U.S. HOSPITALS FACING STEEP PENALTIES FOR MEDICAL DEVICE NON-COMPLIANCE

SPEND MEND

What the OIG Found:

210

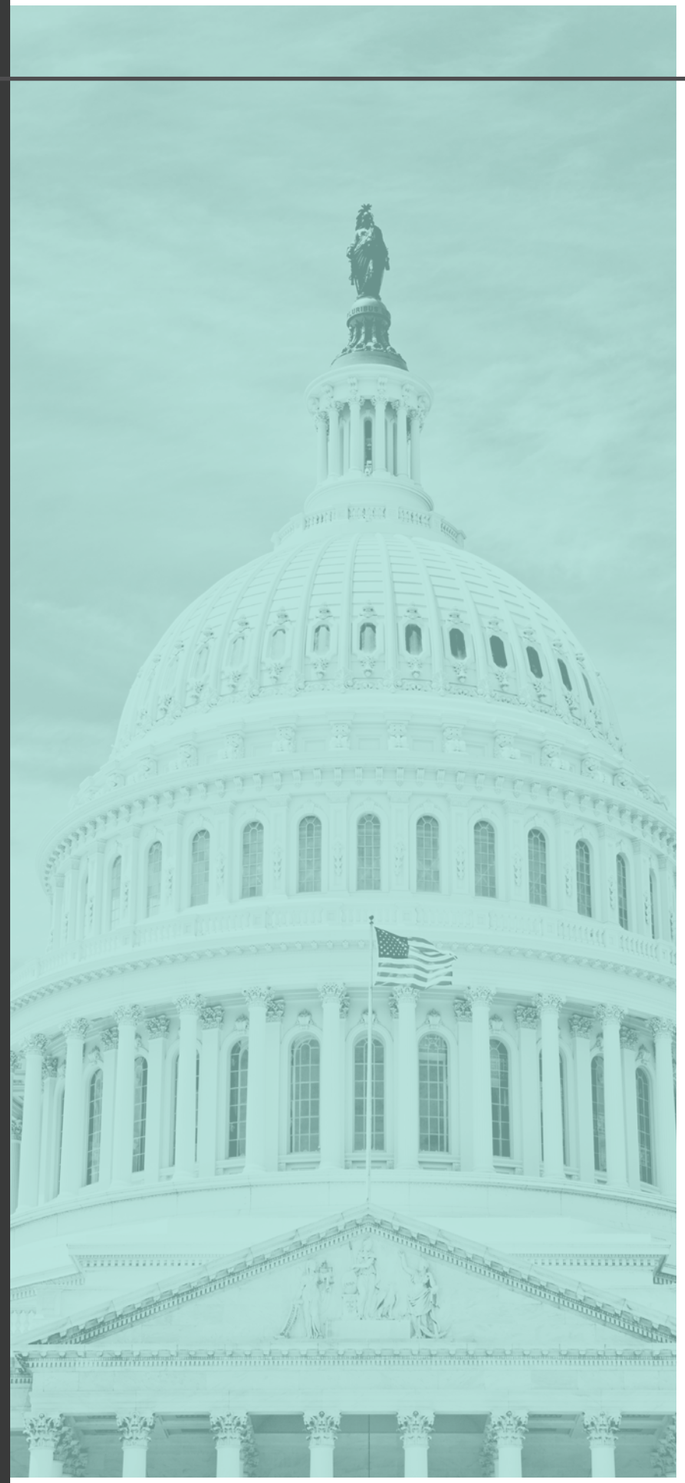
hospitals in the OIG sample audit

296

high-risk claims included in the audit sample

100%

of high-risk claims were out of compliance



The OIG Has its Sight Set on Healthcare

A recent sample audit completed by the Office of Inspector General (OIG) uncovered an unexpectedly high volume of medical device warranty overpayments made by the Center for Medicare and Medicaid Services (CMS). The audit discovered that hospitals receiving overpayments, overwhelmingly failed to return the unearned dollars back to the CMS.

In response to the findings, the Department of Health and Human Services (HHS) has tasked the OIG to continue auditing hospitals and identifying medical device warranty credits that have been inaccurately paid to hospitals and subsequently unreturned to CMS. To support the initiative, new legislation was signed into effect on November 1, 2018 encouraging risk-adjustment data-validation audits for all Medicare Advantage organizations. In other words, the OIG has its sights firmly set on auditing any and all hospitals which receive Medicare credits for medical devices.

All involved agencies expect the audit efforts to drive massive dollars back to government coffers. In fact, CMS has stated that by using extrapolation in RADV contract-level audits they will recoup $1 Billion in improper payments by 2020, as well as an additional $381 million a year subsequently.

The OIG's inspection of medical device warranty payments is nothing new, but in the past government agencies have not always imposed the strictest penalties and fees on hospitals that have fallen out of compliance with regulations. Anecdotal evidence suggests that the CMS "promise" to claim back billions of dollars in the next several years will drive a shift in behavior. Moving forward, hospitals which may have at one point been spared the hefty fines will now be forced to pay. As 2020 draws closer it is imperative that hospitals properly report medical devices or face financial penalties or jail time.

> "Acting Assistant Attorney General Chad A. Readler for the Justice Department's Civil Division states, "We are determined to hold accountable healthcare providers that knowingly claim taxpayer funds to which they are not entitled."

SPENDMEND

How Did All Of This Start?

The US Government is the largest purchaser of implantable medical devices in the country; spending $35 billion per year. During the years 2012-2014, Medicare paid $30 billion for cardiac devices alone. The extreme amount of money being spent by the government on medical devices led to a sample audit of hospitals by the OIG. The goal of this audit was to determine whether hospitals complied with Medicare requirements for reporting manufacturer credits associated with five recalled or prematurely failed cardiac devices.

A list of warranty credits from two device manufacturers issued to hospitals for the five cardiac devices was obtained by the OIG. From the sample of 210 hospitals - 296 claims were considered high risk because the hospital billed and received a credit of 50% or greater and did not include in the UB-04 a value code or modifier on the claim as is required.

All 296 reviewed credits did not comply with Medicare requirements for reporting manufacturer credits. Hospitals had been paid a total of $7.7 million for cardiac device replacements when the payment should have been $3.3 million. The resulting $4.4 million in overpayments proved Medicare is overpaying hospitals.

CMS has instructed Medicare contractors to notify the 210 hospitals associated with the $4.4 million in overpayments, exercise reasonable diligence to investigate, and return the overpayment according to the 60-day Rule.

The 60-day Rule states providers and suppliers receiving funds under the Medicare program are to report and return overpayments 60 days after the date the overpayment was identified, or the date the cost report is due. If the hospital does not pay or return the overpayments the claim is subject to the False Claims Act.

A hospital that fails to return the credit payment is subject to a minimum fine of $11,463 to a maximum of $22,927 per instance plus a penalty equivalent to 3X the value of the individual credit in question. A New York Times article dated May 4, 2017 stated a New York hospital had to repay $14 million in overpayments. If a violation of the False Claims Act occurs, then the penalty is transferred to individuals because an entity cannot be put in prison. The Department of Justice can end up pursuing criminal charges and a felony offense against individuals in hospital management including President, CEO, CFO, or Medical Director.

The Rules

The past 15 years have brought major developments to healthcare technology which led to an increase in surgically implanted medical devices. While these devices are designed to enhance life they will malfunction, fail, or have early battery depletion. Even devices like knees can fail or have a recall. Manufacturers of these errored products provide either a free replacement or a partial cost replacement.

The 50% Rule

When an item is explanted the hospital is required to find if the device is under warranty and available for credit or a no cost solution. The hospital sends the explanted device back to the manufacturer for testing to find where the failure occurred, and if applicable, follow up with a credit. This is where the hospital is supposed to report the credits received if the value is greater than or equal to 50% of the cost. This is called the 50% Rule. Legally the hospital must return the money credited to the payor of the initial procedure.

SPENDMEND

The Prudent Buyer Standard

Alternatively, if the malfunction occurs under warranty the Prudent Buyer Standard applies, which states a hospital owes the payor the warranty money even if the hospital does not send the explant for review or if they do not recover the funds.

> “They are doing more fishing than they were before,” says one compliance officer, whose hospital went through a medical-device audit.”

How Does This Cost You?

$11,463

minimum fine per instance

$22,927

maximum fine per instance

+3X

the amount of the credit

According to Regulation 31 U.S.C. 3729 of the False Claims Act

Where is the Process Breaking Down?

The short answer for this question is the noncompliance is a direct result of poor communication whether it is between hospital departments, the medical team, the product rep, different software, training methods, the manufacturer's internal review process, credit reporting, credit receiving, returns, reimbursement, and the list could continue.

Communication through the cycle of identifying, tracking, and reporting medical device credits are made more complex due to the explant process, number of departments involved, differing vendor return requirements, and a 3-6-month lag time to figure out the root-cause of the error which occurred. Within the hospital the breakdown can occur with a lack of ownership over the process. The departments involved with explants, recovery, notification, and reimbursement include: clinical, pathology, supply chain, compliance, finance, patient billing, and coding.

Manufacturers often complicate the process as well. A manufacturer will need documentation provided by the hospital before they test the explanted device. But of course, manufacturers have differing device return authorization processes, forms, and formats adding to the time lag between explant and credit assignment.

Once the hospital has received the credit check it has been months since the device was replaced and the Patient Billing Department has no idea the credit was received and has not revised the bill or has already submitted the claim for reimbursement. If the hoWspital does submit the claim to Medicare, the staff they must be made aware of the 50% Rule and the Prudent Buyer Standards

Due to the number of areas and errors can occur, and continuing attention to the issue from the OIG, CMS contractors will increase efforts to identify and recover medical device overpayments.

Ways To Reduce Risk

There are steps that can be taken to avoid liability and reduce risk.

First and foremost, hospitals should figure out their current situation and evaluate risk. Have a third party conduct an audit that provides both tracking and oversite. The oversite audit is important because it will catch what has been missed while tracking will be as effective as staff charting. An audit will also ensure your credits are pursued and claims adjusted properly while you work on process improvement.

When changing a communication-based problem it is important to have a champion or owner. The problem of a process this complicated is there are so many people involved internally and externally. It is imperative someone is in-charge of overseeing the project and keeping lines of communication open.

Explant Policy

Every hospital should have a robust and thorough Explant Policy. This policy should lay out the process with a system of checks and balances that includes:

1. Staff documentation of the type of device, manufacturer, and reason for explant in the medical record.

2. Physicians, nurses and techs are not to discard explanted items. The device may be subject to a warranty credit, discount or replacement at no cost.

3. Develop a report that provides a minimum data set for returns. Put a flag in the EMR when an accepted device is returned. The EMR should also have fields for device description and serial number. Return all explanted devices to the manufacturer due to recall, advisory notice, failure, malfunction, or suspected battery failure. DO NOT let the vendor representative take over the return process, or if they do initiate ensure there is a tracking sign off from supply chain to record in the ERP system which should include important data such as patient name, encounter number, and device serial number.

4. Ensure in the EMR that the RMA and return kit is obtained from the vendor, correctly filled out, and returned within 30-45 days. As previously mentioned, different manufacturers have varying processes, so an experienced staff member is needed here.

5. To aid in communication associated with returns create a specific form and process, which could be managed by supply chain. With every return have a product analysis and report should be provided to the hospital.

6. Pursue warranty credits based on only Medicare and other payor requirements.

7. Maintain an accurate list of reduced, no-cost, and recalled items.

The Explant Policy handles the removal of the device through the return, and a Reconciliation Policy should be put into place as well to close the return.

1. When a device is returned a field should be created that notes approved or denied in the EMR. If approved the claim is then sent to billing only if the credit is in the amount of 50% or more.

2. The billing department sets up flags for claims relating to replacement for later review and adjustment. made especially if the claim was previously submitted.

Also consider adding technology to reduce risk. Consider purchasing OCR technology that will allow for scanning and tracking of credit memos. This technology can consistently create notifications for Patient Accounts of any credit greater than or equal to 50% the cost of the device. Another option is a software program (designed) that will help with the tracking and communication from the explant procedure through remittance with Medicare.

Taking the time now and giving prompt attention to legal requirements put into place by the OIG will help your hospital lower vulnerability to large overpayments and False Claims Act liabilities. Hospitals failing to take action to improve process flow or audit themselves will find themselves subject to an OIG and CMS audit and overpayments.

CONTACT US:

616.777.0687
hello@spendmend.com
www.spendmend.com

SPEND MEND