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.

The full report can be found at https://oig.hhs.gov/oas/reports/region7/71900560.asp.