

# Medicare's Cost for Defective Cardiac Devices: \$1.5B Over 10 Years, Report Shows

According to a report released last month by the Department of Health and Human Services Office of Inspector General (OIG), Medicare paid out more than \$1.5 billion over a ten-year period to replace cardiac devices that were found to be defective.

The report, entitled "Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices," summarizes a review conducted by the OIG at the decade-old behest of the Centers for Medicare & Medicaid Services (CMS). In the Federal Register, CMS had highlighted its worry regarding Medicare payments for defective medical devices. The agency pointed to the absence of a means for estimating those expenditures, but said that it wished to find a way of looking into them.

The report states that the OIG's review was conducted with an eye toward meeting two major goals: (1) to explore whether claims data could track government payments for defective ("recalled or prematurely failed") devices, and (2) to estimate Medicare expenditures for seven different cardiac devices that were recalled by the manufacturer or that had prematurely failed.

## How the OIG arrived at its \$1.5 billion estimate

The OIG pored over Medicare claims submitted between 2005 and 2014 for all healthcare services rendered to enrollees who had received replacements for any one of seven recalled cardiac devices. From that subset, the auditors created a random sample of 526 claims and then dug deeper, requesting patient medical records to assess whether the reimbursed Medicare claims involved services needed because of a defective device.

As to the first goal of the review, the OIG discovered that Medicare costs associated with recalled or prematurely failed devices could not be tracked via claims data *only*. (And the OIG recommended that CMS add a field for device-specific information on its claims forms so that the agency could track costs involving defective devices.)

But claims data in conjunction with what the report called "complex and labor-intensive auditing procedures" yielded the \$1.5 billion estimate for the government's cost connected to faulty medical devices. Further, the report states that another \$140 million was paid out by Medicare beneficiaries in the form of copayments and deductibles regarding services surrounding these failed devices.

## Tens of thousands of patients affected

Although the OIG's report does not name the manufacturers of the seven faulty or recalled cardiac devices, it does state that around 73,000 Medicare beneficiaries were impacted, needing to have one of the devices (which include pacemakers and implanted defibrillators) replaced due to a recall, premature failure, infection, or "medically necessary upgrade." The report did not specify whether patients were harmed as a result.

The report notes that over the past six years, over 200 cardiac devices have been recalled; in the majority of instances, the recalls were voluntarily conducted by the product manufacturers when issues were discovered. According to the report, the recall of medical devices almost doubled in the period from 2003 to 2012.

## CMS amenable to OIG's recommendations

The OIG offers two recommendations in light of the audit: (1) that CMS continue its cooperation with the Accredited Standards Committee X12 to create a field for the Device Identifier (DI) on the next iteration of its claims forms, and (2) that CMS stipulate that hospitals use condition codes 49 or 50 when they submit claims involving the replacement of a recalled or prematurely failed device, regardless of whether or not the replacement device was



provided at no cost to Medicare.

The OIG reported that the CMS agreed with the first recommendation and stated that it is already “under consideration.”

Additionally, the CMS agreed with the OIG’s second recommendation, but only “in cases where payment is impacted.”

The OIG holds a broader view of the need to track that information, regardless of whether Medicare had to reach into its wallet, stating that including DI and using the aforementioned condition codes each time a faulty device is involved can “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.”

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