, but which a contractor can reopen upon a hospital's request related to the 60-day repayment rule; and
- educate hospitals on how to appropriately bill for and report medical devices replaced without cost to the hospital or beneficiary, including cochlear devices.

## **CMS COMMENTS AND OUR RESPONSE**

In written comments on our draft report, CMS concurred with our recommendations and stated that it will instruct its contractors to recover the overpayments consistent with its policies and procedures. In addition, CMS said it will continue to educate providers on these requirements.

With respect to our third recommendation, CMS did not address how it would assist hospitals in returning the overpayments for claims that are outside of the 4-year reopening period. We have concerns as to whether the hospitals will be able to return the overpayments in accordance with the 60-day repayment rule.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

Prior Office of Inspector General (OIG) reviews have found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for replaced medical devices.<sup>1</sup>

Our compliance reviews at specific hospitals nationwide identified approximately \$10 million in Medicare overpayments due to hospitals not reporting to the Centers for Medicare & Medicaid Services (CMS) device manufacturer credits that they received or were entitled to receive under the terms of manufacturer warranties that they did not obtain.

Our reviews of claims for replaced medical devices have identified that the devices are at risk of noncompliance with Medicare billing requirements. Most of this work has focused on credits for defective cardiac devices. In this review, we have expanded our focus to Medicare claims for cochlear devices.

### OBJECTIVE

The objective of this review was to determine whether hospitals nationwide complied with Medicare requirements for reporting cochlear devices replaced without cost to the hospital or beneficiary.

### BACKGROUND

#### The Medicare Program

Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. CMS administers the Medicare program.

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

#### Hospital Outpatient Prospective Payment System

Under the outpatient prospective payment system (OPPS), Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes

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<sup>1</sup> Some examples of past OIG reviews include the following: *Review of Yale New Haven Hospital's Claims for Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2007 and 2008* (A-01-10-00504), issued November 2010; *Review of Massachusetts General Hospital's Claims for Outpatient Procedures That Included the Replacement of Medical Devices for Calendar Years 2007 and 2009* (A-01-10-00501), issued December 2010; and *Review of Beth Israel Deaconess Medical Center's Claims That Included Medical Device Replacements* (A-01-14-00502), issued January 2015.

and descriptors to identify and group the services within each APC group.<sup>2</sup> All services and items within an APC group are comparable clinically and require comparable resources. The cochlear devices covered by this review were replaced on an outpatient basis.

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

Medicare does not cover items or services for which neither the beneficiary nor anyone on his or her behalf has an obligation to pay (Social Security Act § 1862(a)(2)).

Federal regulations require a payment reduction in the OPPS 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)).

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2).

### **Cochlear Device**

A cochlear device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers and part of which is worn or carried by the individual to capture, analyze, and code sound. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communications for persons who are moderately to profoundly hearing impaired.

### **Use of Modifier -FB or Value Code FD To Identify No-Cost Replacement Devices**

For services furnished on or after January 1, 2007, and prior to January 1, 2014, CMS required the hospital to report the modifier -FB and reduced charges on a claim that included a procedure code for the insertion of a replacement device if the hospital incurred no cost or received full credit for the replaced device. If the hospital received a replacement device without cost from the manufacturer, the hospital was required to report a charge of no more than \$1 for the device. For services furnished on or after January 1, 2008, CMS required the hospital to report the modifier -FC if the hospital received a partial credit of 50 percent or more of the cost of a new replacement device.<sup>3</sup>

Effective January 1, 2014, CMS no longer recognized the -FB or -FC modifiers to identify a device furnished without cost or with a full or partial credit. For services furnished on or after

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<sup>2</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>3</sup> CMS provided guidance on how a hospital should report no-cost, full credit, and partial credit devices under the OPPS (CMS Transmittal 1103, dated November 3, 2006, CMS Transmittal 1383, dated November 23, 2007, and the Manual, chapter 4, § 61.3).

January 1, 2014, hospitals must report the amount of the device credit in the amount portion for value code FD (credit received from the manufacturer for a replaced medical device). The OPSS payment is reduced by the amount of the device credit for specified procedure codes reported with value code FD. The payment reduction is limited to the full device offset when the FD value code appears on a claim. Hospitals must also report either condition code 49 (product replacement within product lifecycle) or 50 (product replacement for known recall of a product) when the value code FD is present on the claim.<sup>4</sup>

## **HOW WE CONDUCTED THIS REVIEW**

We matched a list of no-cost replacements that cochlear device manufacturers issued to hospitals<sup>5</sup> nationwide for devices that prematurely failed or were otherwise covered under warranty during calendar years (CYs) 2012 through 2014 to claims that were at risk for noncompliance with Medicare billing requirements. Our audit covered \$4,298,959 in Medicare payments to 78 hospitals nationwide for 149 outpatient claims for replaced cochlear devices. These claims had dates of service in CYs 2012 through 2014.

We limited our review of internal controls at hospitals to those related to reporting cochlear devices replaced without cost to the hospital or beneficiary. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary. This report focuses on a select risk area and does not represent an overall assessment of all claims that the hospitals submitted for Medicare reimbursement.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Appendix contains the details of our scope and methodology.

## **FINDINGS**

Hospitals nationwide did not always comply with Medicare requirements for reporting cochlear devices replaced without cost to the hospital or beneficiary. Specifically, for 116 of the 149 claims we reviewed, hospitals did not report the appropriate modifiers and charges (for claims with dates of service in CYs 2012 and 2013) or a combination of the appropriate value code and condition codes (for claims with dates of service in CY 2014) to alert the Medicare contractors of the need for payment adjustments. For the remaining 33 claims, we confirmed that the hospital

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<sup>4</sup> Payments are reduced only for procedure codes that map to the APCs on the list of APCs subject to the adjustment (i.e., APCs with device offset amounts greater than 40 percent), CMS Transmittal 2903, dated March 11, 2014, and the Manual, chapter 4, §§ 61.3.5 and 61.3.6.

<sup>5</sup> The list from the manufacturers included five ambulatory surgical centers. In this review, we refer to all of the providers as “hospitals.”

had paid for the device, or the medical records showed that the procedure performed was not a device replacement.

For the 116 incorrectly billed claims we identified, hospitals received \$2,685,588 in Medicare overpayments. These overpayments occurred because hospitals did not have controls to identify and report no-cost replacements they received from cochlear device manufacturers.

### **HOSPITALS DID NOT ALWAYS REPORT COCHLEAR DEVICES REPLACED WITHOUT COST TO THE HOSPITAL OR BENEFICIARY**

For 116 of the 149 selected claims, hospitals received cochlear devices replaced without cost from manufacturers but did not adjust their claims with the appropriate codes to reduce payment as required. Specifically, for 78 of the claims (with dates of service in CY 2012 or CY 2013), hospitals did not report the appropriate modifier -FB and reduced charges. For 38 of the claims (with dates of service in CY 2014), hospitals did not report the appropriate FD value code along with condition code 49 or 50.

Overpayments of \$2,685,588 occurred because hospitals did not have controls to identify and report no-cost replacements received from cochlear device manufacturers. Specifically, hospitals that had billing errors:

- did not have procedures to coordinate functions among various departments (i.e., clinical departments, patient accounts, and Medicare billing) to ensure that they reported the appropriate information to reflect cochlear devices replaced without cost;
- did not always communicate with the cochlear device manufacturers to obtain a comprehensive list of no-cost replacements;
- had staff that were either unaware of or misunderstood the billing requirements; and
- had not programmed billing edits to identify and flag no-cost replacements for review and follow up.

For the remaining 33 of the 149 claims we reviewed, we confirmed that the hospital had paid for the device, or the medical records showed that the procedure performed was not a device replacement.

### **MEDICARE OVERPAYMENTS**

Federal law requires providers to report and return an overpayment within 60 days after it is identified.<sup>6</sup> For the 116 incorrectly billed claims that we identified, hospitals agreed that they billed these claims incorrectly and returned \$1,446,179 of the \$2,685,588 in overpayments to the Medicare contractors during our audit. Hospitals stated that they attempted to return most of the remaining identified overpayments of \$1,239,409. However, for these claims, the hospitals

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<sup>6</sup> See, 1128J(d) of the Social Security Act, 42 USC 1320a-7k(d).

either did not provide us with proof that the Medicare contractor adjusted the claim or stated that the Medicare contractor would not allow the adjustment to process or reopen the claim.<sup>7</sup> This includes \$553,374 in overpayments that were within the 4-year reopening period when the hospitals received our audit notice of the potential overpayment but are now outside the 4-year reopening period.<sup>8</sup>

## RECOMMENDATIONS

We recommend that CMS instruct the Medicare contractors to:

- verify the \$1,446,179 in identified overpayments for incorrectly billed claims that hospitals stated they refunded to Medicare during our review;
- recover \$686,035 in identified overpayments for CYs 2013 and 2014 that had not been refunded to Medicare by the conclusion of our audit;
- assist hospitals in returning the agreed-upon overpayments of \$553,374 for CY 2012 claims that are outside the Medicare 4-year reopening period, but which a contractor can reopen upon a hospital's request related to the 60-day repayment rule;<sup>9</sup> and
- educate hospitals on how to appropriately bill for and report medical devices replaced without cost to the hospital or beneficiary, including cochlear devices.

## CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and stated that it will instruct its contractors to recover the overpayments consistent with its policies and procedures. In addition, CMS said it will continue to educate providers on these requirements.

With respect to our third recommendation, CMS noted that six claims are within the 4-year claim reopening period and are eligible for potential overpayment recovery.

CMS's comments appear in their entirety as Appendix B.

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<sup>7</sup> We informed CMS of the hospitals' stated difficulties adjusting and reopening claims.

<sup>8</sup> 42 CFR 405.980(b)(2) (permitting a contractor to reopen within 4 years for good cause) and 42 CFR 405.980(c)(2) (permitting a party to request that a contractor reopen within 4 years for good cause).

<sup>9</sup> See, 42 CFR §§401.305 and 405.980(c)(4), which were added by 81 FR 7654 (Feb. 12, 2016) and permit a party to request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment.

## OFFICE OF INSPECTOR GENERAL RESPONSE

With respect to our third recommendation, CMS did not address how it would assist hospitals in returning the overpayments for claims that are outside of the 4-year reopening period. We have concerns as to whether the hospitals will be able to return the overpayments in accordance with the 60-day repayment rule. The hospitals agreed that they billed these claims incorrectly (making the overpayments provider-identified overpayments subject to the 60-day repayment rule) and stated that they attempted to return most of these overpayments. For all of these claims, the hospitals either did not provide us with proof that the Medicare contractor adjusted the claim or stated that the Medicare contractor would not allow an adjustment to process or reopen the claim.

### OTHER MATTERS

#### UNIQUE DEVICE IDENTIFIER NOT REQUIRED ON MEDICARE CLAIM FORMS

The Food and Drug Administration Amendments Act of 2007 charged the U.S. Food and Drug Administration (FDA) with creating a Unique Device Identifier (UDI) system to better detect adverse events, improve product recalls, and enable robust post-market surveillance. In 2013, FDA released a final rule establishing a UDI system designed to adequately identify devices through distribution and use. The rule requires the label of most medical devices to include a UDI that identifies the device's labeler and its version or model, and it requires each labeler to submit certain information concerning each device with a UDI on its label to FDA's Global Unique Device Identification Database.

CMS currently does not require hospitals to report device-specific information on Medicare claim forms. Because claim forms list only the procedures performed, we were unable to discern from the claim data alone the device manufacturer and model and whether the cochlear device implantation was due to a device that prematurely failed, as opposed to an initial implant. Additionally, we were unable to match the hospital claim data directly to the manufacturer data to quickly identify devices replaced at no cost. The lack of specificity in the claims necessitates a review of the medical record to determine whether the device implanted during the procedure matches the manufacturer's listing of devices replaced at no cost.

If UDIs are included on Medicare claim forms, we can match the hospital claim data directly to the manufacturer data and do not have to rely on the medical records. Some of the problems that could be resolved by using UDIs include:

- allowing more accurate reporting, reviewing, and analyzing of medical device reports<sup>10</sup> so that problem devices can be identified and corrected more quickly, which would reduce the Medicare costs associated with adverse events; and

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<sup>10</sup> Medical device reporting is defined in 21 CFR § 803.1, requiring manufacturers to report deaths or serious injuries that a device has or may have caused or contributed to. This section also requires device manufacturers to report certain device malfunctions and establish and maintain adverse event files.

- reducing medical errors by enabling health care professionals and others, such as Medicare contractors and CMS, to more rapidly and precisely identify a device that is potentially contributing to a medical error and obtain important information concerning the characteristics of the device.

The costs Medicare incurs because of recalled or failed medical devices and the role the UDI could play in identifying these costs are the subject of an ongoing OIG review.

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our audit covered \$4,298,959 in Medicare payments to 78 hospitals nationwide for 149 outpatient claims for replaced cochlear devices. We reviewed all claims that represented cochlear devices potentially replaced at no cost on the basis of the data we obtained from the device manufacturers. These claims had dates of service in CYs 2012 through 2014 (audit period).

We limited our review of internal controls at hospitals to those related to reporting cochlear devices replaced without cost to the hospital or beneficiary. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary. This report focuses on a select risk area and does not represent an overall assessment of all claims submitted by the hospitals for Medicare reimbursement.

We conducted our fieldwork from July 2015 to February 2016.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable laws, regulations, and guidance;
- requested and received from three cochlear device manufacturers a list of no-cost replacements issued to hospitals nationwide for devices that prematurely failed or were otherwise covered under warranty during our audit period;
- used CMS's National Claims History file to identify claims that included procedures for the implant or replacement of a cochlear device during our audit period;
- reviewed claims data and available data from the Common Working file to determine (1) whether the claims had been canceled or adjusted and (2) whether the hospitals submitted the claims with the appropriate modifier -FB and reduced charges (for claims with dates of service in CYs 2012 or 2013) or the FD value code along with condition code 49 or 50 (for claims with dates of service in CY 2014);
- selected the 149 claims for detailed review that had not been canceled or adjusted with the appropriate modifier or value code;
- requested that each hospital conduct its own review of the selected claims to determine whether the services represented a no-cost device replacement that should have been reported to Medicare;
- reviewed the medical and billing record documentation provided by each hospital to support the sampled claims;

- reviewed the hospitals' procedures for identifying and obtaining no-cost replacements and reporting them on their Medicare claim forms;
- reviewed documentation provided by the hospitals to determine the causes of noncompliance with Medicare billing requirements;
- requested that the hospitals return overpayments for any incorrectly billed claims and provide us with the adjusted remittance advices, if available;
- calculated the correct payments for those claims requiring adjustments; and
- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.



OCT 11 2016

200 Independence Avenue SW  
Washington, DC 20201

**To:** Daniel R. Levinson  
Inspector General  
Office of the Inspector General

**From:** Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services

**Subject:** Hospitals Did Not Always Comply With Medicare Requirements for Reporting Cochlear Devices Replaced Without Cost (A-01-15-00508)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) report. CMS strives to provide Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

CMS recognizes the importance of continuing to provide Medicare beneficiaries with access to essential services and, at the same time, working to improve appropriate use. CMS has also taken actions to prevent Medicare overpayments by educating providers on proper billing. CMS educates providers on avoiding Medicare billing errors through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.

In addition to provider education, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including prepayment and postpayment reviews, prior authorization for certain items and services, and the Comprehensive Error Rate Testing program to identify and address incorrect billing caused by coverage or coding errors made by providers.

#### **OIG Recommendation**

The OIG recommends that CMS verify the \$1,446,179 in identified overpayments for incorrectly billed claims that hospitals stated they refunded to Medicare during our review.

#### **CMS Response**

CMS concurs with this recommendation. Based on the overpayment data provided, the OIG has already verified that \$1,077,269 has been refunded to Medicare. CMS will work with its contractors to verify that the remaining \$368,910 in identified overpayments were refunded to Medicare.

**OIG Recommendation**

The OIG recommends that CMS recover \$696,035 in identified overpayments for CYs 2013 and 2014 that had not been refunded to Medicare by the conclusion of this audit.

**CMS Response**

CMS concurs with this recommendation. CMS will instruct its contractors to determine which claims have not been previously adjusted and recover all overpayments consistent with the agency's policies and procedures.

**OIG Recommendation**

The OIG recommends that CMS assist hospitals in returning the agreed-upon overpayments of \$553,374 for CY 2012 claims that are outside the Medicare 4-year reporting period, but which a contractor can reopen based upon a hospital's request related to the 60-day repayment rule.

**CMS Response**

CMS concurs with this recommendation. Based on the overpayment data provided by the OIG, 6 claims valued at \$140,671 have paid claim dates in CY 2013. These claims are within the 4-year claim reopening period and are eligible for potential overpayment recovery. In addition, CMS will instruct its contractors to determine which claims of the remaining \$413,703 have not been previously adjusted and recover all overpayments consistent with the agency's policies and procedures.

**OIG Recommendation**

The OIG recommends that CMS educate hospitals on how to appropriately bill for and report medical devices replaced without cost to the hospital or beneficiary, including cochlear devices.

**CMS Response**

CMS concurs with this recommendation. CMS routinely educates providers on avoiding Medicare billing errors through various channels, including the Medicare Learning Network, weekly electronic newsletters and quarterly compliance newsletters. CMS will continue to use channels such as these to educate providers on these requirements as necessary.