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Hospitals Hit Snags With Device Credits; Mayo Has Workflow to Improve Reporting

The HHS Office of Inspector General continues to find overpayments for manufacturer credits for replaced medical devices, possibly because it's not the easiest compliance problem for hospitals to solve. Identifying and reporting device credits requires something along the lines of Hands Across America—a lot of people have to be involved to pull it off—but hospitals are hammering away at compliance improvements in this area.

"This is not a simple process, nor is there one solution," says Jesse Schafer, explant control manager for Mayo Clinic. His position—a joint creation of the integrity and compliance office and the supply chain department—is an attempt to address the formidable challenge of identifying and tracking explanted medical devices and passing on the credits to Medicare, as required by CMS. Mayo Clinic has analyzed the obstacles to compliance and developed a workflow to help ensure that explanted devices are followed from shipping to the manufacturer through claim adjustment, Schafer says.

Manufacturer credits for explanted medical devices often turn up in OIG audits (*RMC 5/8/17, p. 1*). When patients need their medical devices replaced because they malfunctioned or are recalled, manufacturers may refund all or some of the cost of the replacement device, depending on its age (and whether warranties apply). CMS requires hospitals to pass on credits to Medicare, which foots the bill for surgeries to implant replacement devices. Medicare uses credit information on claims to reduce payments for inpatient and outpatient procedures performed to replace or fix faltering devices, such as pacemakers and defibrillators. If hospitals neglect to pass on the credits, they may face recoupment in an OIG audit, and the dollars can swell through extrapolation.

In a way, the area sounds straightforward—hospitals are obliged to give Medicare the credits they receive from manufacturers when devices are replaced—but getting from Point A to B can be harrowing. It's not always easy to determine which devices are eligible for credits, and some credits don't have to be passed along to Medicare. But there are ways to improve the process, Schafer says.

"Mayo Clinic's approach is to send back all devices" when they're removed because of malfunctions, early battery depletion, recalls and advisories or other eligible conditions, he says. "We are putting the onus on the vendor to approve or reject. We are proactive in returning any devices that are potentially eligible for warranty, which places the hospital in the best position for the vendor to make a final determination on eligibility."

There Are Many Roadblocks to Compliance

The road to compliance is paved with good intentions, but first it has to be cleared of obstacles. Here are some of them:

◆ There are too many fingers in the pie. It takes a lot of people to identify, track and report credits, which touches a number of departments, including materials manage-

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ment, revenue cycle, accounts payable, compliance, data management and clinical departments. That usually isn't a recipe for compliance. "It's hard to know who owns the medical device warranty credit process," Schafer says.

◆ Device-credit eligibility can be confusing. There's uncertainty about which devices are eligible for warranty. It depends on the duration of the implant (e.g., has the warranty expired?) and the circumstances of the removal.

◆ Device-intensive procedures muddy the waters. It's a challenge to determine which devices are part of device-intensive procedures, Schafer says. CMS identifies these devices by HCPCS and MS-DRG codes, which indicate that 40% or more of the cost of the procedures are attributable to the device, he says. "If hospitals don't reference these device-intensive procedures lists, they may be overlooking specific devices that are likely to have eligible warranties. The scope of devices includes cardiac devices (e.g., pacemakers), cochlear implants, neurostimulator devices and joint replacements.

◆ Different manufacturers have disparate device return authorization processes. Some device manufacturers give hospitals a return kit in advance of the explant procedure, while some send it after and some don't send a kit at all, Schafer says. But most require a return merchandise authorization (RMA), which extracts details about the patient and the explanted device, before they will accept the explanted device. It's a burden on the hospital to have to complete different forms that demand different details in varying formats.

◆ Credit memos from device manufacturers shed little light on what devices are eligible for warranties. Hospitals receive thousands of credit memos, which Schafer says are like IOUs to the hospital, every year, but they may not explain what they're for. "It can be very challenging to interpret a credit memo as belonging to an explanted device," he says. Local device sales representatives may fill out the return kit for the hospital, and "that level of service feels helpful, but it also creates a relationship of dependence and lack of transparency—a black hole where the fate of the warrant claim and credit decision may go undetected," Schafer explains.

◆ Ensuring all device credits are applied to claims and/or the Medicare cost report can be difficult. All rebates and credits go on the cost report, Schafer says. If they are worth 50% or more of the price the hospital paid for the replacement device, the credit must also be reported as a deduction on the patient claim (*RMC 2/8/16, p. 4)*. That means Medicare pays less for the procedure performed to implant the replacement device.

Pop-Ups Remind People About Warranty Eligibility

In light of the formidable challenge of identifying and tracking device credits, Schafer recommends assigning a team inside the hospital that can consistently package and ship the explanted device. "It greatly improves the hospital's awareness of device tracking as compared to when the vendor representative handles the return," he says. To increase the efficiency of acquiring the RMA, which varies by manufacturer, Mayo Clinic created a two-page standardized data collection sheet with patient and device details. "It attempts to capture and provide a common set of minimally required information, which provides a consistent starting point for initiating the returns process," Schafer says.

Mayo Clinic also developed policies and procedures endorsed by leadership and a detailed process to bring them to life. Mayo Clinic uses job aids, checklists, work flows and pop-ups in its electronic health record (EHR) to remind surgical staff when the explant is potentially eligible for warranty coverage (see box, p. 3-4).

It's also essential to identify incoming credits that are attributable to the explanted device and determine the credit vs. replacement device cost ratio for purposes of the 50% rule. "That's the backbone of our process," Schafer notes. Explanted devices should be followed

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Medical Device Explants: Improving the Process for Reporting Credits

Information for Device Credits: Here are examples of the patient and device details that manufacturers typically request about explanted devices when initiating the device returns process, says Jesse Schafer, explant control manager at the Mayo Clinic (see story, p. 1). Contact Schafer at schafer.jesse@mayo.edu.

Category	Information*
Facility information	Facility name, contact info
Contact information	Contact name, title/function, contact info
Patient information	Name, DOB, gender
Device/lead information	Manufacturer, product description, model, serial/lot, implant/explant dates
Provider information	Implant/explant physician, contact info
Yes/No/Unknown	● Device replaced? ● Device failure or malfunction suspected? ● Device suspected to have caused serious patient harm or injury? ● Did event occur at a hospital, during surgery or have direct patient impact? ● Did medical professional allege a deficiency in the device performance? ● Single-use device that was reprocessed and reused on a patient?
Additional information typically requested (if available)	● Reason for device removal ● Relevant clinical history ● Relevant test data
Claim information (yes/no)	● Date of event ● Product return kit requested? ● Device evaluation requested? ● Destructive analysis permitted? ● Device stored in formalin? ● Device disinfected? ● Who should return kit be mailed to? ● Was vendor rep involved with case?

**Information commonly requested by the device manufacturer*

Workflow for Pursuing Device Warranty Credits: Here are examples of the steps that Mayo Clinic takes when pursuing device warranty credits.

Phase	Action	Detail
1	Procure, document, package and ship device	● Identify and set aside all devices with potential warranty claim eligibility ● Document relevant patient and device data ● Package and ship per vendor instructions
2	Claim follow-up, claim outcome, credit recognition	● Contact vendor to reconcile shipped devices against credit outcome ● Document credit outcome (approved, denied, pending) ● Document credit approval amount or denial reason ● If approved, affirm receipt of corresponding credit memo or part/product replacement
3	Apply 50% rule, adjust patient claim (as needed)	● Apply 50% rule on credits received ● If required, route credit for patient claim adjustment
All	General	● Document all steps of the warranty claim activity ● Track progression of each device ● Establish controls and internal reporting to monitor for devices that get 'stuck' in the process

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from shipping to credit outcome to credit received to patient claim adjustment. To smooth the way, Mayo Clinic has an automated reporting feature that flags returned devices. That way, billing can be adjusted or, if documentation of the credit outcome is missing, Mayo Clinic can follow up.

Fate of Device Is Closely Monitored

As part of its compliance improvements, Mayo Clinic co-developed technology with Champion Healthcare Technologies that enables hospitals to track potential credits and assign them to specific devices. But not everything is about technology. Schafer has identified local "champions" at Mayo Clinic's various departments to help maintain and improve workflows. "It's intuitive for people to think 'If I write a policy, I fixed the problem,' but unless it ties into the day-to-day workflows of end users, it doesn't change anything," he says.

Here is Mayo Clinic's workflow for improving compliance with the medical device explant control process:

(1) The surgeon lets the nurse or technician know the reason for the device removal.

Medical Device Explants: Improving the Process for Reporting Credits (continued)

General Guidance about Device Credits: Here's a brief overview of elements relevant to the device warranty claim process.

Topic	Notations
Device cleaning	Follow manufacturer instructions.
Device packaging	Follow manufacturer instructions.
Device shipment	For cardiac devices, obtain pre-paid return kit from vendor/sales rep. For surgical devices, contact vendor/sales rep to request return merchandise authorization (RMA). Obtain pre-paid return kit (if available). Document package tracking # for troubleshooting purposes.
Credit memo tracking	Document device serial, RMA and PO. Cross-reference these numbers against incoming credit memos to detect warranty credits on explanted medical devices. Scanning technology is available.
Electronic Health Record (EHR) documentation	Common device data for warranty purposes: device model/serial, implant/explant date, implant/explant physician, explant reason.
Monthly explant credit summaries	Some manufacturers will provide monthly summaries of credits issued specific to medical device explants.
Protected Health Information (PHI)	Manufacturers sometimes request additional data that may not be minimally necessary. Advise development of hospital policy for disclosure of PHI.
Warranty conditions	Warranties for implantable medical devices typically require product replacement with another device of the same type from the same manufacturer. A return window of 30-45 days post explant may also be enforced.
Warranty outcome	Manufacturers may reserve the right to thoroughly inspect the device and to request additional clinical information. Determination of warranty outcome can take 60-90 days. Approved warranties typically are communicated in the form of credit memo via US mail. Other approved warranties are restricted to product/part replacement only.

Source: Mayo Clinic

(2) If the device is potentially eligible for warranty coverage, the returns process is set in motion.

(3) A pop-up appears in the EHR system, informing the nurse or tech to send the device to a central location, such as pathology.

(4) The supply chain or clinical support services department runs a report in the EHR and retrieves the device.

(5) The two-page form required by vendors is completed and routed to accounts payable (AP) "because the hospital needs to work with the vendor to initiate the returns process," Schafer says.

(6) The device return, including the device serial number, is logged into Mayo Clinic's enterprise resource planning system. This is used to note that devices are shipped with potential credits. Cardiac devices can be immediately shipped because a return kit is typically available in advance from the sales rep, while non-cardiac devices must be obtained from the vendor as needed.

(7) After 60 days, Mayo Clinic follows up with manufacturers if they haven't made credit determinations.

(8) When credits are approved, manufacturers usually issue credit memos. To make the connection between generic credit memos and specific devices, Mayo Clinic uses an optical character scanning tool. It matches data points between the serial number RMA or purchase order with the credit memo. "If a match is made against the device serial number, RMA or purchase order, the credit is identified as belonging to an explant. Credit memos not automatically recognized are manually reviewed," Schafer says.

(9) All explant credits are logged in the enterprise resource planning system and EHR, which calculates the value of the credit relative to the cost of the replacement device. "If the ratio is equal to or more than 50%, the EHR generates an automated email to revenue cycle, with relevant data to prompt the adjustment of the patient claim to the insurer," he says.

Schafer suggests keeping a centralized record of claim activity for audit and control purposes. "We maintain a centralized record in the EHR of all phases—what we explanted, the reason for the explant, what we shipped, what the credit outcome was, the credit amount (or denial reason) and the patient claim activity," he says.

Contact Schafer at schafer.jesse@mayo.edu. ✧