

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



**Amy J. Frontz  
Deputy Inspector General  
for Audit Services**

November 2020  
A-01-18-00502

# ***Office of Inspector General***

<https://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## ***Office of Evaluation and Inspections***

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## ***Office of Investigations***

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## ***Office of Counsel to the Inspector General***

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## Report in Brief

Date: November 2020

Report No. A-01-18-00502

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



### Why OIG Did This Audit

Prior OIG audits with audit periods ranging from 2005 through 2016 found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for medical devices that were replaced. Specifically, hospitals did not always report to CMS device manufacturer credits that they received. One prior audit estimated that services related to the replacement of seven recalled and prematurely failed cardiac 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 recalled or prematurely failed cardiac devices.

### How OIG Did This Audit

We obtained a list of warranty credits from the device manufacturers and matched the device recipients to the Medicare enrollment database to determine which recipients were Medicare beneficiaries. Next, we matched the beneficiaries to the Medicare National Claims History to identify claims that had a cardiac device replacement procedure for which the date of service matched to the device replacement procedure date on the credit listing. We evaluated compliance with selected billing requirements.

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

### What OIG Found

For 3,233 of the 6,558 Medicare claims that we reviewed, hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. Device manufacturers issued reportable credits to the hospitals for recalled or prematurely failed cardiac medical devices, but the hospitals did not adjust the claims with proper condition and value codes to reduce payments as required. As a result, 911 hospitals received payments of \$76 million rather than the \$43 million they should have received, resulting in \$33 million in potential overpayments. Medicare contractors made these overpayments because they do not have a postpayment review process that would ensure that hospitals reported manufacturer credits for cardiac medical devices.

### What OIG Recommends and CMS Comments

We recommend that CMS: (1) instruct Medicare contractors to recover the portion of the \$33 million in identified Medicare overpayments that are within the reopening period; (2) notify hospitals associated with potential overpayments outside the reopening period so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (3) require hospitals to use condition codes 49 and 50 on claims; (4) instruct Medicare contractors to implement a postpayment review process; (5) obtain device credit listings from manufacturers and determine whether providers reported credits as required, (6) direct Medicare contractors to determine whether hospitals, which we have identified as having billed incorrectly in both this audit and our prior audit (A-05-16-00059), have engaged in a pattern of incorrect billing after our audit period and, if so, take appropriate action in accordance with CMS policies and procedures; and (7) consider eliminating the current Medicare requirements for reporting device credits by reducing the payments for cardiac device replacement procedures.

CMS concurred with three of our seven recommendations and described the actions it planned to take to address them. For the four recommendations that CMS did not concur with, we maintain that CMS should require the use of condition codes, implement a postpayment process, acquire the credit listings from manufacturers, and determine whether providers identified as having billed incorrectly continued to do so after the audit period.

## TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program .....	1
Hospital Inpatient Prospective Payment System.....	2
Hospital Outpatient Prospective Payment System.....	2
Manufacturer Credits and Payment Reductions for Medical Devices .....	2
Cardiac Medical Devices .....	3
Challenges To Properly Identifying, Tracking, and Reporting Credits .....	3
Medicare Requirements for Providers To Identify, Report, and Return Overpayments.....	4
Manufacturers’ Efforts To Assist Hospital Compliance .....	4
How We Conducted This Audit .....	5
FINDINGS.....	6
Hospitals Did Not Comply With Requirements for Reporting Manufacturer Credits.....	7
Federal Requirements.....	7
Hundreds of Hospitals Did Not Properly Report Manufacturer Credits for Recalled or Prematurely Failed Cardiac Devices .....	7
Hospitals We Visited Did Not Establish Adequate Controls To Comply With Medicare Requirements .....	9
Medicare Policies Are Not Sufficient To Ensure Hospitals Reported Credits .....	10
CONCLUSION.....	11
RECOMMENDATIONS .....	12
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE .....	13
Recommendations To Require the Use of Condition Codes 49 and 50 and Implement A Postpayment Review Process.....	13
CMS Comments.....	13
OIG Response .....	13

Recommendation To Obtain Device Credit Listings From Manufacturers .....	14
CMS Comments.....	14
OIG Response.....	14
Recommendation To Direct Medicare Contractors To Determine Whether Providers Have Engaged in a Pattern of	
Incorrect Billing.....	15
CMS Comments.....	15
OIG Response.....	15
OTHER MATTERS.....	15
Unique Device Identifier System .....	15
Claim Forms Lack Unique Device Identifier Information .....	16
Bipartisan Support for the Unique Device Identifier .....	16
APPENDICES	
A: Audit Scope and Methodology .....	18
B: Related Office of Inspector General Reports.....	21
C: Congressional Letters Supporting Use of Unique Device Identifier .....	22
D: CMS Comments .....	23

## INTRODUCTION

### WHY WE DID THIS AUDIT

Prior Office of Inspector General (OIG) audits 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 2012<sup>1</sup> and can be quite costly to the Medicare program. Cardiac medical devices are susceptible to early failure and often covered by warranties. A prior OIG audit estimated that services related to the replacement of seven types of recalled and prematurely failed cardiac medical devices cost Medicare \$1.5 billion during calendar years 2005 through 2014.<sup>2</sup> The top three cardiac device manufacturers account for over 50 percent of worldwide cardiac device sales. We conducted this audit of manufacturer credits that these three manufacturers issued to hospitals.

### OBJECTIVE

Our objective was to determine whether hospitals complied with Medicare requirements for reporting manufacturer credits associated with recalled or prematurely failed cardiac 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 Medicare contractor oversight, such as facilitating contractor compliance with current

---

<sup>1</sup> The U.S. Food and Drug Administration (FDA) medical device recall reports fiscal years 2003 through 2012.

Available online at:

<https://web.archive.org/web/20170722041027/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM388442.pdf>. Accessed on September 9, 2019.

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

regulations, ensuring Medicare contractors' performance of CMS operating instructions, and providing ongoing feedback and guidance to Medicare contractors regarding the Medicare program. Medicare contractors must establish and maintain efficient and effective internal controls.<sup>3</sup>

### **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.<sup>4</sup> 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 certain implanted devices<sup>5</sup> if: (1) the device is replaced without cost to the hospital, (2) the

---

<sup>3</sup> CMS, *Medicare Financial Management Manual*, Pub. No. 100-06, chapter 7, § 10.1.2.

<sup>4</sup> HCPCS codes are used throughout the healthcare industry to standardize coding for medical procedures, services, products, and supplies.

<sup>5</sup> For hospital inpatient services, 42 CFR § 412.89(b) states that payment is reduced if the implantation of the device determines the DRG assignment. For hospital outpatient services, 42 CFR § 419.45(a) states that payment is reduced if CMS determines that a significant portion of the payment is attributable to the cost of an implanted device.



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<sup>6</sup> (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, 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. Such defects may result in recalls or premature failures. When a hospital follows a manufacturer's warranty 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.

## **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, and 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 that submit Medicare claims must be aware of credits that are at least 50 percent of the cost of the replacement device and report the credit as a deduction on the claim. However, hospitals may not know whether they will receive a credit or how much that credit will be at the time they bill for the device replacement procedure. In those situations, the hospital has two options. First, the hospital may hold the claim until it determines whether it will receive a reportable credit and then submit the claim with the appropriate condition code<sup>7</sup> and value code<sup>8</sup> if it receives the credit.

---

<sup>6</sup> We refer to the three types of reductions as "reportable credits" throughout the report.

<sup>7</sup> Condition codes are applied to claims to indicate the presence of certain circumstances, such as a patient's condition, the reason a procedure was performed, or the medical appropriateness of a certain procedure.

<sup>8</sup> Value codes are a combination of a code and an amount applied to a claim and used to accurately process the claim.

Second, the hospital may submit the claim immediately without a condition code and value code and, if the hospital receives a reportable credit later, submit an adjustment claim with the appropriate condition code and value code. Prior OIG audits have identified insufficient hospital controls that resulted in the improper reporting of manufacturer credits. Hospitals attributed this improper reporting to inadequate policies and procedures for reporting manufacturer credits, lack of awareness of warranties and credit availability, misunderstanding of Medicare billing requirements, and hospital misapplication of the credit amounts.<sup>9</sup>

### **Medicare Requirements for Providers To Identify, Report, and Return Overpayments**

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>10</sup>

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>11</sup>

### **Manufacturers' Efforts To Assist Hospital Compliance**

We determined that the three manufacturers associated with our audit attempted to make it easier for hospitals to comply with Medicare requirements for reporting manufacturer credits associated with recalled or prematurely failed cardiac devices. Specifically, the manufacturers:

- deployed representatives to expedite the return of the replaced devices back to the manufacturer;
- remitted credits promptly to hospitals (Figure 1 on page 8 and Figure 2 on page 9);

---

<sup>9</sup> See *Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits* (A-05-13-00029) and *Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits* (A-05-16-00059).

<sup>10</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>11</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual—Part 1*, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

- provided information to hospitals reminding them to fully and accurately report all credits received consistent with the requirements of all Federal healthcare programs, including but not limited to Medicare and Medicaid;<sup>12</sup> and
- offered to send quarterly reports to hospitals to reconcile prior credits.

## HOW WE CONDUCTED THIS AUDIT

We obtained a list of warranty credits for cardiac medical devices that the top three cardiac device manufacturers provided to hospitals.<sup>13</sup> The list included credits issued from January 1, 2015, through June 30, 2017 (audit period). We did not verify the receipt of the credits reported by the manufacturers with all hospitals; however, we verified with four hospitals<sup>14</sup> in Arkansas, Massachusetts, and New York that they received the credits reported by the manufacturers.<sup>15</sup> For the credits on the list provided that we identified as reportable, we matched the device recipients to the Medicare Enrollment Database to determine which recipients were Medicare beneficiaries. We performed two matches. When manufacturers provided Social Security numbers, we matched them to the enrollment database. When manufacturers did not provide recipient Social Security numbers, we matched the recipient names, addresses, and dates of birth to the enrollment database. These matches identified 7,960 Medicare beneficiaries who had cardiac devices implanted. Using the warranty credit data and the CMS National Claims History (NCH) file, we subsequently identified 6,558 claims that had a cardiac device replacement procedure for which the date of service matched to the device replacement procedure date on the credit listing. We determined that 3,233 of these claims, or nearly 50 percent, were billed without the required condition and value codes. We considered these 3,233 claims at risk for overpayment because they did not include the required condition and value codes.

---

<sup>12</sup> Credit memorandums from the manufacturers include the beneficiary’s name, the explanted and replacement cardiac device model and serial number, the beneficiary’s date of service, and the credit amount. Furthermore, all of these manufacturers stated they directed the hospitals to accurately report the credit to all Federal health programs. For example, one of the manufacturer’s credit memorandum specifically noted: “Your institution must fully and accurately report all credits received in connection with a warranty for an [company names redacted] product, consistent with the requirements of all federal health care programs, including, but not limited, to Medicare and Medicaid.” Similar language was used by the other two manufacturers.

<sup>13</sup> Evaluate MedTech World Preview 2018, Outlook to 2024 available at [https://www.evaluate.com/sites/default/files/media/download-files/WPMT2018\\_0.pdf](https://www.evaluate.com/sites/default/files/media/download-files/WPMT2018_0.pdf). Accessed on August 18, 2020.

<sup>14</sup> One hospital had the highest dollar value of reportable credits, over \$1 million, during our audit period. The three remaining hospitals had reportable credits that were among the top 5 percent of all hospitals during our audit period. Also, all four hospitals had findings related to cardiac device credits in previous OIG audits.

<sup>15</sup> We verified with these hospitals that they received and did not report the credits issued by the manufacturers associated with all 134 claims (4 percent of the 3,233 claims), which totaled \$1,932,455 (6 percent of the \$33,095,065 potential overpayments).

Our audit covered \$76,066,480 in Medicare payments to 911 hospitals for 514 inpatient and 2,719 outpatient claims for replaced cardiac medical devices. These claims had dates of service during our audit period. We determined whether hospitals complied with selected billing requirements for these claims, 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.

Appendix A contains the details of our audit scope and methodology.

## FINDINGS

For 3,233 of the 6,558 Medicare claims that we reviewed, hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. On the basis of the information provided by the device manufacturers, we concluded they issued reportable credits for 514 inpatient and 2,719 outpatient claims that averaged \$10,124 each, to the hospitals for recalled or prematurely failed cardiac medical devices, but the hospitals did not adjust the claims with proper condition and value codes to reduce payments as required.<sup>16</sup> As a result, 911 hospitals received \$33,095,068 in potential overpayments that were not identified and returned by the beginning of our audit.<sup>17</sup> As of the publication of this report, these potential overpayments include claims outside of the 4-year reopening period.<sup>18, 19</sup>

---

<sup>16</sup> Hospitals did not bill initial claims with the appropriate condition and value codes for a manufacturer credit issued prior to billing Medicare for the replacement procedure, nor did they resubmit claims to adjust initial claims when a manufacturer credit was issued after the initial claim submission.

<sup>17</sup> We did not determine the exact amount of the potential overpayments by calculating the reduction in payments required under Federal regulations (42 CFR §§ 412.89(c) and 419.45(b)). Instead, the \$33,095,068 in potential overpayments is the sum of the reportable warranty credits issued by device manufacturers during our audit period associated with Medicare claims. We conducted site visits at 4 hospitals and verified that the credit information for the 134 credits received by these hospitals was accurate.

<sup>18</sup> 42 CFR § 405.980(b)(2) (permitting a contractor to reopen an initial determination within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a provider to request that a contractor reopen within 4 years for good cause).

<sup>19</sup> Notwithstanding, a provider can request that a contractor reopen an initial determination for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period. 42 CFR § 405.908(c)(4).

Medicare overpaid hospitals because Medicare contractors do not have a postpayment review process that would ensure that hospitals reported manufacturer credits for cardiac medical devices.

## **HOSPITALS DID NOT COMPLY WITH REQUIREMENTS FOR REPORTING MANUFACTURER CREDITS**

### **Federal Requirements**

Federal regulations for IPPS and OPPI payments require hospitals to report the replacement of certain implanted devices if: (1) the device is replaced without cost to the hospital, (2) the hospital receives a reportable 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(a) and 419.45(a)). Hospitals that do not report that a device was replaced without cost or that they received a credit greater than or equal to 50 percent for the device will incur a Medicare overpayment.

The Medicare Claims Processing Manual, Pub. No. 100-04 (the Manual), states that to bill correctly for a replacement device that either was provided at no cost to the hospital or was associated with a credit, hospitals must report 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 (which communicates to Medicare the amount of the credit, or cost reduction, received by the hospital for the replaced device).<sup>20</sup>

### **Hundreds of Hospitals Did Not Properly Report Manufacturer Credits for Recalled or Prematurely Failed Cardiac Devices**

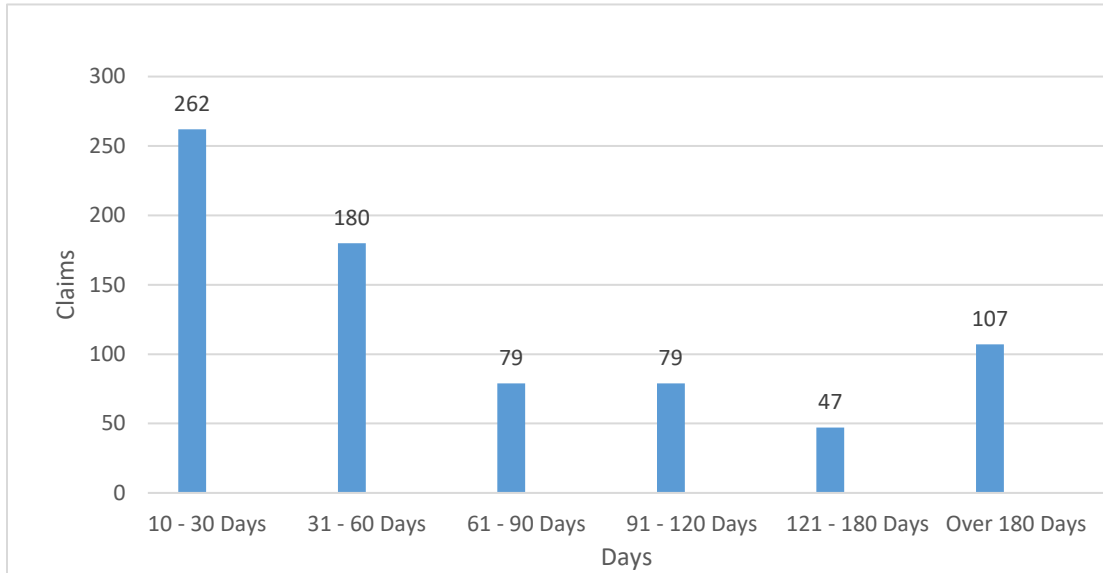
Hundreds of hospitals did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. Of the 911 hospitals that billed 3,233 claims at risk for overpayments, none reported the correct condition and value codes for the manufacturer issued reportable credits for cardiac medical devices associated with those claims.

For 754 of the Medicare claims (see Figure 1 on the next page) associated with a recalled or prematurely failed cardiac medical device, 405 hospitals were issued reportable credits at least 10 days before they billed Medicare for reimbursement. Since these hospitals were issued credits from the manufacturer prior to submitting the original claim, the hospitals could have complied with Medicare regulations when billing for replaced cardiac devices by reporting the credit on the claim.

---

<sup>20</sup> The Manual, chapter 3, § 100.8 and chapter 4, § 61.3.5.

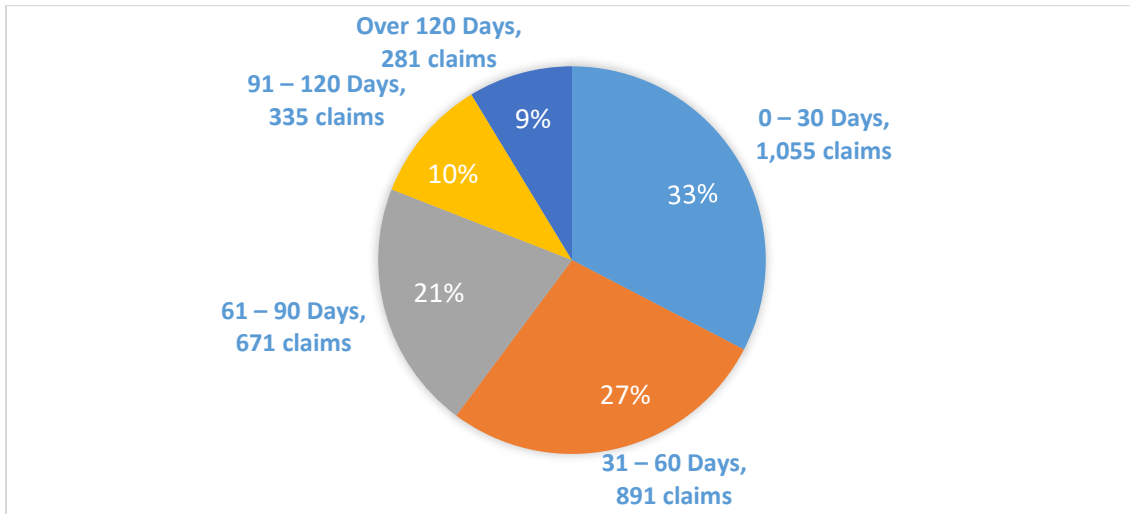
**Figure 1: The Number of Days Between Credit Issuance and Hospital Billing Medicare**



For example, a manufacturer issued a credit to a hospital for a recalled cardioverter-defibrillator prior to the hospital billing for the device replacement procedure, but the hospital did not report condition code 50 and value code FD on the claim as required. As a result, the Medicare contractor paid the hospital \$25,781 when it should have paid \$10,341, resulting in a potential overpayment of \$15,440.

In addition, we found that most of the hospitals we audited were issued reportable credits shortly after the surgery to replace the medical device. Specifically, 817 hospitals were issued 2,643 reportable credits for 2,617 claims (81 percent of the 3,233 claims) within 90 days of the date the beneficiary received a replaced medical device. (See Figure 2 on the next page.)

**Figure 2: The Days Between Device Replacement and Issuance of Credit**



We determined that hospitals did not take appropriate action to identify potential overpayments resulting from reportable manufacturer credits associated with a recalled or prematurely failed cardiac medical devices. Because they did not properly report manufacturer credits on the original claims, when the credit was issued prior to submitting the claim to Medicare, or adjust the claims, when the manufacturer credit was issued after submitting the original claim with proper condition and value codes to reduce payments as required, these hospitals received \$33,095,068 in potential overpayments. Of the 911 hospitals included in our audit, we found that 163 (18 percent) of these hospitals were also part of a prior OIG audit<sup>21</sup> of cardiac device credits. Our current audit found that 24 of the 163 hospitals each received potential overpayments totaling more than \$100,000.

**HOSPITALS WE VISITED DID NOT ESTABLISH ADEQUATE CONTROLS TO COMPLY WITH MEDICARE REQUIREMENTS**

We conducted site visits at 4 of the 911 hospitals in Arkansas, Massachusetts, and New York to discuss 134 claims in which the hospitals received \$1,932,455 in reportable credits for recalled or prematurely failed cardiac devices. The hospital officials at these 4 hospitals reviewed and confirmed that the reportable credits for the recalled or prematurely failed cardiac devices for all 134 claims involved overpayments that they should have identified and refunded to the Medicare program.

Inadequate internal controls for reporting manufacturer credits to the Medicare program at these four hospitals were the underlying cause of the overpayments. The hospital officials said

<sup>21</sup> *Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits (A-05-16-00059)*. This audit found that, for all 296 Medicare claims reviewed, hospitals did not comply with Medicare requirements for reporting manufacturer credits associated with recalled cardiac medical devices.

that they did not report the manufacturer credits associated with the recalled or prematurely failed cardiac medical devices on initial or subsequent resubmitted claims because of:

- billing systems that were not updated to reflect changes in 2014 regarding new condition and value code requirements,
- a lack of written policies and procedures,
- insufficient communication between departments when receiving reportable credits, and
- inadequate compliance testing.

The officials at these four hospitals said that they have initiated processes to report and return \$1,932,455 in overpayments associated with the reportable credits. They also stated that they have initiated other corrective actions since our site visits.<sup>22</sup>

#### **MEDICARE POLICIES ARE NOT SUFFICIENT TO ENSURE HOSPITALS REPORTED CREDITS**

Current CMS policy requires that providers use condition codes 49 or 50 on a claim only when value code FD is on the claim. As a result, this policy does not identify claims at risk for overpayment. Requiring hospitals to use condition codes 49 and 50 on claims for cardiac device replacement procedures that result from a recall or premature failure, regardless of whether the hospital receives a credit of 50 percent or more prior to submitting the claim, would allow Medicare contractors to implement a postpayment review process. Such a process could identify claims that could have received a credit and involve requiring that the claim be adjusted if the credit was 50 percent or more of the cost of the replacement device.

We recommended in a prior OIG report (A-01-15-00504)<sup>23</sup> that CMS require hospitals to use condition codes 49 or 50 on claims for all procedures that resulted from a device recall or premature failure, regardless of whether the device was provided at no cost or with a credit of 50 percent or more. CMS concurred with this recommendation in situations where payment would be impacted. Another OIG report (A-05-16-00059)<sup>24</sup> recommended that, if CMS implemented the previous referenced recommendation, it should instruct its Medicare contractors to implement a postpayment process to follow up with any hospital that submits a

---

<sup>22</sup> The hospital officials said they established a reporting system with device manufacturers, conducted periodic audits of reportable credits, improved their credit reporting process workflow, created edits in their accounting system to flag for potential reportable credits, and established written policies and procedures. We did not evaluate these corrective actions.

<sup>23</sup> *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices.*

<sup>24</sup> *Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits.*



claim for certain cardiac device replacement procedures with condition codes 49 or 50 but no value code FD to determine whether an adjustment claim should be submitted. CMS did not concur with this recommendation because a device could be replaced under warranty or due to a recall without the hospital receiving a reportable credit.

## CONCLUSION

Since 2005, CMS has made a significant effort to educate hospitals on the Medicare requirements associated with manufacturer credits for recalled cardiac medical devices. In addition, in 2016, CMS issued regulations to provide clarity to all Medicare Part A and B providers on identifying, reporting, and returning overpayments.<sup>25</sup>

Despite CMS's efforts to educate the hospital industry about requirements for reporting manufacturer credits<sup>26</sup>, we found that during our audit period, nearly 50 percent of the reportable credits issued to the hospitals were not returned to the Medicare program. These credits totaled more than \$33 million. In addition, past OIG audits have found that, for over a decade, hospitals have failed to comply with the Medicare requirements for reporting credits received for replaced medical devices. This audit is further evidence that our previous recommendations were valid. We believe that most, if not all, of the potential overpayments identified by this audit would have been identified and returned to the Medicare program if CMS had required the use of condition codes 49 and 50 when a device is replaced due to a recall or premature failure regardless of whether a credit was received prior to billing for the service and required its contractors to implement a postpayment process for claims with certain cardiac device procedures to ensure that hospitals comply with Medicare requirements for reporting applicable manufacturer credits. Hospitals that we visited have not established the necessary controls to comply with the device credit reporting requirements. Furthermore, CMS does not have an adequate process to identify those hospitals that have received reportable credits but not refunded the credits to Medicare. CMS relies on hospitals to properly identify and report manufacturer credits received and to return any overpayments associated with these device credits.

---

<sup>25</sup> 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>26</sup> On March 11, 2014, and in January 2015, CMS posted guidance (available online at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8653.pdf> and <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medqtrlycomp-newsletter-icn909177.pdf>) regarding the Medicare hospital requirements for reporting manufacturer credits associated with recalled or prematurely failed cardiac medical devices on the CMS Medicare Learning Network website. CMS issued the guidance to ensure that hospitals properly report manufacturer credits for cardiac devices and avoid overpayment recoveries.

## RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:<sup>27</sup>

- instruct the Medicare contractors to recover, in accordance with Federal regulations, the portion of the \$33,095,068 in identified Medicare potential overpayments from the 911 hospitals for the 3,233 incorrectly billed claims that are within the 4-year reopening period;
- based upon the results of this audit, notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation;
- require hospitals to use condition codes 49 or 50 on claims for a device-replacement procedure that resulted from a recall or premature failure, regardless of whether the hospital received a reportable credit prior to billing for the device replacement procedure;
- under the assumption that the prior recommendation will be implemented, instruct Medicare contractors to implement a postpayment review process to ensure that hospitals have adjusted claims, as required, for the device credits they received;
- obtain device credit listings from manufacturers and determine whether providers reported the credits as required by Medicare regulations;<sup>28</sup>
- direct the Medicare contractors to determine whether the hospitals, which we have identified as having billed incorrectly in both this audit and our prior audit (A-05-16-00059), have engaged in a pattern of incorrect billing after our audit period and, if so, take appropriate action in accordance with CMS policies and procedures;<sup>29</sup> and

---

<sup>27</sup> Our third, fourth, and seventh recommendations supersede similar recommendations, which remain unimplemented, made in prior reports (A-01-15-00504 and A-05-16-00059).

<sup>28</sup> We will provide CMS with our contacts at the three device manufacturers included in this review.

<sup>29</sup> We identified 24 hospitals that submitted incorrect claims in both this audit and the prior audit. In this audit, these hospitals each received total potential overpayments greater than \$100,000; these potential overpayments totaled approximately \$5.6 million. We will provide a list of these hospitals along with associated payment amounts to CMS.

- as an alternative to our third, fourth, and fifth recommendations, consider eliminating the current Medicare requirements for reporting device credits by reducing IPPS and OPSS payments for cardiac device replacement procedures.

## **CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, CMS concurred with three of the seven recommendations we made and described the steps it plans to take in response to those recommendations. Specifically, CMS concurred with our recommendations to instruct Medicare contractors to recover potential overpayments; notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of overpayments) so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and consider eliminating the current Medicare requirements for reporting device credits by reducing the IPPS and OPSS payments for cardiac device replacement procedures.

We summarize CMS's nonconcurrences and provide our responses below. CMS's comments, excluding technical comments that we addressed in the report as appropriate, are included as Appendix D.

### **RECOMMENDATIONS TO REQUIRE THE USE OF CONDITION CODES 49 AND 50 AND IMPLEMENT A POSTPAYMENT REVIEW PROCESS**

#### **CMS Comments**

CMS did not concur with our third recommendation to require hospitals to use condition codes 49 or 50 on claims for a device-replacement procedure that resulted from a recall or premature failure, regardless of whether the hospital received a reportable credit prior to billing for the device replacement procedure. CMS stated that it does not require that information for purposes of processing the claim when there is no reportable device credit.

CMS also did not concur with our fourth recommendation that, assuming that CMS implemented our third recommendation, CMS should instruct Medicare contractors to implement a postpayment process. CMS stated that it does not concur with this recommendation because it does not concur with our third recommendation.

#### **OIG Response**

If CMS is unable to identify an alternative method of accounting for device credits that is both administratively efficient and that treats all hospitals fairly, OIG believes that the best course of action would be to require the use of condition code 49 or 50 for device replacement procedures that resulted from a recall or premature failure, regardless of whether the hospital has received a reportable credit prior to billing for the device replacement procedure. Hospitals

already include these codes when billing to reflect that a reportable credit has been received. We do not believe that it would be overly burdensome for providers to include these codes when billing for device replacement procedures prior to receiving a credit, when the device is replaced due to a recall or premature failure.

If providers are required to include the condition codes on these types of claims, the Medicare contractors could implement a postpayment review process, which would allow them to periodically query the claims processing system to identify claims that were billed with one of the condition codes and without the value code. Using that list of claims, the Medicare contractors could then contact the provider to determine whether the provider received a reportable credit either before or after the provider submitted its initial claim. If so, the provider would then be required to adjust the original claim to reflect the credit received.

## **RECOMMENDATION TO OBTAIN DEVICE CREDIT LISTINGS FROM MANUFACTURERS**

### **CMS Comments**

CMS did not concur with our fifth recommendation that CMS should obtain device credit listings from manufacturers and determine whether providers reported credits as required by Medicare regulations. CMS stated that it does not concur with this recommendation because creating and maintaining a registry of product lifecycles and known recalls across all device manufacturers would be overly burdensome and outside the scope of its general mandates. CMS also stated that hospitals are in the best position to manage information on recalls and product lifecycles for devices they have implanted and are required to adjust their billing accordingly.

### **OIG Response**

This report and our prior reports show that the hospitals are not adequately managing information on recalls and product lifecycles, nor are they adjusting all claims to reflect reportable credits issued. Our current audit found that in nearly 50 percent of cases, the hospitals did not adjust claims to reflect the reportable credits issued totaling over \$33 million. Our recommendation was for CMS to obtain a listing of device credits issued from manufacturers and determine whether providers reported the credits as required by Medicare regulations just as OIG did. We did not create and maintain a registry of product lifecycles and known recalls across all device manufacturers, nor are we suggesting that CMS create such a registry, since a registry of this type is not necessary to implement this recommendation.

In our draft report, we recommended that CMS, as an alternative to our third, fourth, and fifth recommendations, should consider eliminating the current Medicare requirements for reporting device credits by reducing IPPS and OPPI payments for cardiac device replacement procedures. As mentioned above, CMS concurred with that recommendation. Specifically,

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

## **RECOMMENDATION TO DIRECT MEDICARE CONTRACTORS TO DETERMINE WHETHER PROVIDERS HAVE ENGAGED IN A PATTERN OF INCORRECT BILLING**

### **CMS Comments**

CMS did not concur with our sixth recommendation to determine whether providers identified as having billed incorrectly in both this audit and a prior OIG audit have engaged in a pattern of incorrect billing after our audit period and, if so, take appropriate action in accordance with CMS policies and procedures. CMS stated that it routinely provides outreach and education. However, CMS stated that it will notify the providers that appeared in both audits to remind them of the cardiac device credit reporting obligations. CMS said it believes that this is the most effective use of its resources.

### **OIG Response**

CMS has provided outreach and education over the years, some of which predated previous OIG audits that identified overpayments. Providing educational articles and outreach has not been enough to ensure that hospitals pursue credits that are due and then adjust claims to reflect the credits received. Several OIG audits, covering various audit periods that ranged from 2007 through our current audit period of June 2017, have identified combined potential overpayments of at least \$43 million. This indicates to us that CMS needs to do more than provide outreach and education, especially concerning providers who have been identified in multiple audits as having billed incorrectly. Therefore, we maintain that our recommendation is valid.

## **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 such information on claims would allow for the identification of devices that manufacturers have recalled or that have prematurely failed and for which a credit from the manufacture 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.<sup>30</sup> The rule requires the label of most medical devices to include a UDI that identifies the device's labeler (manufacturer) 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, serial number, expiration date, manufacture date, or its HCT/P (Human Cell, Tissue or Cellular and Tissue-Based Product) identification code.

### **CLAIM FORMS LACK UNIQUE DEVICE IDENTIFIER INFORMATION**

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

CMS and FDA expressed support<sup>31</sup> for capturing on the claim form the DI portion of the UDI if sufficient funding and resources are provided to make the necessary changes to the Medicare claims processing system. In addition, in a prior OIG report,<sup>32</sup> we recommended that CMS continue to work with the Accredited Standards Committee X12 (ASC X12) to ensure that the DI is included on the next version of claim forms. CMS stated at the time that this policy was under review by its new administration and it would evaluate whether it would impose unnecessary burden on physicians. In August 2019, CMS informed us that this recommendation remains unimplemented.

### **BIPARTISAN CONGRESSIONAL SUPPORT FOR THE UNIQUE DEVICE IDENTIFIER**

Over the past 4 years, the U.S. Department of Health and Human Services (HHS) and the ASC X12 have received letters from both Republican and Democratic Senators advocating for the inclusion of a medical device unique identifier on electronic health records and claims. (See Appendix C for a list of these letters.) The latest letter to the HHS Secretary and the CMS

---

<sup>30</sup> 78 Fed. Reg. 58825 (Sept. 24, 2013) and 21 CFR part 830.

<sup>31</sup> FDA and CMS joint letter to the Chair of the Accredited Standards Committee X12 addressing UDI on claims, July 13, 2016.

<sup>32</sup> *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (A-01-15-00504).

Administrator, sent on November 26, 2019, by a bipartisan group of United States Senators and Representatives encouraged them to improve the safety and quality of care of patients that rely on medical devices. To this end, they urge CMS to support the inclusion of device identifiers on claims, as recommended by the ASC X12,<sup>33</sup> and promulgate the regulations needed to implement the change.

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 recommendations outlined in our prior report (A-01-15-00504).

---

<sup>33</sup> X12, *X12 Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Institutional (837)*, October 2019.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

During our audit period, January 1, 2015, through June 30, 2017, device manufacturers issued warranty credits to hospitals for recalled and defective cardiac medical devices. We obtained a list of warranty credits that the top three device manufacturers provided to hospitals for cardiac medical devices. We verified with four hospitals in Arkansas, Massachusetts, and New York that they received the credits reported by the manufacturers. For the credits on the list provided that we identified as reportable, we matched the device recipients to the Medicare Enrollment Database to determine which recipients were Medicare beneficiaries. We performed two matches. When manufacturers provided Social Security numbers, we matched them to the enrollment database. When manufacturers did not provide recipient Social Security numbers, we matched the recipient names, addresses, and dates of birth to the enrollment database. These matches identified 7,960 Medicare beneficiaries who had cardiac devices implanted.

Using the warranty credit data and the CMS NCH file, we subsequently identified 6,558 claims that had a cardiac device replacement procedure for which the date of service matched to the device replacement procedure date on the credit listing. We determined that 3,233<sup>34</sup> of the 6,558 claims or nearly 50 percent were billed without the required condition and value codes. Our audit covered \$76,066,480 in Medicare payments to 911 hospitals for 514 inpatient and 2,719 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 the hospitals that submitted Medicare claims covered by our audit because our objective did not require us to do so. Rather, we limited our review to controls related to cardiac device claims processing.

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 the NCH file, but we did not assess the completeness of the file.

We conducted our audit from January 2018 through September 2020.

---

<sup>34</sup> This number is the result of removing claims with a paid amount of \$0, claims in which the dates of service were outside the audit period, managed care claims, and claims that were billed with the appropriate condition and value codes.



## 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;
- identified the top 3 cardiac device manufacturers and requested and received warranty credit data from each for recalled devices;
- matched those credits to the Medicare enrollment database and identified 7,960 Medicare beneficiaries;
- extracted 6,558 cardiac device replacement claims from CMS's NCH file for those recipients during the audit period;
- 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 for reporting manufacturer credits);
- determined that 3,233 of the 6,558 claims for cardiac device replacements did not include the appropriate condition and value codes;
- matched claims data for the claims extracted from NCH that did not include the appropriate condition and value codes to claims data in the Integrated Data Repository<sup>35</sup> (IDR) to determine whether any claims had been canceled or adjusted;
- verified that the NCH and IDR data were accurate by comparing 134 claims that four hospitals billed without the appropriate condition and value codes to claim data in CMS's Common Working File;
- met with hospital officials from the four hospitals to gain an understanding of their policies and procedures for reporting to Medicare device credits received from manufacturers and the reasons they did not properly report the manufacturer credits received;

---

<sup>35</sup> The IDR houses NCH data obtained from CMS. The NCH claim file is processed through a final action routine to determine the correct final version of a claim. CMS separately processes this file before placing claim data in the IDR.

- identified potential overpayments (footnote 17) that resulted from hospitals not properly reporting these credits on Medicare claims; and
- discussed the results of the audit 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**

<b>Report</b>	<b>Report Number</b>	<b>Issue Date</b>
<i>Hospitals Did Not Comply with Medicare Requirements for Reporting Certain Cardiac Device Credits</i>	A-05-16-00059	03/08/2018
<i>Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices</i>	A-01-15-00504	09/28/2017
<i>Hospitals Did Not Always Comply With Medicare Requirements for Reporting Cochlear Devices Replaced Without Cost</i>	A-01-15-00508	11/22/2016
<i>Review of Tufts Medical Center Claims That Included Medical Device Replacements</i>	A-01-15-00503	04/15/2016
<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	03/16/2016
<i>Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits</i>	A-05-13-00029	10/29/2014
<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	10/24/2011

## APPENDIX C: CONGRESSIONAL LETTERS SUPPORTING USE OF UNIQUE DEVICE IDENTIFIER

- From Senators Warren and Grassley to Sylvia Matthews Burwell, Andy Slavitt, and Robert Califf, March, 8, 2016, [https://www.grassley.senate.gov/sites/default/files/news/upload/2016\\_03\\_09%20CEG%20to%20HHS%20regarding%20UDI.PDF](https://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF).
- From Senators Warren and Grassley to Gary Beatty, Accredited Standards Committee X12, August 29, 2016, [https://www.warren.senate.gov/files/documents/2016-8-29\\_UDI\\_letter\\_to\\_ASC\\_X12.pdf](https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf).
- From Senators Warren and Grassley to Gary Beatty, Accredited Standards Committee X12, June 1, 2017, [https://www.warren.senate.gov/files/documents/2017-6-1\\_Letter\\_to\\_X12.pdf](https://www.warren.senate.gov/files/documents/2017-6-1_Letter_to_X12.pdf).
- From Senators Warren and Grassley to CMS Administrator Seema Verma, November 8, 2017, [https://www.warren.senate.gov/files/documents/2017\\_11\\_08\\_Letter\\_to\\_CMS\\_re\\_UDI\\_and\\_claims.pdf](https://www.warren.senate.gov/files/documents/2017_11_08_Letter_to_CMS_re_UDI_and_claims.pdf).
- From Senators Warren and Grassley to FDA Commissioner Scott Gottlieb, June 12, 2018, <https://www.warren.senate.gov/imo/media/doc/2018.06.12%20Letter%20to%20Gottlieb%20on%20UDI%20and%20claims.pdf>.
- From Senators Warren and Grassley and Congressmen Lloyd Doggett, Brian Fitzpatrick, and Bill Pascrell, Jr., to Alex M. Azar II and Seema Verma, November 26, 2019, <https://www.warren.senate.gov/imo/media/doc/2019.11.26%20Letter%20to%20HHS%20and%20CMS%20re%20UDIs.pdf>.

## APPENDIX D: CMS COMMENTS




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator  
Washington, DC 20201

**DATE:** October 9, 2020

**TO:** Amy J. Frontz  
Deputy Inspector General for Audit Services

**FROM:** Seema Verma  
Administrator 

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits, A-01-18-00502*

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 recognizes the importance of providing Medicare beneficiaries with access to medically necessary services and, at the same time, protecting the Medicare Trust Funds from improper payments for recalled or prematurely failed medical devices.

As part of CMS's effort to protect Medicare Trust Funds from improper payments under the Outpatient Prospective Payment System (OPPS), CMS requires hospitals to report the amount of device credits received from manufacturers for replaced medical devices. Specifically, hospitals are required to report the amount of the device credit when the initial placement of a medical device is furnished, without cost, as part of a clinical trial or a free sample medical device, or when a replacement device is furnished without cost or with a credit of 50 percent or more of the cost of a new replacement from a manufacturer, due to warranty, recall, or field action. CMS also 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.

Effective January 1, 2014, under the OPPS, CMS requires hospitals to report these credits with value code "FD" on the claim, signifying the credits to be deducted from the device offset amount for applicable procedures. As part of the policy change, CMS began processing full credits, including no-cost devices, and partial credits in the same manner by deducting the lesser of the amount of the device credit reported with the FD value code, or the full offset amount from the Medicare payment.<sup>1</sup>

OIG's recommendations and CMS' responses are below.

### **OIG Recommendation**

---

<sup>1</sup> Medicare Claims Processing Manual, Chapter 4, 61.3.6. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>

CMS should instruct Medicare contractors to recover, in accordance with Federal regulations, the portion of the \$33,095,068 in identified Medicare potential overpayments from the 911 hospitals for the 3,233 incorrectly billed claims that are within the 4-year reopening period.

**CMS Response**

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

**OIG Recommendation**

Based upon the results of this audit, CMS should notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

**CMS Response**

CMS concurs with this recommendation. CMS will analyze the OIG's data to identify appropriate providers to notify of potential overpayments. Within CMS's policies and procedures, CMS will then instruct its Medicare contractors to notify the identified providers of OIG's audit findings. CMS will track any returned overpayments made in accordance with this recommendation and the 60-day rule.

**OIG Recommendation**

CMS should require hospitals to use condition codes 49 or 50 on claims for a device-replacement procedure that resulted from a recall or premature failure, regardless of whether the hospital received a reportable credit prior to billing for the device replacement procedure.

**CMS Response**

CMS does not concur with this recommendation. CMS does not require this information for purposes of processing the claim when there is no reportable device credit.

**OIG Recommendation**

Under the assumption that the prior recommendation will be implemented, CMS should instruct Medicare contractors to implement a postpayment review process to ensure that hospitals have adjusted claims, as required, for the device credits they received.

**CMS Response**

CMS does not concur with this recommendation because, as stated above, CMS does not concur with the recommendation to require hospitals to use condition codes 49 or 50 regardless of whether the hospital has already received a reportable credit prior to billing for the device replacement procedure.

**OIG Recommendation**

CMS should obtain device credit listings from manufacturers and determine whether providers reported the credits as required by Medicare regulations.

**CMS Response**

CMS does not concur with this recommendation. Creating and maintaining a registry of product lifecycles and known recalls across all device manufacturers would be overly burdensome and outside the scope of CMS' general mandates. Hospitals are in the best position to manage information on recalls and product lifecycles for devices they have implanted and are required to adjust their billing accordingly.

**OIG Recommendation**

CMS should direct the Medicare contractors to determine whether the hospitals, which we have identified as having billed incorrectly in both this audit and our prior audit (A-05-16-00059), have engaged in a pattern of incorrect billing after our audit period and, if so, take appropriate action in accordance with CMS policies and procedures.

**CMS Response**

CMS does not concur with this recommendation. CMS routinely provides outreach and education to providers to ensure that they understand their obligation to report these credits. Specifically, CMS has issued messages to providers with the requirements for reporting manufacturer credits for cardiac devices six times from 2018 to 2019 and added a fact sheet to the provider compliance webpage. In addition, as described above, 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. However, CMS will also notify providers that have appeared in both audits and remind them of the cardiac device credit reporting obligations. CMS believes that this process will ensure the most effective use of CMS resources.

**OIG Recommendation**

As an alternative to our third, fourth, and fifth recommendations, CMS should consider eliminating the current Medicare requirements for reporting device credits by reducing IPPS and OPPS payments for cardiac device replacement 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.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.