

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CMS DID NOT ENSURE THAT  
MEDICARE HOSPITAL PAYMENTS FOR  
CLAIMS THAT INCLUDED MEDICAL  
DEVICE CREDITS WERE REDUCED IN  
ACCORDANCE WITH FEDERAL  
REGULATIONS, RESULTING IN  
AS MUCH AS \$35 MILLION  
IN OVERPAYMENTS**

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# *Office of Inspector General*

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## Report in Brief

Date: November 2020

Report No. A-07-19-00560

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



### Why OIG Did This Audit

Medicare regulations and guidance require hospitals and ambulatory surgical centers (ASCs) to report the occurrence of credits received from manufacturers for replaced medical devices. Our audit focused on the risk that reported medical device credits may have been processed in a manner that resulted in Outpatient Prospective Payment System (OPPS) overpayments.

Our objective was to determine whether the Centers for Medicare & Medicaid Services (CMS) ensured that OPPS payments for claims that included medical device credits were reduced in accordance with Federal regulations.

### How OIG Did This Audit

We reviewed OPPS claims for calendar years (CYs) 2016 through 2018 that included both a medical device credit and a device offset amount to determine whether ambulatory payment classification payments were reduced for replaced medical devices in accordance with Federal regulations. Our audit included 4,637 OPPS claims totaling \$56.2 million that included both a medical device credit and a device offset amount. We also evaluated Federal requirements and CMS's policies and procedures to determine whether they were designed to ensure that payments for OPPS claims that included medical device credits were properly reduced.

## CMS Did Not Ensure That Medicare Hospital Payments for Claims That Included Medical Device Credits Were Reduced in Accordance With Federal Regulations, Resulting in as Much as \$35 Million in Overpayments

### What OIG Found

CMS did not ensure that OPPS payments for claims that included medical device credits were reduced in accordance with Federal regulations. These regulations require the use of the device offset amount—100 percent of the device offset amount for each without cost or full credit replacement device and 50 percent of the device offset amount for each partial credit replacement device—when calculating the reduced OPPS payment amount. By following the *Medicare Claims Processing Manual* (the Manual) instructions, Medicare administrative contractors (MACs) did not comply with these regulations when calculating the claims that we reviewed. As a result, Medicare made estimated overpayments of as much as \$35.4 million to hospitals for our audit period. This error occurred because as part of Federal rulemaking in CY 2014, CMS announced its intention to update Federal regulations to reduce OPPS payments for replaced medical devices. This intended update was not finalized in the text of the Federal regulations. However, CMS revised the relevant language in its guidance—the Manual.

### What OIG Recommends and CMS Comments

We recommend that CMS: (1) work with the MACs to recover from hospitals Medicare OPPS overpayments, which total as much as an estimated \$35.4 million; (2) work with the MACs to recover Medicare OPPS overpayments from hospitals for any additional claims that included medical device credits and that were outside of our audit period; and (3) revise the OPPS regulations or the Manual instructions to resolve the conflict between these requirements for OPPS claims with medical device credits.

CMS did not concur with our recommendations but acknowledged that it did not codify in regulations the changes made to the Manual for the calculation of medical device credits under the OPPS. CMS also said that we overstated the payment amount because we assumed that all medical device credits are full credits. We revised our third recommendation but otherwise maintain that our findings and recommendations remain valid. We acknowledge the steps CMS is taking to correct the oversight we identified but maintain that CMS is still required to collect the resulting overpayments.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Medicare regulations and guidance require hospitals and ambulatory surgical centers (ASCs) to report the occurrence of credits received from manufacturers for replaced medical devices. Medicare reimbursement for hospital outpatient services and ASC services are both based on the assigned ambulatory payment classification (APC), and, currently, the Outpatient Prospective Payment System (OPPS) regulations and the ASC prospective payment system (PPS) regulations require use of the same methodology to calculate medical device credits. We reviewed the calendar year (CY) 2014 OPPS regulation and found that the Centers for Medicare & Medicaid Services (CMS) proposed, but did not codify, changes to how medical device credits are calculated under the OPPS. However, CMS did not provide a reason for the change or consider making the same change to the ASC PPS. Instead, CMS merely revised the CMS guidance to reflect the proposed change to the OPPS calculation, and CMS began reducing the OPPS payments for claims that included a medical device credit in accordance with the revised CMS guidance rather than applicable regulations. Because the revised CMS guidance is inconsistent with Federal regulations for OPPS claims that included a medical device credit, our audit focused on the risk that reported medical device credits may have been processed in a manner that resulted in OPPS overpayments.<sup>1</sup>

### OBJECTIVE

Our objective was to determine whether CMS ensured that OPPS payments for claims that included medical device credits were reduced in accordance with Federal regulations.

### BACKGROUND

#### Hospital Outpatient Prospective Payment System

CMS implemented an 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>2</sup> All services and items within an APC group are comparable clinically and require comparable resources.

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<sup>1</sup> Our discovery of this conflict between Federal regulations and CMS guidance occurred while we were conducting a related audit involving OPPS payments for claims that include medical device credits and outlier payments.

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

## **Ambulatory Surgical Center Payment System**

In general, an ASC provides outpatient surgical services to patients who need no hospitalization. CMS implemented a revised ASC payment system, which is effective for services furnished on or after January 1, 2008, for these services. Like OPPS payments, Medicare pays ASCs on a rate-per-service basis that varies according to the assigned APC. CMS has estimated that average ASC payment rates have declined relative to OPPS payment rates over a recent 10-year period, from 65 percent of average OPPS rates in CY 2008 to 56 percent (as proposed) of average OPPS rates in CY 2018.<sup>3</sup>

## **Medicare Administrative Contractors**

Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. CMS administers Part B and contracts with Medicare administrative contractors (MACs) to, among other things, determine reimbursement amounts and pay claims, conduct reviews and audits, and safeguard against fraud and abuse. CMS relies on a network of MACs to serve as the primary operational contact between the Medicare fee-for-service program and the health care providers enrolled in the program. MACs calculate the payment for each outpatient service using the OPPS or the ASC payment system.

## **Reporting and Payment Reduction for Medical Devices Replaced Without Cost or When a Full or Partial Credit Is Received**

Medicare prohibits payments for 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 specify when hospitals and ASCs must report the replacement of a Medicare beneficiary's implanted medical device if the hospital or ASC receives a no-cost device or a full or partial credit for the cost of the replaced device. These regulations generally require reductions in OPPS and ASC payments for the replacement of certain implanted devices if (1) the device is replaced without cost to the hospital or ASC, (2) the hospital or ASC receives full credit for the device cost, or (3) the hospital or ASC receives a credit equal to 50 percent or more of the device cost (42 CFR §§ 419.45 and 416.179).

OPPS and ASC Federal regulations require payment reductions for medical device credits to be based on the device offset amount (42 CFR §§ 419.45 and 416.179). The device offset amount is CMS's best estimate of the device cost that is included in the APC payment. Appendix B contains additional information that defines the term "device offset."

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<sup>3</sup> 82 Fed Reg. 59216, 59422 (Dec. 14, 2017).

CMS guidance specifies how a hospital or ASC must report the occurrence of a medical device credit, as part of its claim under the OPSS or ASC payment system, each time the hospital or ASC:

- furnishes a replacement device received without cost or with a full credit or
- furnishes a replacement device for which the hospital or ASC receives a partial credit of 50 percent or more of the cost of a new replacement from a manufacturer, due to warranty, recall, or a defect in a previous device.

For ASCs, CMS guidance states that the ASC must report a modifier on claims that include a medical device (if replaced at no cost or if replaced with a full or partial credit). *Medicare Claims Processing Manual* (the Manual), Pub. No. 100-04, chapter 14, section 40.8. See also 72 Fed. Reg. 66580, 66845 – 66847 (Nov. 27, 2007). ASC payments are reduced based on the device offset amount (42 CFR § 416.179).

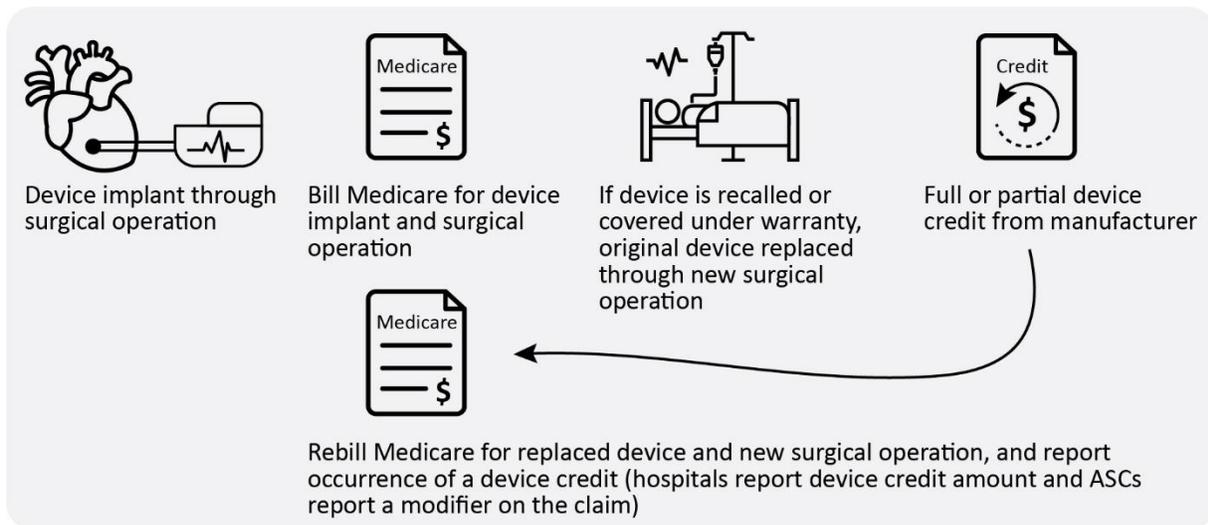
Before January 2014, for outpatient hospitals, CMS guidance also stated that the hospital must report a modifier on claims that include a medical device (if replaced at no cost or if replaced with a full or partial credit). The Manual, chapter 4, sections 61.3.1, 61.3.2, and 61.3.3. When a hospital reported this modifier, CMS guidance stated that the OPSS payment was reduced based on the device offset amount, which is consistent with 42 CFR § 419.45. The Manual, chapter 4, section 61.3.4. However, after CMS's publication in CY 2013 of an OPSS Final Rule effective for CY 2014 (the CY 2014 Final Rule<sup>4</sup>), CMS revised its guidance to state that, effective January 2014, hospitals must report the amount of the device credit in the amount portion of the value code and that OPSS payments for replaced devices are reduced by using the lower of the device credit reported with the value code or device offset amount. The Manual, chapter 4, sections 61.3.5 and 61.3.6. This Manual provision is inconsistent with the current OPSS regulation at 42 CFR § 419.45 and the ASC regulation at 42 CFR § 416.179.

The figure on the following page depicts the reporting and payment processes for medical device credits under the OPSS and the ASC payment systems.

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<sup>4</sup> 78 Fed Reg. 74826 (Dec. 10, 2013). See also Appendix B.

**Figure: Reporting and Payment Processes**



## HOW WE CONDUCTED THIS AUDIT

We reviewed OPPS claims for CYs 2016 through 2018 that included both a medical device credit and a device offset amount to determine whether APC payments were reduced for replaced medical devices in accordance with Federal regulations. Our audit included 4,637 OPPS claims totaling \$56,234,029 that included both a medical device credit and a device offset amount. We also evaluated Federal requirements and CMS's policies and procedures to determine whether they were designed to ensure that payments for OPPS claims that included medical device credits were properly reduced.

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

CMS did not ensure that OPPS payments for claims that included medical device credits were reduced in accordance with Federal regulations. These regulations, in effect since CY 2007 for full credits and CY 2008 for partial credits, require the use of the device offset amount —100 percent of the device offset amount for each without cost or full credit replacement device and 50 percent of the device offset amount for each partial credit replacement device —when calculating the reduced OPPS payment amount. By following the Manual instructions, MACs did not comply with these regulations when calculating the 4,637 OPPS claims for

CYs 2016 through 2018 that we reviewed. As a result, Medicare made estimated overpayments of as much as \$35.4 million to hospitals for our audit period.<sup>5</sup>

This error occurred because as part of Federal rulemaking in CY 2014, in the preamble, CMS announced its intention to update Federal regulations to reduce OPPS payments for replaced medical devices.<sup>6</sup> This intended update was not finalized in the text of the Federal regulations. However, CMS revised the relevant language in its guidance—the Manual. The revised language in the Manual stated that effective January 1, 2014 (before our audit period), the reduced OPPS payment amount would be calculated using the lesser of (1) the medical device credit or (2) the device offset amount. From that point forward, the reduced OPPS payment amounts were made in the manner prescribed in the Manual, but these calculations were incorrect because the CY 2008 regulations, which require the use of the device offset amounts (either 100 percent or 50 percent), were and are still in effect.

At that time, CMS provided no rationale for its change in policy, which was written in the preamble to the CY 2014 Final Rule and subsequent Manual revisions (which we discuss further below and in Appendix B). If CMS had updated Federal regulations in accordance with the preamble and Manual instructions, the OPPS and ASC regulations that reduce payment for claims that include a medical device credit would differ when the services are the same and basis for payment (i.e., the APC) are the same. Furthermore, the current CY 2008 OPPS Federal regulatory text is consistent with the text of ASC regulations for claims that included a medical device credit. Both of these regulations state that the payment will be reduced by the full device offset amount for a device replaced without cost or upon receipt of a full credit or will be reduced by 50 percent of the device offset amount for devices replaced with partial credit. Because the device offset amount is usually higher than the credit amount, the OPPS regulations generally result in a lower payment to providers when compared with the payment using instructions in the Manual.<sup>7</sup>

## **FEDERAL REQUIREMENTS**

Medicare prohibits payment for items or services for which neither the beneficiary, nor anyone on his or her behalf, has an obligation to pay (the Act § 1862(a)(2)).

Federal regulations in effect for our audit period require that reduced payment amounts be calculated in a similar manner both for payments under the OPPS and for payments under the ASC payment system.

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<sup>5</sup> We estimated the amount of the overpayments was as much as \$35,398,147. For our audit, we considered all replaced medical device credits as full credits because the claim processing system does not distinguish between full and partial credits as a result of the CMS's change to its guidance in CY 2014. In a related audit of 381 claims, we determined that 13 percent of claims with device credits were for partial credits.

<sup>6</sup> 78 Fed Reg. 74826, 75006 – 75007 (Dec. 10, 2013).

<sup>7</sup> We determined that 286 of the 4,637 claims reported a device credit that exceeded the device offset amount.

- Federal regulations generally require reductions in OPSS payments for certain procedures involving the replacement of an implanted device if (1) the device is replaced without cost to the hospital or the beneficiary, (2) the hospital receives full credit for the device cost, or (3) the hospital receives a partial credit equal to 50 percent or more of the device cost. The amount of the reduction to the APC payment is 100 percent of the device offset amount for no cost or full credit devices and 50 percent of the device offset amount for partial credit devices (42 CFR § 419.45).
- Federal regulations state that for certain procedures, when a replacement device is supplied to an ASC at no cost or with full credit by the manufacturer, the ASC payment for the procedure to implant the device is reduced by 100 percent of the device payment reduction. For partially credited replacement devices for which the ASC receives a credit of 50 percent or more of the estimated cost of the new replacement device, the ASC payment is reduced by 50 percent of the device payment reduction (42 CFR § 416.179).

These regulations are consistent with language in a Final Rule effective January 1, 2008. According to this CY 2008 Final Rule, the device offset amount, also referred to as the device offset percentage, is “our best estimate of the percentage of device cost that is included in an APC payment under the OPSS.”<sup>8</sup>

Appendix B contains additional Federal requirements.

**CMS DID NOT ENSURE THAT MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PAYMENTS FOR MEDICAL DEVICES REPLACED WITHOUT COST OR WHEN A FULL OR PARTIAL CREDIT WAS RECEIVED WERE PROPERLY REDUCED**

Medicare OPSS payments for claims that included medical device credits were not reduced in accordance with Federal regulations. These regulations, in effect since CY 2007 for full credits and CY 2008 for partial credits, require the use of the device offset amount—100 percent of the device offset amount for each without cost or full credit replacement device and 50 percent of the device offset amount for each partial credit replacement device—when calculating the reduced OPSS payment amount. MACs did not follow these regulations when calculating the 4,637 OPSS claims for CYs 2016 through 2018 that we reviewed, each of which included a medical device credit and a device offset amount. The CMS claim processing system did not properly reduce OPSS payments for claims that included medical device credits in accordance with Federal regulations; instead, it processed claims in accordance with Manual instructions. Because the reduced OPSS payment amounts were incorrectly calculated, estimated overpayments of as much as \$35.4 million were made to hospitals for our audit period (footnote 5). Appendix C provides examples of overpayments that resulted from using the Manual instructions to process payments instead of using the provisions of Federal regulations.

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<sup>8</sup> 72 Fed Reg. 66580, 66829 (Nov. 27, 2007). See also Appendix B.

## **CMS REVISED ITS GUIDANCE WITHOUT MAKING CORRESPONDING REVISIONS TO RELEVANT REGULATIONS**

In CY 2013, CMS published the CY 2014 Final Rule and revised Manual instructions for medical devices replaced without cost or when a full or partial credit was received. (See Appendix B.) In accordance with the preamble of that Final Rule, CMS revised its instructions in the Manual to read that effective January 1, 2014, for certain procedures, the Medicare hospital OPPS payment is reduced by the amount of the device credit for specified procedure codes reported with value code “FD.” The payment reduction is limited to the full device offset when the “FD” value code appears on a claim (the Manual, chapter 4, section 61.3.6).

However, although CMS revised instructions for calculating the reduction in the Manual, it did so in a manner that was inconsistent with the corresponding Federal regulations. MACs used the revised provisions in the Manual—which no longer aligned with the Federal regulations still in effect—to process claims for replaced medical devices. We estimated that, as a result of this inconsistency, Medicare paid as much as an additional \$35.4 million for replaced medical devices for CYs 2016 through 2018 (footnote 5).

## **OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER FEDERAL REGULATIONS ARE CONSISTENT FOR CLAIMS THAT INCLUDE A MEDICAL DEVICE CREDIT**

OPPS regulations (42 CFR § 419.45) and ASC regulations (42 CFR § 416.179) are consistent with each other and with the pre-CY 2014 OPSS Manual instructions for claims that include a medical device credit. The OPSS and ASC regulations require a reduction to payment for claims that include a medical device credit based on 100 percent of the device portion of the APC payment for full credits and 50 percent of the device portion of the APC payment for partial credits.

As part of Federal rulemaking in CY 2014, in the preamble, CMS announced its intention to update Federal regulations for the OPSS payment system to reduce the OPSS payment for medical device credits by the lesser of the device credit amount or the device offset amount. This intended update was not finalized in the text of Federal regulations.

## **CONCLUSION**

If CMS had updated the regulations for OPSS payments in accordance with the language in the preamble to the CY 2014 Final Rule, the OPSS and ASC regulations that reduce payment for claims that include a medical device credit would differ when the services are the same. The OPSS claims in our audit resulted in as much as a \$35.4 million overpayment because they were paid using Manual instructions instead of the current Federal regulations. An overpayment of this size adds credence to the idea that OPSS claims that include a medical device credit should be reduced in a manner consistent with the pre-CY 2014 OPSS Manual instructions. The pre-CY 2014 OPSS Manual instructions reduce payments for replaced medical devices using the device

offset amount, which we believe would result in greater cost savings for the Medicare program as compared to using the lower of the device credit or device offset. Furthermore, when CMS announced its intention to update the OPSS payment system, it did not provide a rationale for why the OPSS and ASC regulations and payment systems should differ for the same services.

## **RECOMMENDATIONS**

We recommend that the Centers for Medicare & Medicaid Services:

- work with the MACs to recover from hospitals Medicare OPSS overpayments, which total as much as an estimated \$35,398,147;
- work with the MACs to recover Medicare OPSS overpayments from hospitals for any additional claims that included medical device credits and that were outside our audit period; and
- revise the OPSS regulations or the Manual instructions to resolve the conflict between these requirements for OPSS claims with medical device credits.

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

In written comments on our draft report, CMS did not concur with any of our recommendations. CMS acknowledged, however, that in the process of updating the CY 2014 OPSS regulations it did not codify in regulation text the changes made to the Manual, effective January 1, 2014, for the calculation of medical device credits under the OPSS.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, are included as Appendix D.

After reviewing CMS's comments, we revised our third recommendation; otherwise, we maintain that our findings and recommendations remain valid.

## **CMS COMMENTS**

CMS did not concur with any of our recommendations. Regarding our first recommendation, CMS stated:

We appreciate the OIG [Office of Inspector General] identifying this oversight, which we have proposed to correct in the CY 2021 OPSS/ASC proposed rule displayed on August 4, 2020. However, the CY 2014 policy change related to OPSS payment for medical device credits was . . . finalized in notice-and-comment rulemaking and has been subsequently discussed in proposed and final rule preamble, the Medicare Claims Processing System manual, as well as the payment logic that determines OPSS payment for medical device credits.

Therefore, payment amounts that are greater under the policy change applied in CY 2014 than these payments would have been under the pre-2014 payment policy for no-cost/full credit and partial credits for medical devices would not be considered an ‘overpayment.’ These are correct payments based on the revised policy . . . .

Additionally, CMS expressed its belief that we are overstating the payment impact of the CY 2014 policy change. CMS referred to our “assumption . . . that all credits the hospitals reported [were] for full credit replacement,” and stated that “the sample claims include several examples where the amount of the credit is a very small percentage of the device offset amount.” CMS opined that the “additional payment amounts made under the revised policy compared to the previous policy would in most cases be fairly small as the additional payment amounts would be for situations in which the hospital receives a credit for the medical device but such credit is less than the reduction to the device portion of the Ambulatory Payment Classification payment amount under the pre-CY 2014 policy.”

Finally, CMS stated: “[t]he MACs have been expected to follow the policy set forth in CMS guidance and reflected in Medicare rules. While CMS routinely recovers payments for services provided to Medicare beneficiaries, the overpayments identified by the OIG are not subject to recovery given that they are based on policy that was changed in 2014.” CMS added that it would continue to educate the MACs and providers on proper billing of device credits under the OPSS, including the proper use of the value code “FD.”

Regarding our second recommendation, CMS referred to the reasons described above for its nonconcurrency with the first recommendation and restated some of those reasons.

Regarding our third recommendation, CMS stated:

the Medicare Claims Processing Manual correctly reflects CMS’s policy of 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, or the full offset amount from the Medicare payment. This current policy more closely aligns with reporting medical device credits under the IPPS than the previous policy. CMS notes that hospitals and ASCs use different claim forms and claims processing systems, and due to these differences, such as the ‘FD’ value code for device credits or the Comprehensive Ambulatory Payment Classification policy in the OPSS, CMS is unable to fully adopt OPSS payment policies into the ASC payment system.

CMS also stated that in the CY 2021 OPSS/ASC proposed rule, CMS proposed to revise the regulatory text to conform to the policy that was finalized in CY 2014.

## OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing CMS's comments, we revised our third recommendation to state that CMS either update the OPPTS regulations to be consistent with the Manual instructions or update the Manual instructions to be consistent with the current regulations. Otherwise, we maintain that our findings and recommendations remain valid.

We acknowledge the steps CMS is taking to correct the oversight in its CY 2014 Final Rule by proposing in the CY 2021 OPPTS/ASC proposed rule to update the regulation text to align with the CY 2014 policy change. However, when a conflict exists, a regulation takes precedence over CMS guidance, including guidance in preambles and Medicare manuals. Accordingly, our audit findings and recommendations are based on the regulation in effect during our audit period, not on the conflicting sub-regulatory guidance describing the CY 2014 policy change. Therefore, we maintain that our findings and recommendations are valid.

We also acknowledge CMS's comment (regarding our first recommendation) that we overstated the payment impact due to our assumption that all credits were full credits. It is correct that for this report we assumed that all credits were full credits; we did so for the reasons conveyed in footnote 5. That footnote states that in a related audit, we found that approximately 13 percent of claims with device credits were for partial credits. As footnote 5 states, the current payment system makes no distinction between full and partial credits that hospitals report. This fact creates the possibility that the estimated overpayments we identified may have been overstated. If the payment system identified partial credits, we would have calculated those claims in a different manner, which may have reduced our estimate of the total overpayments. Having said this, we do not believe that our assumption led us to significantly overstate the payment impact for this report on our current audit.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

We reviewed OPPS claims for CYs 2016 through 2018 that included both a medical device credit and a device offset amount to determine whether APC payments were reduced for replaced medical devices in accordance with Federal regulations. Our audit initially included 5,395 OPPS claims totaling \$65,837,413. We also evaluated Federal requirements and CMS's policies and procedures to determine whether they were effective in ensuring that payments for OPPS claims that included medical device credits were properly reduced.

Our audit objective did not require an understanding or assessment of CMS's complete internal control structure. We limited our review of internal controls to obtaining an understanding of the controls that CMS had in place to ensure the accuracy of the payments.

We conducted our audit from May 2019 to April 2020.

### METHODOLOGY

To accomplish our objectives, we took the following steps:

- We reviewed applicable Federal laws and regulations and CMS's policies and procedures pertaining to medical device credits.
- We used computer matching, data mining, and other data analysis techniques to identify claims in which medical device credits and device offset amounts were reported. Specifically:
  - We identified 5,395 OPPS paid claims that included a medical device credit.
  - We excluded claims that did not have both a medical device credit and device offset amount on the same claim (758).<sup>9</sup>
  - We identified the remaining claims (4,637), totaling \$56,234,029, that had both a medical device credit and a device offset amount.
  - We calculated the difference between the device offset amount and the lower of the medical device credit or the device offset amount for the 4,637 claims.
- We discussed the inconsistency between the Manual instructions and relevant Federal regulations with CMS officials on December 3, 2019. These officials concurred that the

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<sup>9</sup> These 758 claims did not include a device offset amount.

Manual instructions are inconsistent with Federal regulations for claims that include medical device credits.

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: FEDERAL REQUIREMENTS

### FEDERAL REGISTER PROVISIONS

The CY 2008 Final Rule established the payment methodology for ASC claims that included medical device credits:

Under the payment policy finalized in the revised ASC payment system final rule, we use a modified payment methodology to establish the ASC payment rates for device-intensive procedures (72 Fed. Reg. 42503). We identify device-intensive procedures under the revised ASC payment system as covered surgical procedures that, under the OPSS, are assigned to those device-dependent APCs for which the “device offset percentage” is greater than 50 percent of the APC’s median cost. The device offset percentage is our best estimate of the percentage of device cost that is included in an APC payment under the OPSS [72 Fed Reg. 66580, 66829 (Nov. 27, 2007)].

This payment methodology is included in Federal regulations at 42 CFR § 416.179, which was in effect for our audit period and which remains in effect. 72 Fed. Reg. at 66932. The Manual contained similar language.

The CY 2008 Final Rule also modified the payment methodology for OPSS claims that included medical device credits. This modified payment methodology is included in the Federal regulations at 42 CFR § 419.45, which was in effect for our audit period and which remains in effect. 72 Fed. Reg. at 66933. The preamble to the CY 2014 Final Rule explains the OPSS payment methodology as it is specified in the CY 2008 Final Rule. The preamble states in part: “For CY 2013 and prior years, our policy has been to reduce OPSS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device” (78 Fed. Reg. 74826, 75006 (Dec. 10, 2013)).

Additionally, the preamble to the CY 2014 Final Rule mentioned CMS’s intent to finalize a change to the OPSS payment methodology:

After consideration of the public comments we received, we are finalizing our CY 2014 proposal to modify our existing policy of reducing OPSS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, we are finalizing our proposal to require hospitals to report the amount of the 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 than the cost of the device. We also are finalizing our proposal to limit the OPSS payment deduction for the applicable APCs . . . to the

total amount of the device offset when the “FD” value code appears on a claim [78 Fed Reg. 74826, 75006 – 75007 (Dec. 10, 2013)].

Although the preamble mentioned CMS’s intent to finalize this change, the CY 2014 Final Rule did not change, revise, or update the OPPS payment methodology at 42 CFR § 419.45. Therefore, the regulatory text of 42 CFR § 419.45 as set forth in the CY 2008 Final Rule remains in effect.

## APPENDIX C: OUTPATIENT PROSPECTIVE PAYMENT SYSTEM OVERPAYMENT EXAMPLES

Below are 5 examples from the 4,637 claims we audited that illustrate the overpayments for processed claims based on the Manual instructions instead of on Federal regulations. In each instance, the claim resulted in an overpayment because it was processed based on Manual instructions.

The tables below show payment amounts for claims that were processed based on Manual Instructions, those that were processed based on the Federal regulations, and the difference between those amounts.

**Table 1: Claims Processed Using Manual Instructions**

<b>Example Number</b>	<b>APC Number<sup>10</sup></b>	<b>(a) Initial APC Claim Amount</b>	<b>(b) Device Reduction— Lower of Device Credit or Device Offset Amount<sup>11</sup></b>	<b>(a)–(b) Reduced APC Claim Amount— Based on Manual Instructions<sup>12</sup></b>
1	5232	\$29,801.05	\$19,665.00	\$10,136.05
2	5232	29,234.08	13,045.28	16,188.80
3	5231	25,893.23	12,500.00	13,393.23
4	5232	31,338.62	3,500.00	27,838.62
5	5193	8,934.98	1,225.00	7,709.98

<sup>10</sup> APC number 5231 is for a Level 1 Implantable Cardioverter-Defibrillator. APC number 5232 is for a Level 2 Implantable Cardioverter-Defibrillator. APC number 5193 is for Level 3 Endovascular Procedures.

<sup>11</sup> This amount represents the lower of the medical device credit or the device offset amount, whichever amount was lower for each claim.

<sup>12</sup> Each of these amounts represents the difference between the APC claim amount and the lower of the device credit or the device offset amount.

**Table 2: Claims Processed Using Federal Regulations**

<b>Example Number</b>	<b>APC Number</b>	<b>(a) Initial APC Claim Amount</b>	<b>(c) Device Offset Amount</b>	<b>(a)–(c) Reduced APC Claim Amount—Based on Federal Regulations<sup>13</sup></b>
1	5232	\$29,801.05	\$23,782.01	\$6,019.04
2	5232	29,234.08	24,409.56	4,824.52
3	5231	25,893.23	16,967.26	8,925.97
4	5232	31,338.62	23,658.59	7,680.03
5	5193	8,934.98	4,026.78	4,908.20

**Table 3: Overpayment Calculation**

<b>Example Number</b>	<b>(a)–(b) Reduced APC Claim Amount—Based on Manual Instructions</b>	<b>(a)–(c) Reduced APC Claim Amount—Based on Federal Regulations</b>	<b>Overpayment Amount<sup>14</sup></b>
1	\$10,136.05	\$6,019.04	\$4,117.01
2	16,188.80	4,824.52	11,364.28
3	13,393.23	8,925.97	4,467.26
4	27,838.62	7,680.03	20,158.59
5	7,709.98	4,908.20	2,801.78

<sup>13</sup> The difference between the APC claim amount and the device offset amount.

<sup>14</sup> The difference between amounts processed based on the Manual instructions and amounts processed based on Federal regulations.

*Administrator*

Washington, DC 20201

**DATE:** August 31, 2020

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

**FROM:** Seema Verma   
Administrator  
Centers for Medicare & Medicaid Services

**SUBJECT:** Office of Inspector General (OIG) Draft Report - CMS Did Not Ensure That Medicare Hospital Payments for Claims That Included Medical Device Credits Were Reduced in Accordance With Federal Regulations, Resulting in as Much as \$35 Million in Overpayments (A-07-19-00560)

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.

As part of CMS's effort to protect the 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 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, for 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> Prior to 2014, CMS required hospitals to use the "FB" or "FC" modifiers to report device credits, and the payment reduction was equal to the full offset amount for no-cost or full credits and 50 percent of the offset amount for partial credits. CMS made these changes to

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

more closely align with the manner in which the Inpatient Prospective Payment System (IPPS) processes credits for replaced medical devices and to provide more accurate OPSS payments when a hospital receives a medical device credit.

Since 2014, CMS has required the Medicare Administrative Contractors (MACs) to process claims with medical device credits in accordance with the revised policy. CMS updated our guidance to reflect the policy change in Chapter 4 of the Medicare Claims Processing Manual; however, as the OIG noted in their report, in the process of updating the CY 2014 OPSS regulations, CMS finalized the policy change but did not codify in regulation text the changes to how medical device credits are calculated under the OPSS. The CY 2014 policy change related to OPSS payment for medical device credits was finalized in notice-and-comment rulemaking and has been subsequently discussed in proposed and final rule preamble, the Medicare Claims Processing System manual, as well as applied to the payment logic that determines OPSS payment for medical device credits. CMS's policy is accurately described in the guidance and CMS has effectively communicated with MACs and providers the revised policy through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.<sup>2</sup> CMS will update the regulation text to align with our policy set forth in our guidance, and proposed to do so in the CY 2021 OPSS/Ambulatory Surgical Center (ASC) proposed rule displayed on August 4, 2020.

OIG's recommendations and CMS' responses are below.

### **OIG Recommendation**

Work with the MACs to recover from hospitals Medicare OPSS overpayments, which total as much as an estimated \$35,398,147.

### **CMS Response**

CMS does not concur with this recommendation. We appreciate the OIG identifying this oversight, which we have proposed to correct in the CY 2021 OPSS/ASC proposed rule displayed on August 4, 2020. However, the CY 2014 policy change related to OPSS payment for medical device credits was, as stated above, finalized in notice-and-comment rulemaking and has been subsequently discussed in proposed and final rule preamble, the Medicare Claims Processing System manual, as well as the payment logic that determines OPSS payment for medical device credits. Therefore, payment amounts that are greater under the policy change applied in CY 2014 than these payments would have been under the pre-2014 payment policy for no-cost/full credit and partial credits for medical devices would not be considered an "overpayment." These are correct payments based on the revised policy and the greater total payment amount results from a policy choice that was made for the CY 2014 final rule.

Additionally, we believe the OIG is overstating the payment impact of the CY 2014 policy change. The modifiers, which are used to indicate a change in the description of a procedure on a claim, should only be applied when the provider received a credit of at least 50 percent of the cost of the device. However, the OIG's assumption is that all credits the hospitals reported are for full credit replacement, and the sample claims include several examples where the amount of the credit is a very small percentage of the device offset amount. The additional payment amounts made under the revised policy compared to the previous policy would in most cases be fairly small as the additional payment amounts would be for situations in which the hospital receives a credit for the medical

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<sup>2</sup> April 2014 Update of the Hospital Outpatient Prospective Payment System (OPSS), Medicare Learning Network. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8653.pdf>  
*Medicare Overpayments for Outpatient Claims That Included Medical Device Credits (A-07-19-00560)*

device but such credit is less than the reduction to the device portion of the Ambulatory Payment Classification payment amount under the pre-CY 2014 policy.

The MACs have been expected to follow the policy set forth in CMS guidance and reflected in Medicare rules. While CMS routinely recovers payments for services provided to Medicare beneficiaries, the overpayments identified by the OIG are not subject to recovery given that they are based on policy that was changed in 2014. CMS will continue to educate the MACs and providers on proper billing of device credits under the OPSS including the proper use of value code FD.

### **OIG Recommendation**

Work with the MACs to recover Medicare OPSS overpayments from hospitals for any additional claims that included medical device credits and that were outside our audit period.

### **CMS Response**

CMS does not concur with this recommendation for the reasons stated above. The MACs have been expected to follow the policy set forth in CMS guidance and reflected in Medicare rules. The overpayments identified by the OIG are not subject to recovery given that they are based on policy that was changed in 2014. CMS will continue to educate the MACs and providers on proper billing of device credits under the OPSS including the proper use of value code FD.

### **OIG Recommendation**

Revise the outpatient hospital Manual instructions for medical devices replaced without cost or when a full or partial credit was received, and ensure that MACs reduce OPSS payment amounts for medical device credits, in a manner consistent with the OPSS and ASC regulations and the pre-CY 2014 OPSS Manual instructions.

### **CMS Response**

CMS does not concur with this recommendation. As stated above, the Medicare Claims Processing Manual correctly reflects CMS's policy of 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, or the full offset amount from the Medicare payment. This current policy more closely aligns with reporting medical device credits under the IPPS than the previous policy. CMS notes that hospitals and ASCs use different claim forms and claims processing systems, and due to these differences, such as the "FD" value code for device credits or the Comprehensive Ambulatory Payment Classification policy in the OPSS, CMS is unable to fully adopt OPSS payment policies into the ASC payment system. In the CY 2021 OPSS/ASC proposed rule displayed on August 4, 2020, CMS proposed to revise the regulatory text to conform to the policy that was finalized in CY 2014.