

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**HOSPITALS DID NOT
COMPLY WITH MEDICARE
REQUIREMENTS FOR
REPORTING CERTAIN
CARDIAC DEVICE CREDITS**

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Office of Inspector General

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Report in Brief

Date: March 2018

Report No. A-05-16-00059

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

Prior OIG reviews found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for replaced medical devices.

Recalls of medical devices can be quite costly to the Medicare program. A recent OIG review estimated that services related to the replacement of seven recalled and prematurely failed medical devices cost Medicare \$1.5 billion during calendar years 2005 through 2014.

Our objective was to determine whether hospitals complied with Medicare requirements for reporting manufacturer credits associated with five recalled or prematurely failed cardiac medical devices.

How OIG Did This Review

We obtained a list of warranty credits that two device manufacturers issued to hospitals for five cardiac medical devices that had been recalled or had high failure rates. We reviewed the 296 claims that we considered at risk for overpayment because the hospitals billed for a device-intensive procedure, received a credit of 50 percent or greater, and did not include a value code or modifier on the claim as required.

Our audit covered \$7.7 million in Medicare payments to hospitals for 153 inpatient and 143 outpatient claims for replaced cardiac medical devices. These claims had dates of service during calendar years 2008 through 2013.

Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits

What OIG Found

All 296 payments reviewed for recalled cardiac medical devices did not comply with Medicare requirements for reporting manufacturer credits. Medicare contractors incorrectly paid hospitals \$7.7 million for cardiac device replacement claims rather than the \$3.3 million they should have been paid, resulting in potential overpayments of \$4.4 million.

For all payments reviewed, manufacturers issued reportable credits to hospitals for recalled cardiac medical devices, but the hospitals did not adjust the claims with the proper condition codes, value codes, or modifiers to reduce payment as required. The overpayments occurred because Medicare controls were not sufficient to ensure that hospitals properly reported manufacturer credits for cardiac devices.

What OIG Recommends and CMS Comments

We recommend that CMS instruct its Medicare contractors to notify the 210 hospitals associated with the 296 claims with potential overpayments of \$4.4 million so that those hospitals can exercise reasonable diligence to investigate and return any identified overpayments in accordance with the 60-day rule. We also recommend that CMS educate providers on the requirements for reporting manufacturer credits and instruct its Medicare contractors to implement a post-payment process to follow up with hospitals that submit claims for certain cardiac device replacement procedures to determine whether an adjustment claim should be submitted. Finally, we recommend that CMS consider studying alternatives to implementing edits in order to eliminate the current Medicare requirements for reporting device credits. The full text of recommendations can be found in the report.

In written comments on our draft report, CMS generally concurred with our first, second, and fourth recommendations and provided information on actions that it planned to take to address them. However, CMS did not concur with our third recommendation because not all devices replaced under warranty or due to recall will result in a credit affecting payment. This review and others have shown that hospitals are receiving reportable cardiac device credits and are not properly reporting these credits on claims. While we acknowledge that hospitals may not receive a reportable credit in all cases of cardiac device replacement, previous OIG reviews have found that credits are provided for most cardiac devices replaced within the product lifecycle or due to recall. We maintain that our recommendation is valid and that CMS should direct contractors to implement a post-payment process for claims with certain cardiac device procedures to ensure hospitals are complying with Medicare requirements for reporting manufacturer credits.

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INTRODUCTION

WHY WE DID THIS REVIEW

Prior Office of Inspector General (OIG) reviews with audit periods ranging from 2009 through 2016 found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for medical devices that were replaced. (See Appendix B for a list of related reports.) Specifically, hospitals did not always report to the Centers for Medicare & Medicaid Services (CMS) device manufacturer credits that they received.

Recalls of medical devices nearly doubled from 2003 through 2012¹ and can be quite costly to the Medicare program. A recent OIG review estimated that services related to the replacement of seven recalled and prematurely failed medical devices cost Medicare \$1.5 billion during calendar years 2005 through 2014.²

OBJECTIVE

Our objective was to determine whether hospitals complied with Medicare requirements for reporting manufacturer credits associated with five recalled or prematurely failed cardiac medical devices.

BACKGROUND

The Medicare Program

Medicare provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

CMS is responsible for administering the Medicare program. CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals, conduct reviews and audits, and safeguard against fraud and abuse. CMS is responsible for providing contractor oversight, such as facilitating contractor compliance with current regulations, ensuring Medicare contractors' performance of CMS operating instructions, and providing

¹ The U.S. Food and Drug Administration (FDA) medical device recall reports fiscal years 2003 through 2012. Available online at <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm388442.pdf>. Accessed on May 15, 2017.

² *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (A-01-15-00504).

ongoing feedback and guidance to contractors regarding the Medicare program. Medicare contractors must establish and maintain efficient and effective internal controls.³

Hospital Inpatient Prospective Payment System

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

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.⁴ All services and items within an APC group are comparable clinically and require comparable resources.

Manufacturer Credits and Payment Reductions for Medical Devices

Federal regulations and guidance specify how hospitals must report the replacement of a beneficiary's implanted device if a hospital receives a full or partial credit from the manufacturer for a medical device that is covered under warranty or replaced because of a defect or recall.

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 (the Act) § 1862(a)(2)). Federal regulations generally require reductions in both IPPS and 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).

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 because of defects,

³ CMS, *Medicare Financial Management Manual*, Pub. No. 100-6, chapter 7, § 10.

⁴ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

recalls, battery depletions, or mechanical complications, which may be covered under the device manufacturer's warranty.

Generally, cardiac medical device manufacturers provide warranties for defects in materials or workmanship that happen at any time during the life of the product, which include recalls and premature failures.⁵ When a hospital follows a manufacturer's warranty credit process for its cardiac medical device, the manufacturer may issue a full or partial credit to the hospital to cover the cost of the failed or recalled device or provide a replacement without charge. Therefore, in most, if not all cases, hospitals can receive replacement cardiac devices at no cost or a full or partial credit from manufacturers.

Challenges to Properly Identifying, Tracking, and Reporting Credits

The process for reporting medical device credits on Medicare claims involves a number of separate hospital departments and requires many different staff disciplines (e.g., materials management, accounts payable, clinicians) to identify, track, and report the credits. Different hospital personnel are responsible for contacting the manufacturer, tracking the availability of the credit, and determining whether an adjustment claim needs to be submitted to pass along the credit to Medicare.

It is the hospital, not the manufacturer, that initiates the warranty credit process. Each manufacturer has a distinct device return authorization process and different forms that require details in varying formats. Furthermore, hospital staff submitting Medicare claims must be aware of credits that are at least 50 percent of the price the facility paid for the replacement device, and staff must report the credit as a deduction on a submitted claim.

However, hospitals may not know whether they will receive a credit or how much that credit will be at the time of billing for the device replacement procedure. In those situations, the hospital has two options. First, the hospital may hold the claim until a determination is made about the credit and then submit the claim with the appropriate condition code⁶ and value code⁷ or modifier⁸ if it receives a reportable credit. Second, the hospital may submit the claim immediately without a condition code and value code or modifier and, if the hospital receives a

⁵ We reviewed the device warranties for the two cardiac device manufacturers involved in this review and determined that they may issue warranty credits when a product is recalled or prematurely fails. Previous OIG reviews have found that manufacturers generally issue warranty credits for most recalled and prematurely failed cardiac medical devices.

⁶ Condition codes are entered on a claim to describe certain conditions or events.

⁷ Value codes are a combination of a code and an amount/value entered on a claim and used to accurately process the claim.

⁸ Modifiers are codes appended to a procedure or HCPCS code to provide additional information about the billed procedure, such as indicating the receipt of a full or partial credit.

reportable credit later, submit an adjustment claim with the appropriate condition code and value code or modifier.

Additionally, prior OIG reviews have identified insufficient hospital controls to properly report manufacturer credits. Specifically, hospitals attributed their 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.⁹

These prior reviews found that it is this involvement by the separate hospital departments and personnel, as well as insufficient hospital controls, that has contributed to the lack of identification, tracking, and reporting of these credits on Medicare claims.

Medicare Requirements for Providers To Return Overpayments

Under the 60-day rule, upon receiving credible information of a potential overpayment, providers must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments.¹⁰ OIG believes that this audit report constitutes credible information of potential overpayments.

HOW WE CONDUCTED THIS REVIEW

We obtained a list of warranty credits that two device manufacturers issued to hospitals for calendar years 2008 through 2013 (audit period) for five cardiac medical devices that had been recalled or had high failure rates. We did not contact the hospitals to verify receipt of the credits reported by the manufacturers. From this list, we matched the names and Social Security numbers of the device recipients to the Medicare Enrollment Database and identified 3,336 Medicare beneficiaries who had these devices implanted.

Using the warranty credit data and the CMS National Claims History file, we subsequently identified 2,986 claims that had a cardiac device replacement procedure for these beneficiaries. We excluded 2,690 of these claims because they did not meet the payment reduction criteria for replaced medical devices, such as being a device-intensive procedure¹¹ or having received a credit of 50 percent or greater. We reviewed the remaining 296 claims for which 210 hospitals billed for a device-intensive procedure and were issued a credit of 50 percent or greater. We

⁹ See, e.g., *Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits* (A-05-13-00029).

¹⁰ The Act § 1128J(d) and 42 CFR part 401, subpart D (the 60-day rule); 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

¹¹ A device-intensive procedure is one in which the cost of the device is greater than 40 percent of the total cost of the procedure.

considered these 296 claims at risk for overpayment because these claims also did not include the required value code or modifier.

Our audit covered \$7,729,337 in Medicare payments to hospitals for 153 inpatient and 143 outpatient claims for replaced cardiac medical devices. These claims had dates of service during our audit period. We evaluated compliance with selected billing requirements, but we did not 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 audit scope and methodology.

FINDINGS

For all 296 Medicare claims that we reviewed, hospitals did not comply with Medicare requirements for reporting manufacturer credits associated with recalled cardiac medical devices. Specifically, for 153 inpatient and 143 outpatient claims, hospitals were issued reportable manufacturer credits for recalled cardiac medical devices but did not adjust the claims with the proper condition codes, value codes, or modifiers to reduce payment as required. For the 296 billed claims, hospitals received payments of \$7,729,337 rather than the \$3,318,769 they should have received, resulting in \$4,410,568 in potential overpayments that were not identified, refunded, or adjusted by the beginning of our audit.¹²

HOSPITALS DID NOT COMPLY WITH REQUIREMENTS FOR REPORTING MANUFACTURER CREDITS

Hospitals Did Not Properly Report Manufacturer Credits on Inpatient Claims

Federal Requirements

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 hospital, (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(a)).

¹² We calculated the \$4,410,568 in potential overpayments using warranty credit information received from device manufacturers but did not verify these amounts with the 210 hospitals.

The *CMS Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), states that to bill correctly for a replacement device that was provided with a credit or at no cost, hospitals must code Medicare claims with a combination of condition code 49 (product replacement within product lifecycle) or 50 (replacement for a known recall of a product) along with value code FD (a credit of 50 percent or greater was received from the manufacturer for a replaced medical device) to communicate the amount of the credit or cost reduction (the Manual, chapter 3, § 100.8). Medicare deducts the partial/full credit amount, reported in the amount for value code FD, from the final IPPS reimbursement.¹³

Inpatient Condition and Value Codes Not Reported Correctly

For all 153 inpatient claims that we reviewed, hospitals were issued reportable manufacturer credits for cardiac medical devices but did not adjust the claims with the proper condition and value codes to reduce payment as required.

For example, one hospital was issued a credit for a recalled cardiac resynchronization therapy defibrillator but did not report condition code 50 and value code FD on the claim as required. As a result, the Medicare contractor paid the hospital \$31,025 when it should have paid \$3,825, resulting in a potential overpayment of \$27,200.

Because of these errors, Medicare contractors paid hospitals \$4,494,725 for inpatient claims for which they should have paid \$2,107,665, resulting in potential overpayments of \$2,387,060.

Hospitals Did Not Properly Report Manufacturer Credits on Outpatient Claims

Federal Requirements

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)).

Prior to January 1, 2014, if a hospital incurred no cost or received full credit for a replaced device, CMS required the hospital to report the modifier FB and condition code 49 or 50 and to reduce charges on the outpatient claim that included a procedure code for the insertion of a replacement device.¹⁴ In addition, prior to January 1, 2014, if a hospital received a partial credit

¹³ This policy applies only to DRGs where the implantation of the device determines the DRG assignment (42 CFR § 412.89(b)). A list of DRGs for which this policy applies can be found in the applicable IPPS Final Rule (the Manual, chapter 3, § 100.8).

¹⁴ The Manual, chapter 4, §§ 61.3.1 and 61.3.2, and the Manual, chapter 32, § 67.2.1. If the hospital receives a replacement device without cost or with a full credit from the manufacturer, the hospital must report a charge of no more than \$1 for the device.

of 50 percent or more of the cost of a new replacement device, CMS required the hospital to report the modifier FC on the outpatient claim that included the procedure code for the insertion of a replacement device.¹⁵ Effective January 1, 2014, CMS no longer recognized the FB or FC modifiers for identifying a device furnished without cost or with a full or partial credit.¹⁶

Outpatient Condition Codes and Modifiers Not Reported Correctly

For all 143 outpatient claims that we reviewed, hospitals were issued reportable manufacturer credits for cardiac medical devices but did not report the correct condition codes and modifiers and reduce charges on the claims.

For example, one hospital was issued a full credit for a recalled implantable cardioverter defibrillator, but it did not report condition code 50 (replacement for a known recall of a product) and modifier FB (a credit was received from the manufacturer for a replaced medical device) on the claim as required. As a result, the Medicare contractor paid the hospital \$28,779 when it should have paid \$3,824, resulting in a potential overpayment of \$24,955.

Because of these errors, Medicare contractors paid hospitals \$3,234,612 for outpatient claims for which they should have paid \$1,211,104, resulting in potential overpayments of \$2,023,508.

MEDICARE CONTROLS NOT SUFFICIENT TO ENSURE COMPLIANCE WITH CREDIT REPORTING REQUIREMENTS

Medicare contractors overpaid hospitals because CMS guidance and Medicare contractors' specific edits did not ensure that hospitals reported manufacturer credits for cardiac medical devices. A Medicare contractor in a prior OIG review stated that unless a hospital reported the appropriate condition, value, and modifier codes on the claim, the contractor would not know that a device was subject to a recall or under warranty and therefore warranted no payment or a reduced payment. That contractor further stated that it was incumbent upon hospitals to identify these situations and ensure that they have adequate controls and processes in place for submitting accurate claims.¹⁷ However, past OIG reviews have found that hospitals often misunderstand Medicare requirements and, as a result, are not appropriately using the condition, value, and modifier codes necessary to identify that a credit to Medicare might be

¹⁵ The Manual, chapter 4, § 61.3.3.

¹⁶ For services furnished on or after January 1, 2014, the Manual states that, when a hospital furnishes a replacement device received without cost or with a credit of 50 percent or more of the cost of a replacement because of a warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for value code FD and report either condition code 49 or 50 (the Manual, chapter 4, § 61.3.5).

¹⁷ The Medicare contractor stated this in comments on the OIG report *Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits* (A-05-13-00029).

warranted.¹⁸ Of the 296 claims in this review, none contained a value code or modifier, and only 11 claims had condition codes 49 or 50.

Currently, CMS guidance requires condition codes 49 and 50 only when the FD value code is present on the claim. CMS stated that there is currently a contractor billing edit in place to check for condition codes 49 and 50 when value code FD is billed on the claim. With this edit, contractors are reviewing only those claims for which a credit has already been billed. As a result, this edit fails to identify instances of noncompliance with reporting device credits.

A recently issued OIG report¹⁹ recommended that CMS require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure for all procedures that resulted from a recall or premature failure, regardless of whether the hospital received a device at no cost or with a credit of 50 percent or more.

Requiring the use of these condition codes would help CMS identify and track Medicare costs that result from medical device recalls or premature failures. In addition, if condition codes 49 or 50 were required on all replacement device procedures resulting from recall or premature failure, contractors could use this information to identify claims for which a manufacturer credit might be issued. Therefore, implementation of that recommendation would also support one of the recommendations in this report.

RECOMMENDATIONS

We recommend that CMS:

- instruct its Medicare contractors to notify the 210 hospitals associated with the 296 claims with potential overpayments of \$4,410,568 so that those hospitals can exercise reasonable diligence to investigate and return any identified overpayments in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation;
- educate providers on the requirements for reporting manufacturer credits for cardiac devices using value code FD and the need to use condition codes to report the reason for device replacement;

¹⁸ Please see Appendix B for a list of related reports on hospitals that did not bill for medical devices in accordance with Medicare requirements.

¹⁹ Recommendation from OIG Report entitled *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (A-01-15-00504).

- assuming the OIG recommendation requiring the use of condition codes 49 and 50 is implemented, instruct its Medicare contractors to implement a post-payment process to follow up with any hospital that submits a claim for certain cardiac device replacement procedures (see Appendix C) with condition code 49 or 50 but no value code FD to determine whether an adjustment claim should be submitted; and
- consider studying alternatives to implementing edits in order to eliminate the current Medicare requirements for reporting device credits, for instance, by reducing IPPS and OPSS payments for device-intensive procedures.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS COMMENTS

In written comments on our draft report, CMS generally concurred with our first, second, and fourth recommendations and provided information on actions that it planned to take to address them. However, CMS did not concur with our third recommendation. CMS stated that when a hospital reports a credit (value code FD), condition code 49 or 50 should be reported as well; however, the converse is not true because a device could have been replaced under warranty or recall without the hospital receiving a credit that affected payment. Therefore, value code FD is not always required when condition codes 49 or 50 are reported. CMS's comments are included in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

This review and others have shown that hospitals are receiving reportable credits and not properly reporting these credits on claims (value code FD). While we acknowledge that hospitals may not receive a reportable credit in all cases of cardiac device replacement, previous OIG reviews have found that credits are provided for most cardiac devices replaced within the product lifecycle or due to a recall. Appending condition code 49 or 50 at the time of claim submission, where applicable, would indicate whether a cardiac device had been replaced within the product lifecycle (code 49) or replaced because of a recall (code 50).

Current CMS policy does not use these condition codes in a way that could help identify claims at risk for overpayment. Requiring hospitals to use condition codes 49 and 50 on claims for cardiac device replacement procedures that resulted from a recall or premature failure, regardless of whether the hospital received a device at no cost or with a credit of 50 percent or more, would allow for the identification of claims likely to receive a credit. Through the use of condition codes 49 and 50, and in conjunction with cardiac device replacement codes, CMS should instruct its Medicare contractors to identify claims for which reportable credits are likely to be received. In turn, MACs will be able to follow up with hospitals on a post-payment basis to determine whether an adjustment claim is necessary.

For these reasons, we maintain that our recommendation, which we have modified for clarity, is valid and that CMS should require its contractors to implement a post-payment process for claims with certain cardiac device procedures to ensure hospitals are complying with Medicare requirements for reporting applicable manufacturer credits.

OTHER MATTERS

Medicare claim forms lack unique device-specific information that would enable CMS to identify claims for which a specific device was billed. Including this information on claims would allow for the identification of devices that are recalled or prematurely fail and for which a credit from the manufacturer may need to be reported to Medicare.

UNIQUE DEVICE IDENTIFIER SYSTEM

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 for medical devices to facilitate better detection of adverse events, improve product recalls, and enable robust post-market surveillance. In 2013, FDA promulgated a final rule establishing a UDI system designed to adequately identify medical devices throughout their distribution and use.²⁰ The rule requires the label of most medical devices to include a UDI that identifies the device's labeler and its version or model.

The UDI has two parts: the device identifier (DI) portion and production identifier (PI) portion(s). The DI portion identifies the device labeler and the specific version or model of the device. The PI portion is a variable portion of the UDI that identifies one or more of the following when included on the device label: the device's lot or batch, its serial number, its expiration date, its manufacturing date, or its HCT/P (Human Cell, Tissue or Cellular or Tissue-Based Product) identification code.

CLAIM FORMS LACK UNIQUE DEVICE IDENTIFIER INFORMATION

Medicare claim forms lack UDI information. By including the DI on claim forms and expanding the use of condition codes, CMS could more effectively identify claims for which a recalled device was billed. Eventually, including the PI portion(s) of the UDI on the claim forms would allow the identification of specific batches and lots of devices that are recalled or prematurely fail and thus are due a credit from the manufacturer that must be reported to Medicare.

CMS and FDA had initially expressed support²¹ for capturing the DI portion of the UDI on the claim forms for implantable devices if sufficient funding and resources are provided to make

²⁰ 78 Fed. Reg. 58825 (Sept. 24, 2013) and 21 CFR part 830.

²¹ FDA and CMS joint letter to the Chair of the Accredited Standards Committee X12 addressing UDI on claims, dated July 13, 2016.

the necessary Medicare claims processing system changes, and in a recently issued OIG report,²² we recommended that CMS continue to work with the Accredited Standards Committee X12 to ensure that the DI is included on the next version of claim forms. However, in its response to that OIG recommendation, CMS stated that the new Administration is currently reviewing this policy to determine whether the policy would impose an unnecessary burden on physicians.

We maintain that the results of this review further support the addition of the DI to the claim form to provide a means to identify unreported manufacturer credits. Therefore, we continue to support the implementation of the recommendation outlined in report A-01-15-00504.

²² Recommendation from OIG report entitled *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (A-01-15-00504).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period, calendar years 2008 through 2013, device manufacturers issued warranty credits to hospitals for recalled cardiac medical devices. We obtained a list of warranty credits that two device manufacturers issued to hospitals for five cardiac medical devices that had been recalled or had high failure rates. We did not contact the hospitals to verify receipt of the credits reported by the manufacturers. From this list, we matched the names and Social Security numbers of the device recipients to the Medicare Enrollment Database and identified 3,336 Medicare beneficiaries who had these devices implanted.

Using the warranty credit data and the CMS National Claims History (NCH) file, we subsequently identified 2,986 claims that had a cardiac device replacement procedure for these beneficiaries. We excluded 2,690 of these claims because they did not meet the payment reduction criteria for replaced medical devices, such as being a device-intensive procedure or having received a credit of 50 percent or greater. We reviewed the remaining 296 claims for which 210 hospitals billed for a device-intensive procedure and were issued a credit of 50 percent or greater. We considered these 296 claims at risk for overpayment because these claims also did not include the required value code or modifier. Our audit covered \$7,729,337 in Medicare payments to hospitals for 153 inpatient and 143 outpatient claims for replaced cardiac medical devices.

We evaluated compliance with selected billing requirements, but we did not determine whether services were medically necessary.

We did not review the overall internal control structure of CMS, its Medicare contractors, or hospitals submitting Medicare claims because our objective did not require us to do so. Rather, we limited our review to controls related to CMS edits.

We reviewed claims obtained from the NCH file. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

We conducted our audit from December 2015 through October 2016.

METHODOLOGY

To accomplish our objective, we:

- met with CMS program officials to discuss the Medicare requirements for reporting medical device credits;
- reviewed applicable Federal laws, regulations, and guidance;

- requested and received warranty credit data from two device manufacturers for five recalled devices;
- matched those credits to 3,336 recipients using the Medicare enrollment database;
- extracted 2,986 cardiac device replacement claims from CMS's NCH file for those recipients during the audit period;
- identified 296 device replacement claims at 210 hospitals that were at risk for noncompliance with Medicare billing requirements;
- reviewed data from CMS's Common Working File for the selected claims to determine whether the claims have been canceled or adjusted;
- compared the warranty credit data to the Medicare claim data to determine whether credits issued to hospitals were reported in accordance with Federal requirements (i.e., claims were billed with the appropriate condition and value codes or modifiers for reporting manufacturer credits);
- calculated potential overpayments that resulted from hospitals not properly reporting these credits on Medicare claims; and
- discussed the results of the 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.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report	Report Number	Issue Date
<i>Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices</i>	A-01-15-00504	9/28/17
<i>Hospitals Did Not Always Comply With Medicare Requirements for Reporting Cochlear Devices Replaced Without Cost</i>	A-01-15-00508	11/22/16
<i>Review of Tufts Medical Center Claims That Included Medical Device Replacements</i>	A-01-15-00503	4/15/16
<i>The Medicare Contractors for Jurisdiction E Overpaid Claims for Replaced Cardiac Medical Devices When Hospitals Had Not Reported Manufacturer Credits</i>	A-09-15-02029	3/16/16
<i>Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits</i>	A-05-13-00029	10/29/14
<i>Review of Cleveland Clinic's Claims for Procedures That Included the Replacement of Medical Devices During 2008 and 2009</i>	A-05-11-00012	10/24/11

**APPENDIX C: CURRENT CARDIAC MEDICAL DEVICE CODES
SUBJECT TO PAYMENT REDUCTION CRITERIA**

**Table 1: DRGs Subject to IPPS Replaced Devices
Offered Without Cost or With a Credit²³**

MS-DRG	MS-DRG Title
222	Cardiac defib implant w cardiac cath w ami/hf/shock w mcc
223	Cardiac defib implant w cardiac cath w ami/hf/shock w/o mcc
224	Cardiac defib implant w cardiac cath w/o ami/hf/shock w mcc
225	Cardiac defib implant w cardiac cath w/o ami/hf/shock w/o mcc
226	Cardiac defibrillator implant w/o cardiac cath w mcc
227	Cardiac defibrillator implant w/o cardiac cath w/o mcc
242	Permanent cardiac pacemaker implant w mcc
243	Permanent cardiac pacemaker implant w cc
244	Permanent cardiac pacemaker implant w/o cc/mcc
245	AICD generator procedures
258	Cardiac pacemaker device replacement w mcc
259	Cardiac pacemaker device replacement w/o mcc
265	AICD lead procedures

**Table 2: APCs Subject to OPSS Replaced Devices
Offered Without Cost or With a Credit²⁴**

APC	Group Title
5222	Level 2 pacemaker and similar procedures
5223	Level 3 pacemaker and similar procedures
5224	Level 4 pacemaker and similar procedures
5231	Level 1 ICD and similar procedures
5232	Level 2 ICD and similar procedures

²³ 82 Fed. Reg. 37990, 38065 (Aug. 14, 2017) (for FY 2018).

²⁴ Addendum P of 81 Fed. Reg. 79562 (Nov. 14, 2016) (Final Device-Intensive Procedures for CY 2017).

APPENDIX D: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DEC 21 2017

DATE:

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma 
Administrator

SUBJECT: "Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits" (A-05-16-00059)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS takes seriously its responsibilities to protect beneficiaries and prevent improper payments.

In general, federal regulations require a reduction in payment to hospitals when implanted medical devices are replaced without cost to the hospital or the hospital receives a credit equal to 50 percent or more of the cost of the device. In addition, CMS guidance requires hospitals to report qualifying credits received, along with a condition code indicating whether the device was replaced under warranty or due to recall. In 2014, CMS issued additional guidance and revised the Medicare Claims Processing Manual to reflect updated reporting requirements for device credits.

CMS routinely recovers payments for services provided to Medicare beneficiaries as a result of recalled or defective medical devices through the Medicare Secondary Payer process. When a device manufacturer or its insurer makes a payment in the form of a settlement, judgment, award, or other payments, it is required to notify CMS in order for CMS to pursue recovery for conditional payments it made related to that settlement, judgment, award, or other payment.

OIG's recommendations and CMS's responses are below.

OIG Recommendation

CMS should instruct its Medicare contractors to notify the 210 hospitals associated with the 296 claims with potential overpayments of \$4,410,568 so that those hospitals can exercise reasonable diligence to investigate and return any identified overpayments in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.

CMS Response

CMS concurs with this recommendation. CMS requests that OIG furnish the necessary data to follow up on the status of the potential overpayments. Upon receipt of the files from OIG, CMS will work with its contractors to notify hospitals in accordance with the agency's policies and procedures.

OIG Recommendation

CMS should educate providers on the requirements for reporting manufacturer credits for cardiac devices using value code FD and the need to use condition codes to report the reason for device replacement.

CMS Response

CMS concurs with this recommendation. CMS will work with contractors to provide national education to providers on reporting device replacements and credits in accordance with Medicare billing requirements.

OIG Recommendation

Assuming that the OIG recommendation requiring the use of condition codes 49 and 50, which CMS concurred with, is implemented, CMS should instruct its Medicare contractors to implement a procedure to follow up with any hospital that submits a claim for certain cardiac medical device replacement procedures (see Appendix C) with condition code 49 or 50 but no value code FD to determine whether an adjustment claim should be submitted.

CMS Response

CMS does not concur with this recommendation. When a hospital reports a credit (value code FD), condition code 49 or 50 should be reported as well. However, the converse is not true. A device could have been replaced under warranty or due to recall but the hospital may not have received a credit affecting payment. Therefore, value code FD is not always required when condition codes 49 or 50 are reported.

OIG Recommendation

CMS should consider studying alternatives to implementing edits in order to eliminate the current Medicare requirements for reporting device credits, for instance, by reducing IPPS and OPPS payments for device-intensive procedures.

CMS Response

CMS concurs with this recommendation. CMS will consider whether there are administratively efficient alternative methods of accounting for device credits in a manner that treats all hospitals fairly.