Why OIG Did This Audit
Prior OIG audits with audit periods ranging from 2005 through 2016 found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for medical devices that were replaced. Specifically, hospitals did not always report to CMS device manufacturer credits that they received. One prior audit estimated that services related to the replacement of seven recalled and prematurely failed cardiac medical devices cost Medicare $1.5 billion during calendar years 2005 through 2014.

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

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

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

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

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

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