Report in Brief

Date: March 2018
Report No. A-05-16-00059

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

Why OIG Did This Review

Prior OIG reviews found that hospitals did not always comply with Medicare requirements for reporting credits received from manufacturers for replaced medical devices.

Recalls of medical devices can be quite costly to the Medicare program. A recent OIG review 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.

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

How OIG Did This Review

We obtained a list of warranty credits that two device manufacturers issued to hospitals for five cardiac medical devices that had been recalled or had high failure rates. We reviewed the 296 claims that we considered at risk for overpayment because the hospitals billed for a device-intensive procedure, received a credit of 50 percent or greater, and did not include a value code or modifier on the claim as required.

Our audit covered $7.7 million in Medicare payments to hospitals for 153 inpatient and 143 outpatient claims for replaced cardiac medical devices. These claims had dates of service during calendar years 2008 through 2013.

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

What OIG Found

All 296 payments reviewed for recalled cardiac medical devices did not comply with Medicare requirements for reporting manufacturer credits. Medicare contractors incorrectly paid hospitals $7.7 million for cardiac device replacement claims rather than the $3.3 million they should have been paid, resulting in potential overpayments of $4.4 million.

For all payments reviewed, manufacturers issued reportable credits to hospitals for recalled cardiac medical devices, but the hospitals did not adjust the claims with the proper condition codes, value codes, or modifiers to reduce payment as required. The overpayments occurred because Medicare controls were not sufficient to ensure that hospitals properly reported manufacturer credits for cardiac devices.

What OIG Recommends and CMS Comments

We recommend that CMS instruct its Medicare contractors to notify the 210 hospitals associated with the 296 claims with potential overpayments of $4.4 million so that those hospitals can exercise reasonable diligence to investigate and return any identified overpayments in accordance with the 60-day rule. We also recommend that CMS educate providers on the requirements for reporting manufacturer credits and instruct its Medicare contractors to implement a post-payment process to follow up with hospitals that submit claims for certain cardiac device replacement procedures to determine whether an adjustment claim should be submitted. Finally, we recommend that CMS consider studying alternatives to implementing edits in order to eliminate the current Medicare requirements for reporting device credits. The full text of recommendations can be found in the report.

In written comments on our draft report, CMS generally concurred with our first, second, and fourth recommendations and provided information on actions that it planned to take to address them. However, CMS did not concur with our third recommendation because not all devices replaced under warranty or due to recall will result in a credit affecting payment. This review and others have shown that hospitals are receiving reportable cardiac device credits and are not properly reporting these credits on claims. While we acknowledge that hospitals may not receive a reportable credit in all cases of cardiac device replacement, previous OIG reviews have found that credits are provided for most cardiac devices replaced within the product lifecycle or due to recall. We maintain that our recommendation is valid and that CMS should direct contractors to implement a post-payment process for claims with certain cardiac device procedures to ensure hospitals are complying with Medicare requirements for reporting manufacturer credits.