Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SHORTCOMINGS OF DEVICE CLAIMS DATA COMPLICATE AND POTENTIALLY INCREASE MEDICARE COSTS FOR RECALLED AND PREMATURELY FAILED DEVICES

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Inspector General

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Office of Inspector General

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Report in Brief
September 2017
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices

Why OIG Did This Review

The Centers for Medicare & Medicaid Services (CMS) expressed concerns in the Federal Register about Medicare expenditures associated with recalled or prematurely failed medical devices almost a decade ago. CMS stated that it intended to ensure that these costs would be properly addressed. There is no reliable up-to-date estimate of these costs.

The objectives of our review were to (1) determine whether Medicare costs related to the replacement of recalled or prematurely failed medical devices could be identified and tracked using claim data and (2) identify Medicare costs related to the replacement of seven recalled and prematurely failed medical devices.

How OIG Did This Review

We identified Medicare claims for calendar years 2005 through 2014 for all services provided to Medicare beneficiaries who had replacements of seven selected recalled cardiac medical devices. We then selected a random sample of 526 claims and requested medical records for each sample item to determine whether the claim was associated with a replacement of a recalled or prematurely failed medical device.

What OIG Found

We determined that Medicare costs related to the replacement of recalled or prematurely failed medical devices could not be identified and tracked using only claim data. However, using claim and other data in combination with complex and labor-intensive auditing procedures, we 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. We also estimated $140 million in beneficiary copayment and deductible liabilities related to these recalled and prematurely failed medical devices and their related services and procedures. Medicare claim forms include the medical procedures performed but do not contain a field for reporting medical device-specific information. By including medical device-specific information on the claim forms, CMS could more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices. This could help reduce Medicare costs by identifying poorly performing devices more quickly, which could also protect beneficiaries from unnecessary costs and improve their chances of receiving appropriate followup care more quickly.

What OIG Recommends and CMS Comments

We recommend that CMS (1) continue to work with the Accredited Standards Committee X12 to ensure that the Device Identifier (DI) is included on the next version of claim forms and (2) require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure if the procedure resulted from a recall or premature failure independent of whether there was a device provided at no cost or with a credit.

CMS stated that our first recommendation is a policy that is under consideration and that it concurred with our second recommendation "in cases where payment is impacted." We maintain that by including the DI on claim forms and expanding the use of condition codes, CMS could more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices, reduce Medicare costs by identifying poorly performing devices more quickly, facilitate device recipients' chances of receiving timely followup care, and protect beneficiaries from unnecessary costs.

TABLE OF CONTENTS

APPENDICES

INTRODUCTION

WHY WE DID THIS REVIEW

Recalls of medical devices nearly doubled from 2003 through 2012.[1] Independent studies have shown that recalled or prematurely failed devices have likely cost Medicare billions of dollars in monitoring, hospitalization, surgeries, imaging, postacute care, physician services, and other costs.[2] Furthermore, beneficiaries affected by recalled or prematurely failed devices may incur adverse health events[3] and additional costs in the form of deductibles and coinsurance. There is no reliable up-to-date estimate of the Medicare costs associated with recalled or prematurely failed medical devices.

Although not considered improper payments,[4] the costs that Medicare and its beneficiaries incur to replace recalled or prematurely failed medical devices are substantial. In 2007, the Centers for Medicare & Medicaid Services (CMS) expressed its concerns about these costs, stating its intention to "ensure that costs of the additional physicians' services and diagnostic tests associated with recalled devices are recognized and properly addressed." At that time, CMS stated that it would develop a plan to address this issue.[5]

The ability of CMS to effectively identify and track these costs is essential to assessing their impact on the Medicare trust funds and Medicare beneficiaries. We performed this audit in an effort to identify those costs using Medicare claim data.

OBJECTIVES

The objectives of our review were to (1) determine whether Medicare costs related to the replacement of recalled or prematurely failed medical devices could be identified and tracked using only claim data and (2) identify the Medicare costs related to the replacement of seven recalled and prematurely failed medical devices.

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[1] The U.S. Food and Drug Administration (FDA) Medical Device Recall Reports for fiscal years 2003 through 2012.

[2] *Examining the Sprint Fidelis Effect on Medicare Costs*, H. Dennis Tolley, PhD, ASA, and *Medtronic Sprint Fidelis lead recall: Determining the initial 5-year management cost to Medicare,* Heart Rhythm Center in the Section of Cardiology, Department of Internal Medicine, University of Chicago, Chicago, Illinois, and Electrophysiology Section, Northwestern University, Chicago, Illinois.

[3] An adverse health event is any undesirable experience associated with the use of a medical product that may jeopardize the patient and may require medical or surgical intervention (treatment).

[4] Improper payments include those made to providers for medically unnecessary, insufficiently documented, noncovered, incorrectly coded, or unbundled services.

[5] 72 Fed. Reg. 66222, 66327 (Nov. 27, 2007).

BACKGROUND

The Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people age 65 and older, people with disabilities, and people with end-stage renal disease. CMS administers Medicare. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge. Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services, physician services, laboratory services, and ambulance services.

With respect to medical devices, Medicare Part A pays hospitals for the costs related to the replacement of recalled or prematurely failed medical devices at predetermined rates under the inpatient prospective payment system. Medicare Part B pays for hospital outpatient services for the costs related to the replacement of recalled or prematurely failed medical devices on a rate per service basis that varies under the outpatient prospective payment system.

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

Medical Device Recalls and Premature Failures

Device manufacturers typically recall devices voluntarily after a device exhibits an excessive rate of failure or a new type of failure. FDA evaluates and classifies recalls of medical devices to indicate the relative degree of risk presented by the recalled device.[6] FDA would consider whether the rate of failure is higher than expected in the context of an analysis of a specific type of device. Such information may be considered during, for example, FDA's premarket review, health hazard evaluations, or classification of recalls.

[6] Most recalls are voluntary and are consistent with the responsibility of manufacturers and distributors to protect public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. Recalls are categorized into three classes. Class I—there is a reasonable probability that the use of, or exposure to, the product could cause serious health consequences or death; Class II—use of, or exposure to, the product may cause a temporary or medically reversible adverse health consequence or where probability of serious adverse health consequences is remote; and Class III—use of, or exposure to, the product is not likely to cause an adverse health reaction.

Manufacturer and User Facility Device Experience Database

FDA requires[7] manufacturers, importers, and user facilities to submit Medical Device Reports (MDRs) to FDA for inclusion in its database, known as the Manufacturer and User Facility Device Experience (MAUDE). MDRs contain information about reportable adverse events and malfunctions involving medical devices. FDA defines a "malfunction" as a failure of a device to meet its performance specifications[8] or otherwise perform as intended.

Unique Device Identifier System

Section 226 of the Food and Drug Administration Amendments Act of 2007 charged 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 postmarket surveillance.[9] In 2013, FDA promulgated a final rule establishing a UDI system designed to adequately identify medical devices through distribution and use.[10] There are two parts to the UDI: the Device Identifier (DI) portion and the Production Identifier (PI) portion. The DI portion identifies the device labeler[11] and the specific version or model of the device. The PI portion is that part 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 human cell, tissue or cellular, or tissue-based product identification code. (See the figure on the next page).[12] The standard Medicare (and Medicaid) health insurance claim forms do not include a field to capture data about either the DI or PI portions of the UDI for implantable medical devices.

[7] 21 U.S.C. § 360i and 21 CFR part 803.

[8] Performance specifications include all claims made in the labeling for the device (21 CFR § 803.3(k)).

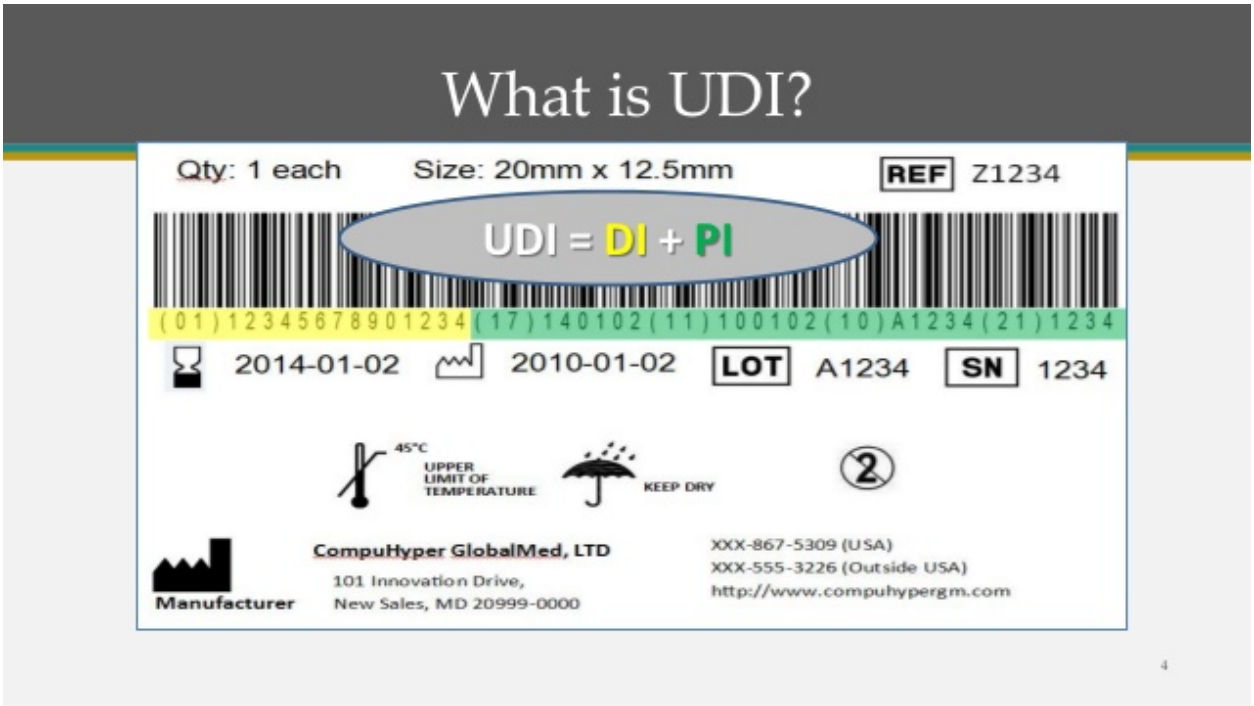
[9] Food and Drug Administration Amendments Act of 2007, P.L. No. 110-85 (enacted Sept. 27, 2007).

[10] 78 Fed. Reg. 58786 (Sept. 24, 2013) and 21 CFR part 830.

[11] A "labeler" generally means anyone who causes a label to be applied to a device, or who causes the label of a device to be replaced or modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. (See 21 CFR § 801.3.)

[12] The PI contains information needed to identify specific batches and lots of recalled or prematurely failed devices. This information is important because it could help to facilitate a beneficiary's timely followup care in the event that a specific subset of a device needs to be replaced. The DI alone would not facilitate timely followup because it does not contain this information.

Figure: Unique Device Identifier



Source: U.S. Food and Drug Administration.

Changes to Claim Forms

The Health Insurance Portability and Accountability Act of 1996 generally requires that changes to claim forms be handled through a multistakeholder standards development process.[13]

The Accredited Standards Committee X12 is the standards organization responsible for defining and developing electronic health care forms. The current claim forms (version 5010) took effect in January 2012. The Accredited Standards Committee X12's ongoing effort to update the claim forms (version 7030) is expected to include the following: an open comment period on the standards, review and approval by various standards organizations, a review and subsequent recommendation to CMS by the National Committee on Vital Health Statistics, and CMS's issuance of an interim final rule that would trigger a statutorily required 27-month implementation phase. The revised claim forms would take effect sometime in 2021.

Current claim forms include only information about the procedure performed and a field for reporting device failures and recalls when a hospital receives a replacement device from a manufacturer at no cost or with a credit of at least 50 percent of the device's cost. The forms do not contain a field for reporting device-specific information.

[13] Standards organizations bring together stakeholders to reach consensus on the benefits and costs of these changes.

CMS and FDA supported capturing the DI portion of the UDI for implantable devices on claim forms in a July 13, 2016, letter to the Accredited Standards Committee X12.[14]

Condition Codes To Identify Device Credits From Manufacturers for Recalls and Premature Failures

A condition code is a two-digit alphanumeric code used to identify conditions relating to a claim for services and procedures that may affect payer processing. CMS Change Request No. 4058, effective April 1, 2006, states that hospitals must include condition codes 49 and 50 on claim forms when a replacement device is received without cost or a credit was received for 50 percent or greater than the cost of the device because it is under warranty, recalled, or was defective. Hospitals must report condition codes 49 and 50 in conjunction with value code FD[15] for inpatient claims after October 1, 2008, and for outpatient claims after January 1, 2014, when a hospital receives a replacement device at no cost or with a credit that is 50 percent or greater than the cost of the device and must report the amount of the device credit.[16] Medicare specifically requires the use of a condition code to reflect the following two situations: Code 49,"Product Replacement within Product Lifecycle," which represents the replacement of a product earlier than the anticipated lifecycle because of an indication that the product is not functioning properly, and Code 50, "Product Replacement for Known Recall of a Product," which represents that the manufacturer or FDA has identified the product for recall and replacement. If a hospital receives a device replacement that is not provided without cost or a credit of 50 percent or greater of the cost of the device was not issued, hospitals are not required to use condition codes 49 or 50.[17]

Medical Device Manufacturer No-Cost Replacements and Warranty Credits Are Limited

Hospitals that replace a recalled or prematurely failed medical device that is covered under a manufacturer warranty may receive a no-cost replacement or warranty credit from the manufacturer upon request. Federal regulations state that Medicare payment to a hospital is to be reduced by applicable warranty credits, as appropriate (42 CFR §§ 412.89 and 419.45). However, most medical devices do not carry a manufacturer warranty and, therefore, are not

[14] Letter to the committee chairman, signed by CMS Administrator Andy Slavitt and FDA Commissioner Robert Califf.

[15] Hospitals are required to report the amount of a device credit in the amount portion for Value Code FD (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater of the cost of the device or a free replacement.

[16] CMS Change Request 5860, effective October 1, 2008, and Change Request 8653, effective January 1, 2014. Change Requests are transmittals CMS uses to communicate new or changed policies or procedures. These policies and procedures are incorporated into the CMS Online Manual System.

[17] *Medicare Claims Processing Manual*, Pub. No. 100-4, chapter 3, § 100.8; chapter 4, § 61.3.5.

subject to no-cost device replacements or warranty credits. For instance, orthopedic device manufacturers rarely offer warranties on their products.[18] As a result, Medicare's recovery of costs associated with recalled and prematurely failed devices is generally limited to the value of no-cost replacement devices and warranty credits supplied by manufacturers.[19]

HOW WE CONDUCTED THIS REVIEW

To determine whether we could identify and track Medicare's costs that resulted from medical device recalls and premature failures, we reviewed the information that hospitals are required to submit on their claim forms to Medicare. To examine the costs Medicare incurred because of recalled or prematurely failed medical devices, we reviewed the Medicare costs associated with seven cardiac devices from three manufacturers that had been recalled or had high failure rates over a 10-year period.[20] To conduct this review, we subpoenaed three manufacturers to obtain a list of patients who had these devices implanted. We matched the names and Social Security numbers of the device recipients to the Medicare Enrollment Database and identified 375,991 Medicare beneficiaries who had these devices implanted. Using the CMS National Claims History file, we subsequently identified 72,710 beneficiaries who had a device replacement procedure and any related claims paid by Medicare for calendar years 2005 through 2014. These seven replaced cardiac devices resulted in 8.2 million replacement-related claims totaling $5.1 billion in Medicare payments to providers[21] and an additional $501 million in beneficiary copayment and deductible liabilities. The devices were replaced because of recalls, premature failures, medically necessary upgrades, and replacements resulting from infections.

We then statistically selected 5 stratified random samples of claims from all the inpatient, outpatient, and physician procedures and services provided on behalf of the 72,710 Medicare beneficiaries. The 5 stratified random samples included a total of 526 claims. We obtained and reviewed the beneficiaries' medical records for each sampled claim to assess whether the claim was the result of (1) a recall or premature failure before the warranty expiration or (2) medically necessary upgrades or replacements resulting from infections. Finally, on the basis of our sample results, we estimated the total costs to Medicare of recalls and premature failures of these seven recalled devices.

[18] "Health System Bears Cost of Implants With No Warranties," *New York Times,* April 2, 2010.

[19] Unlike most other device manufacturers, cardiac device manufacturers offer warranties on their products.

[20] We researched MAUDE to identify specific cardiac devices that were at a high risk of premature failure. We selected cardiac devices because most of these devices have manufacturer warranties that establish a minimum useful life.

[21] The CMS requirement for reporting condition codes 49 and 50 applies specifically to hospitals; however, our review of Medicare payments applies to hospitals that submit claims for device replacement procedures and other types of providers that submit claims for post-device replacement procedures and services.

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 details of our audit scope and methodology.

FINDINGS

We determined that Medicare costs related to the replacement of all recalled or prematurely failed medical devices could not be identified and tracked using only Medicare claim data. Such costs cannot be determined using only claim data because, although Medicare claim forms identify the medical procedures performed, they do not contain a field for reporting medical device-specific information. In addition, although claim forms include a field for reporting specific codes for recalls, premature device failures, and no-cost replacement devices, hospitals rarely used this field because CMS required them to use it only if they received reportable credits or no-cost replacement devices from manufacturers.

The lack of information on the claim forms prevents CMS from being able to fully understand and address the Medicare costs related to recalled or prematurely failed medical devices. In addition, the lack of information impedes the ability of FDA and CMS to identify poorly performing devices as early as possible. This diminishes device recipients' chances of receiving timely followup care.

Although we could not use claim data alone to identify the costs associated with replacing all recalled or prematurely failed medical devices, we were able to use claim and other data in combination with complex and labor-intensive auditing procedures to estimate the cost of Medicare services related to the replacement of seven recalled and prematurely failed cardiac devices. This estimate totaled $1.5 billion over the 10-year period that ended December 31, 2014. In addition, we estimated that beneficiaries had $140 million in copayment and deductible liabilities related to these replacements and their related services and procedures. Although not improper payments, the substantial costs incurred by Medicare and the liabilities incurred by its beneficiaries to replace recalled or prematurely failed medical devices are a significant concern.

MEDICARE COSTS COULD NOT BE IDENTIFIED AND TRACKED FROM CLAIM DATA ALONE

Medicare costs related to the replacement of recalled or prematurely failed medical devices could not be identified and tracked from claim data alone. Current claim forms include information about the device replacement procedures performed by the provider but do not include medical device-specific information. Specifically, the claim forms do not include either the DI or PI portions of the UDI for implantable devices. Several stakeholders have stated that they are reluctant to support including medical device-specific information on claim forms

because of the high implementation costs and technological challenges that could create inefficiencies in the billing and claim adjudication processes.

CMS and FDA, in a July 13, 2016, letter to the Accredited Standards Committee X12, supported the inclusion of the DI portion of the UDI for implantable devices on the claim forms. Several other stakeholders have also recently changed or clarified their positions in support of including the DI on claim forms. However, CMS has not taken a position on the inclusion of the PI, which indicates more detailed information about a device, on the claim forms because the standards development organizations are not considering it for claims form version 7030. Although inclusion of the PI would provide important additional information, the size of the PI (more than 50 characters for some devices) could create technical concerns regarding system functionality.

Further, although the claim forms include a field for reporting premature device failures and recalls, hospitals were required to report condition codes 49 or 50 in the field only if a replacement device was received at no cost or with a credit that was 50 percent or greater of the cost of the device. Hospitals reported these codes when submitting claims that included device replacement procedures on less than 2 percent of the claims we reviewed because manufacturers did not provide no-cost replacements or credits for most device recalls or premature device failures. CMS established these codes to identify medical device credits and the reasons for those credits. Because CMS directed hospitals to use the codes in such limited circumstances, the claim data were not useful for identifying all device recalls and premature failures. As a result of the limitations of the claim forms, CMS would not be able to determine from the claim data alone the specific device implanted and whether the device was replaced because of a recall, a premature failure, or a necessary upgrade.

MEDICARE COSTS ASSOCIATED WITH SEVEN DEVICES THAT WERE RECALLED OR HAD HIGH FAILURE RATES

Although we could not use claim data alone to identify the costs associated with replacing all recalled or prematurely failed medical devices, we were able to use claim and other data in combination with complex and labor-intensive auditing procedures to estimate the cost of Medicare services related to the replacement of seven recalled and prematurely failed cardiac devices.

On the basis of our sample results, we estimated that Medicare made $1.5 billion in payments to providers, and beneficiaries incurred an estimated $140 million in copayment and deductible liabilities, for services and procedures resulting from the seven recalled devices subject to

premature failure in our review.[22] Approximately $1 billion of the $1.5 billion[23] were Medicare payments for device replacement procedures, such as heart surgery to replace prematurely failed pacemakers or internal defibrillators. The remaining $500 million[24] were Medicare payments for post-device replacement services, such as imaging, postacute care, and physician visits to monitor patients after the new devices were implanted.[25] Although not improper payments, the substantial costs incurred by Medicare and beneficiaries to replace recalled or prematurely failed medical devices are a significant cause for concern.

The $1.5 billion in Medicare payments to providers and $140 million in beneficiary copayment and deductible liabilities for services and procedures that resulted from the seven recalled or prematurely failed devices is a conservative estimate because our review did not (1) include device recipients who were younger than 65 as of October 29, 2013, but Medicare-eligible because of disability or end-stage renal disease,[26] (2) link many post-device replacement claims to a recalled or prematurely failed device because of limited information in the medical records, and (3) consider the monitoring costs for beneficiaries who opted to forgo device replacement procedures, which could exceed the costs of a device replacement over the beneficiary's lifetime.[27]

CONCLUSION

The lack of medical device-specific information on the claim forms, along with the limited use of relevant condition codes, impedes CMS's ability to readily identify and effectively track Medicare's total costs related to the replacement of recalled or prematurely failed devices. Without the device-specific information on the claim forms and a more effective use of the condition codes, we had to establish complex audit procedures and undertake the labor-intensive process of obtaining and reviewing the device recipients' medical records to identify the estimated $1.5 billion in Medicare payments to providers and the estimated $140 million in

[22] The remaining $3.6 billion in Medicare payments and $360 million in beneficiary copayment and deductible liabilities reviewed were associated with claims that were due to reasons other than recall or premature failure, such as medically necessary upgrades or infection.

[23] See Appendix C, pages 22-23, sum of Inpatient Device Replacement point estimate and Outpatient Device Replacement point estimate.

[24] See Appendix C, pages 24-26, sum of Inpatient Device Post Replacement point estimate, Outpatient Device Post Replacement point estimate, and Part B Post Replacement point estimate.

[25] As is the case with the costs for device replacement procedures, we could not identify and track, from claim data alone, the additional Medicare costs for post-device replacement services and procedures that resulted from recalled or prematurely failed devices.

[26] About 16 percent of all Medicare beneficiaries.

[27] FDA has recommended that recipients of certain recalled medical devices undergo additional monitoring to determine whether device replacement surgeries are necessary.

beneficiary copayment and deductible liabilities for device replacements and related services and procedures resulting from only seven recalled and prematurely failed devices.

By including the DI on claim forms and expanding the use of condition codes, CMS could more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices. When the DI is added to the claim forms, CMS should use this data to identify and track the additional health care costs incurred by Medicare for recalled or prematurely failed medical devices. Further, as technology continues to advance, we believe consideration should be given to including the PI portion(s) of the UDI on the claim forms. Including this data could further help identify and track Medicare's aggregate costs related to recalled or prematurely failed devices and would provide additional patient safety benefits by enabling the identification of specific batches and lots of recalled or prematurely failed devices.

RECOMMENDATIONS

The recommendations below would (1) facilitate the use of claim data to identify and track the additional health care costs incurred by Medicare resulting from recalled or prematurely failed medical devices and (2) help reduce Medicare costs by identifying poorly performing devices more quickly, protecting beneficiaries from unnecessary costs, and improving beneficiaries' chance of receiving appropriate followup care more quickly. We recommend 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, and

- 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 device was provided at no cost or with a credit of 50 percent or more.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS stated that our first recommendation is a policy that is under consideration. CMS stated that it would carefully evaluate the potential that this policy would impose an unnecessary burden on physicians. CMS stated that it concurred with our second recommendation "in cases where payment is impacted." CMS also provided us written technical comments that we addressed, as appropriate. CMS's comments, excluding its technical comments, are included in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

We support the inclusion of the DI on claim forms, and we continue to recommend that CMS work with the Accredited Standards Committee X12 to ensure that the DI is included on the next version of claim forms. In the July 13, 2016, letter to the Accredited Standards Committee

X12, CMS and FDA stated that collecting the DI on claim forms would (1) allow for evaluation of product performance and identification of safety concerns for devices at the model level, (2) facilitate the collection and analysis of patient data for devices at the model level, (3) help providers and certain payers calculate and compare costs and outcomes on the basis of the device model used, and (4) support program integrity by providing better information to link the patient and implanted device to help track rebates and manufacturers back to the payer or provider.

We continue to recommend that CMS require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure if the procedure resulted from a recall or premature failure regardless of whether there was a payment impact (e.g., a device reported at no cost or with a credit). We note that our recommendation is to use the codes in ALL cases in which a device has prematurely failed or been recalled. We have revised the language of our recommendation to ensure that this is clear.

We continue to maintain that by including the DI on claim forms and expanding the use of condition codes, CMS could more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices, reduce Medicare costs by identifying poorly performing devices more quickly, facilitate device recipients' chances of receiving timely followup care, and protect beneficiaries from unnecessary costs.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We researched MAUDE to identify specific cardiac devices at risk of premature failure. We judgmentally selected seven voluntarily recalled cardiac medical devices produced by three manufacturers for our review. We selected these devices on the basis of our research of FDA data that showed these devices had high incidences of premature failure.

We obtained from the manufacturers information about the seven recalled devices. These manufacturers requested subpoenas before providing us with the list of device recipients who were 65 or older as of October 29, 2013. This information also included the date the device was originally implanted. However, we were unable to verify the completeness of the list of recipients. We subsequently matched the names and Social Security numbers of the recipients to the Medicare Enrollment Database and identified 375,991 Medicare beneficiaries. We then identified all Medicare Part A and Part B claims for calendar years 2005 through 2014 for services provided to a Medicare beneficiary who had a replacement of any of the seven recalled cardiac medical devices. These replaced devices resulted in 8.2 million replacement-related claims totaling $5.1 billion in Medicare payments to providers and an additional $501 million in beneficiary copayment and deductible liabilities, covering 72,710 Medicare beneficiaries. The devices were replaced because of recalls, premature device failures, and medically necessary upgrades or replacements resulting from infections.

We then statistically selected 5 stratified random samples of claims (inpatient replacement, outpatient replacement, inpatient post-replacement, outpatient post-replacement, and Part B post-replacement) from all of the procedures and services provided on behalf of the 72,710 Medicare beneficiaries. The 5 stratified random samples included a total of 526 claims. We obtained and reviewed the beneficiary's medical records for each sampled claim to determine whether the claim was associated with a replacement of a recalled or prematurely failed medical device. Finally, on the basis of our sample results, we estimated the total costs to Medicare of recalls and premature failures of these seven devices on the basis of our sample results.

Cardiac devices are one of many types of Medicare-covered medical devices that have been recalled or that have prematurely failed. These include orthopedic, urological, neurological, and cochlear devices that also affect Medicare costs. We chose cardiac devices because they typically are covered by a warranty. We used the warranty period as a conservative estimate of the expected lifespan of the devices. Typically, the useful life of cardiac devices is a much longer period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- held discussions with CMS officials relative to their concerns about health care costs and Medicare expenditures associated with recalled or prematurely failed medical devices;
- held discussions with FDA officials regarding data that they may have accumulated related to device recalls and to gain a better understanding of their device approval processes;
- analyzed data that providers reported to FDA relative to medical device adverse events associated with recalled devices:
- used FDA data to perform a risk assessment of recalled devices with high premature failure rates;
- used the results of our risk assessment to select seven recalled devices (five implantable cardioverter defibrillators, one pacemaker, and one lead[28]) from three cardiac device manufacturers;
- requested the Medicare beneficiary recipient information from the three manufacturers for each of the seven recalled devices;
- prepared and issued subpoenas, as requested, to the three manufacturers' attorneys to address their concerns regarding privacy, scope, and availability of data and to facilitate an acceptable means of receiving the data necessary for our review;
- obtained and analyzed the requested data;
- used the CMS National Claims History file to identify from the list of the device recipients 375,991 Medicare beneficiaries who had claims related to the replacement of the seven recalled devices;
- selected five stratified random samples that included a total of 526 claims (Appendix B);
- contacted the providers of the services for each of the 526 sampled claims and requested the medical records for each sampled claim;

[28] A cardiac lead is a wire connection that runs from the power source of the cardiac device to the patient's heart and delivers energy to the heart muscle.

- reviewed medical records for each sampled claim to determine whether the claim was related to the replacement of a recalled or prematurely failed medical device;

- estimated the total Medicare costs associated with the replacement of seven recalled and prematurely failed devices on the basis of our review of the sampled items (Appendix C); and

- discussed the results of our review with CMS and FDA 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: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The population consisted of inpatient, outpatient, and Part B claims for services provided to Medicare beneficiaries who had a medical device replacement of one of seven recalled cardiac medical devices during calendar years 2005 through 2014. These devices have demonstrated an abnormally high incidence of failure.

SAMPLING FRAME

We used a list of recipients obtained from the three cardiac device manufacturers through subpoenas. The recipients on this list were 65 or older as of October 29, 2013, and had one of seven selected cardiac medical devices with a high incidence of failure. This list also contained the date the device was implanted. The lists of recipients were not verified for completeness. Our Advanced Audit Techniques Staff (AATS) matched the names and Social Security numbers of the recipients to the Medicare Enrollment Database and identified 375,991 Medicare beneficiaries and their health insurance claim numbers.

For the 375,991 Medicare beneficiaries identified, AATS identified the target claims for five subgroups: (1) inpatient device replacement claims, (2) outpatient device replacement claims, (3) inpatient claims post replacement of a recalled or prematurely failed device, (4) outpatient claims post replacement of a recalled or prematurely failed device, and (5) Part B claims post replacement of a recalled or prematurely failed device. For each of these five groups, AATS applied a set of general filtering criteria to identify records in which:

- the claim date was January 2005 through December 2014,
- the service occurred after the beneficiary had one of the recalled seven devices implanted,
- Medicare was the primary payer, and
- the claim contained 1 of 131 cardiac diagnosis codes that we determined to be associated with the replacement of a recalled or prematurely failed device.

Additional details regarding the frames associated with the five subgroups, including group-specific filtering steps, are described on the following page.

Inpatient Device Replacement Claims

An inpatient replacement claim is defined as a claim for an inpatient service provided to 1 of the 375,991 Medicare beneficiaries to replace a recalled or prematurely failed device. In

addition to the general filtering criteria, we filtered the inpatient device replacement claims to include records in which:

- the service occurred before the warranty on the device expired (5 years after the implant date) and

- the claim contained 1 of 23 inpatient cardiac Diagnosis Related Group codes or 31 impatient cardiac procedure codes that we determined to be associated with the replacement of a recalled or prematurely failed device.

AATS identified 49,673 inpatient device replacement claims totaling $995,402,056.09 for services provided to 39,984 Medicare beneficiaries. The beneficiary copayment and deductible liabilities for these services amounted to $35,923,492.95.

Outpatient Device Replacement Claims

An outpatient replacement claim is defined as a claim for an outpatient service provided to 1 of the 375,991 Medicare beneficiaries to replace a recalled or prematurely failed device. In addition to the general filtering criteria, the outpatient device replacement claims were filtered to include records in which:

- the service occurred before the warranty on the impacted device expired (5 years after the implant date) and

- the outpatient claim Healthcare Common Procedure Coding System (HCPCS) code was 1 of the 51 device-removal HCPCS codes that we determined to be associated with the replacement of a recalled or prematurely failed device, or the outpatient Ambulatory Payment Classification (APC) Health Insurance Prospective Payment System (HIPPS) code is one of the eight outpatient device APC HIPPS codes that we determined to be associated with the replacement of a recalled or prematurely failed device.

AATS identified 40,575 outpatient device replacement claims totaling $641,755,977.27 for services provided to 38,535 Medicare beneficiaries. The beneficiary copayment and deductible liabilities for these services amounted to $51,078,369.66.

Inpatient Claims Post Replacement of a Recalled or Prematurely Failed Device

A post replacement inpatient claim is defined as a claim for an inpatient service provided to 1 of the 72,710 Medicare beneficiaries after the replacement of a recalled or prematurely failed device.

AATS applied the general filtering criteria and identified 222,828 inpatient claims totaling $2,328,406,906.76 for services provided to 54,251 Medicare beneficiaries after the

replacement of a recalled or prematurely failed device. The beneficiary copayment and deductible liabilities for these services amounted to $164,035,553.17.

Outpatient Claims Post Replacement of a Recalled or Prematurely Failed Device

A post replacement outpatient claim is defined as a claim for an outpatient service provided to 1 of the 72,710 Medicare beneficiaries after the replacement of a recalled or prematurely failed device.

AATS applied the general filtering criteria and identified 1,116,057 outpatient claims totaling $487,476,966.76 for services provided to 63,158 Medicare beneficiaries after the replacement of a recalled or prematurely failed device. The beneficiary copayment and deductible liabilities for these services amounted to $89,746,047.27.

Part B Claims Post Replacement of a Recalled or Prematurely Failed Device

A post replacement Medicare Part B claim is defined as a claim for a Part B service provided to 1 of the 72,710 Medicare beneficiaries after the replacement of a recalled or prematurely failed device.

AATS applied the general filtering criteria and identified 6,811,000 Part B claims totaling $644,431,670.42 for services provided to 70,764 Medicare beneficiaries after the replacement of a recalled or prematurely failed device. The beneficiary copayment and deductible liabilities for these services amounted to $159,720,005.97.

SAMPLE UNIT

The sample unit was a claim.

SAMPLE DESIGN AND SAMPLE SIZE

Our sample consisted of 526 claims selected using stratified sampling from 5 sampling frames. The details of the strata are described in Tables 1 through 5 on the next page.

Table 1: Inpatient Device Replacement Claims				
Stratum	**Dollar Range of Frame Units**	**Number of Frame Units**	**Sample Size**	**Dollar Value of Frame Units**
1	$5 to $22,160.00	32,645	35	$279,226,305.25
2	$22,160.01 to $44,320.00	13,238	35	425,648,556.30
3	$44,320.01 to $664,812.47	3,788	35	288,883,487.82
4	$759,958.89 to $883,747.83	2	2	1,643,706.72
Total		**49,673**	**107**	**$995,402,056.09**

Table 2: Outpatient Device Replacement Claims				
Stratum	**Dollar Range of Frame Units**	**Number of Frame Units**	**Sample Size**	**Dollar Value of Frame Units**
1	$8.53 to $10,161.00	16,777	35	$89,793,511.36
2	$10,161.01 to $22,851.00	13,270	35	267,295,535.82
3	$22,851.01 to $63,482.66	10,521	35	284,053,946.89
4	$79,594.52 to $99,031.05	7	7	612,983.20
Total		**40,575**	**112**	**$641,755,977.27**

Table 3: Inpatient Claims Post Replacement of a Recalled or Prematurely Failed Device				
Stratum	**Dollar Range of Frame Units**	**Number of Frame Units**	**Sample Size**	**Dollar Value of Frame Units**
1	$5 to $12,911.00	180,434	35	$1,168,048,031.76
2	$12,911.01 to $25,822.00	29,431	35	510,961,730.57
3	$25,822.01 to $645,532.10	12,961	35	647,682,553.27
4	$710,656.70 to $1,003,934.46	2	2	1,714,591.16
Total		**222,828**	**107**	**$2,328,406,906.76**

Table 4: Outpatient Claims Post Replacement of a Recalled or Prematurely Failed Device				
Stratum	**Dollar Range of Frame Units**	**Number of Frame Units**	**Sample Size**	**Dollar Value of Frame Units**
1	$5 to $1,139.10	1,053,795	69	$143,704,216.41
2	$1,139.11 to $56,710.68	62,261	30	343,664,936.00
3	$107,814.33	1	1	107,814.33
Total		**1,116,057**	**100**	**$487,476,966.74**

Table 5: Part B Claims Post Replacement of a Recalled or Prematurely Failed Device				
Stratum	**Dollar Range of Frame Units**	**Number of Frame Units**	**Sample Size**	**Dollar Value of Frame Units**
1	$5.00 to $168.55	6,040,926	70	$356,702,913.58
2	$168.56 to $32,717.52	770,074	30	287,728,756.84
Total		**6,811,000**	**100**	**$644,431,670.42**

SOURCE OF RANDOM NUMBERS

We generated the random numbers using Office of Inspector General (OIG), Office of Audit Services (OAS), Statistical Software, RAT-STATS 2010.

METHOD OF SELECTING SAMPLE UNITS

For each stratum in each frame, we consecutively numbered the sample units within the stratum. For strata in which a 100-percent review was not performed, we then generated the appropriate quantity of random numbers and selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the dollar value of payments made to providers, beneficiary copay and deductible liabilities, and the number of claims related to seven recalled and prematurely failed devices. We calculated separate estimates for each of the five frames. We then summed the point estimates for these five frames to calculate our overall estimate.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Results—Inpatient Device Replacement Claims

Table 6: Inpatient Device Replacement Claims—Medicare Payments						
Stratum	**Frame Size**	**Total Value of Frame**	**Sample Size**	**Total Value of Sample**	**Sample Items Related to a Recalled Device**	**Value of Items Related to a Recalled Device in Sample**
1	32,645	$279,226,305	35	$290,502	21	$188,444
2	13,238	425,648,556	35	1,153,145	21	658,497
3	3,788	288,883,488	35	2,764,640	12	810,625
4	2	1,643,707	2	1,643,707	0	0
Total	**49,673**	**$995,402,056**	**107**	**$5,851,994**	**54**	**$1,657,565***

* The numbers do not add properly because of rounding.

Table 7: Inpatient Device Replacement Claims—Beneficiary Copayment and Deductible Liabilities						
Stratum	**Frame Size**	**Total Value of Frame**	**Sample Size**	**Total Value of Sample**	**Sample Items Related to a Recalled Device**	**Value of Items Related to a Recalled Device in Sample**
1	32,645	$21,650,057	35	$26,704	21	$15,728
2	13,238	10,034,163	35	46,768	21	40,648
3	3,788	4,160,501	35	73,304	12	10,632
4	2	78,772	2	78,772	0	0
Total	**49,673**	**$35,923,493**	**107**	**$225,548**	**54**	**$67,008**

Estimated Payments—Inpatient Device Replacement Claims
(*Limits Calculated at the 90-Percent Confidence Level*)

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$498,239,385	$31,194,651	28,829
Lower limit	408,410,378	15,519,850	23,937
Upper limit	588,068,393	46,869,453	33,720

Sample Results—Outpatient Device Replacement Claims

Table 8: Outpatient Device Replacement Claims—Medicare Payments

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	16,777	$89,793,511	35	$186,972	26	$152,696
2	13,270	267,295,536	35	678,228	33	643,872
3	10,521	284,053,947	35	931,039	23	591,239
4	7	612,983	7	612,983	6	513,952
Total	**40,575**	**$641,755,977**	**112**	**$2,409,221***	**88**	**$1,901,759**

Table 9: Outpatient Device Replacement Claims—Beneficiary Co-Payment and Deductible Liabilities

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	16,777	$17,087,169	35	$36,191	26	$30,507
2	13,270	17,412,200	35	48,966	33	46,322
3	10,521	16,570,119	35	51,248	23	32,790
4	7	8,883	7	8,883	6	7,085
Total	**40,575**	**$51,078,370***	**112**	**$145,287***	**88**	**$116,705***

* The numbers do not add properly because of rounding.

Estimated Payments—Outpatient Device Replacement Claims
(*Limits Calculated at the 90-Percent Confidence Level*)

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$495,117,232	$41,962,677	31,820
Lower limit	451,043,468	36,899,963	29,184
Upper limit	539,190,996	47,025,390	34,456

Sample Results – Inpatient Post Device Replacement Claims

Table 10: Inpatient Post Device Replacement Claims—Medicare Payments

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	180,434	$1,168,048,032	35	$226,160	4	$21,986
2	29,431	510,961,731	35	599,587	3	57,449
3	12,961	647,682,553	35	1,737,686	5	196,911
4	2	1,714,591	2	1,714,591	0	0
Total	**222,828**	**$2,328,406,907**	**107**	**$4,278,023***	**12**	**$276,347***

* The numbers do not add properly because of rounding.

Table 11: Inpatient Post Device Replacement Claims—Beneficiary Copayment and Deductible Liabilities

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	180,434	$128,176,366	35	$29,496	4	$2,256
2	29,431	19,389,782	35	20,864	3	1,132
3	12,961	16,399,415	35	22,954	5	4,572
4	2	69,990	2	69,990	0	0
Total	**222,828**	**$164,035,553**	**107**	**$143,304**	**12**	**$7,960**

Estimated Payments—Inpatient Post Device Replacement Claims
(*Limits Calculated at the 90-Percent Confidence Level*)

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$234,572,397	$13,856,024	24,995
Lower limit	114,985,703	383,602	8,587
Upper limit	354,159,090	27,328,446	41,403

Sample Results—Outpatient Post Device Replacement Claims

Table 12: Outpatient Post Device Replacement Claims—Medicare Payments

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	1,053,795	$143,704,216	69	$9,862	13	$2,495
2	62,261	343,664,936	30	109,789	5	40,673
3	1	107,814	1	107,814	1	107,814
Total	**1,116,057**	**$487,476,967***	**100**	**$227,465**	**19**	**$150,983***

Table 13: Outpatient Post Device Replacement Claims—Beneficiary Copayment and Deductible Liabilities

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Sample Items Related to a Recalled Device	Value of Items Related to a Recalled Device in Sample
1	1,053,795	$37,899,144	69	$2,266	13	$495
2	62,261	51,846,214	30	24,289	5	6,018
3	1	689	1	689	1	689
Total	**1,116,057**	**$89,746,047**	**100**	**$27,245***	**19**	**$7,202**

* The numbers do not add properly because of rounding.

Estimated Payments—Outpatient Post Device Replacement Claims
(*Limits Calculated at the 90-Percent Confidence Level*)

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$122,627,339	$16,360,371	208,918
Lower limit	38,946,872	7,796,343	126,421
Upper limit	206,307,807	24,924,349	291,415

Sample Results—Part B Post Device Replacement Claims

Table 14: Part B Post Device Replacement Claims—Medicare Payments						
Stratum	**Frame Size**	**Total Value of Frame**	**Sample Size**	**Total Value of Sample**	**Sample Items Related to a Recalled Device**	**Value of Items Related to a Recalled Device in Sample**
1	6,040,926	$356,702,914	70	$4,165	11	$730
2	770,074	287,728,757	30	12,030	6	3,419
Total	**6,811,000**	**$644,431,670***	**100**	**$16,195**	**17**	**$4,149**

Table 15: Part B Post Device Replacement Claims—Beneficiary Copayment and Deductible Liabilities						
Stratum	**Frame Size**	**Total Value of Frame**	**Sample Size**	**Total Value of Sample**	**Sample Items Related to a Recalled Device**	**Value of Items Related to a Recalled Device in Sample**
1	6,040,926	$88,154,779	70	$896	11	$183
2	770,074	71,565,227	30	3,012	6	860
Total	**6,811,000**	**$159,720,006**	**100**	**$3,908**	**17**	**$1,044***

* The numbers do not add properly because of rounding.

Estimated Payments—Part B Post Device Replacement Claims
(*Limits Calculated at the 90-Percent Confidence Level*)

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$145,873,495	$36,705,697	1,103,303
Lower limit	69,759,948	17,695,274	657,913
Upper limit	221,987,041	55,716,120	1,548,693

Estimated Payments—Overall

	Medicare Payment	Beneficiary Copay and Deductible Liabilities	Claims Related to Recalled Devices
Point estimate	$1,496,429,848	$140,079,420	1,397,865

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JUL 21 2017

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma SV
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: With Claim Data for Recalled and Prematurely Failed Devices Lacking, Medicare Cannot Track Its Costs, Protect Beneficiaries From Unnecessary Costs, or Identify Poorly Performing Devices as Early as Possible (A-01-15-00504)

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.

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 payment in the form of 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

Continue to work with the X12 to ensure that the DI is included on the next version of claim transaction.

CMS Response

Similar to other policies under review by the new Administration, this policy is also under consideration. CMS will carefully evaluate the potential that this policy would impose burden on physicians unnecessarily.

OIG Recommendation

Require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure if the procedure resulted from a recall or premature failure independent of whether there was a device reported at no cost or with a credit.

CMS Response

CMS concurs with OIG's recommendation in cases where payment is impacted. Correct coding is key to submitting valid claims. Claims require the use of codes maintained by the National Uniform

Billing Committee, such as condition codes, which are entered by providers to describe any of the conditions or events that apply to the billing period covered by the claim.

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

ACKNOWLEDGMENTS

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