SPEND MEND

Making the Case for a Medical Device Explant Warranty Tracking Solution

written by:

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The Background

Medical Devices are sometimes recalled or fail before their life expediency and need to be replaced. Manufactures offer warranty credits when this occurs. If those credits are equal or exceed 50% of the original cost of the device, those monies need to be reported to CMS as over payments. If the warranty is 49% or less the hospital may keep the warranty monies.

The Office of Inspector General conducted audits in 2005 and 2016 to assess compliance to the federal reimbursement laws. The OIG 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 consistently report to CMS device manufacturer credits that they received. The 2016 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.

The most recent audit released in November 2020 reported that hospitals continue to struggle with compliance. The audit found several consistent areas of failure.

Billing Systems

- Systems not updated to reflect changes in 2014 regarding new condition and value codes. Additionally, hospitals that have made updates to their systems are not using the code when updating the UB-04 on original or resubmitted claims.

Lack of Written Policies and Procedures

- Health systems either have inadequate or lack written policies and procedures or do not enforce the current ones in place.

Insufficient Communication

- Lack of interdepartmental communication when receiving reportable claims. The audits clearly show that hospitals are getting 25% of the credits in time to submit them on the original claim and 81% on the 90-day resubmission.

Inadequate Compliance Testing

- Many factors contribute to this including lack of internal resources or expertise, difficulty collecting the data both from the facility and the vendors.

Vendor Involvement

- Hospitals relied upon the vendor to manage the device return and credit process and gaps resulted.

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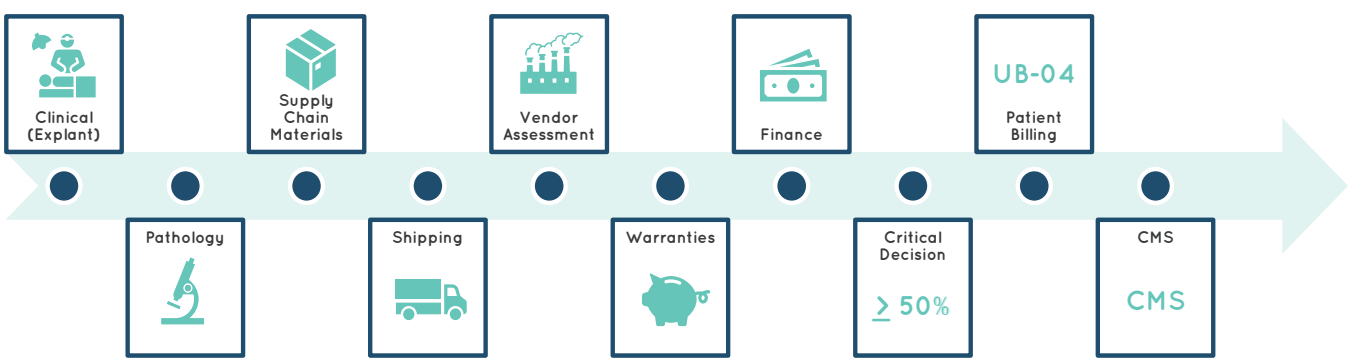
The Cost of Non-Compliance

This could be very significant for our Health System as the OIG under the False Claims Act [31 U.S.C 3729-3733] and Prudent Buyer Standard [42 CFR 413.9 & 1003.103] has implemented fines and penalties for failure to comply with CMS requirements. This includes potential jail time for our executive team if the facility is convicted of Medicare fraud. It is important to understand our health system owes Medicare warranty credit monies for explanted Medical Devices regardless of whether we do or do not send the explant in for review to peruse the warranty credits. Below is the current penalty and fines the OIG is levying:

- Fines: $11,463 minimum and $22,927 maximum per instance of non-compliance
- Hospitals owes 3 times the credit amount received
- Additionally, consider the lost revenues associated with all explants that are not returned or are returned after the 30-day return window. When the credit is below the CMS 50% threshold that is the revenue our hospital can keep.

Complexity of Compliance

There are multiple departments involved in the process of Medical Device Explant replacement and compliance tracking as the graphic below outlines.



Each department has their own procedures and software to track their piece of the process. Reliance on the vendor in any aspect of the process adds to the complexity and leads to additional gaps in compliance.

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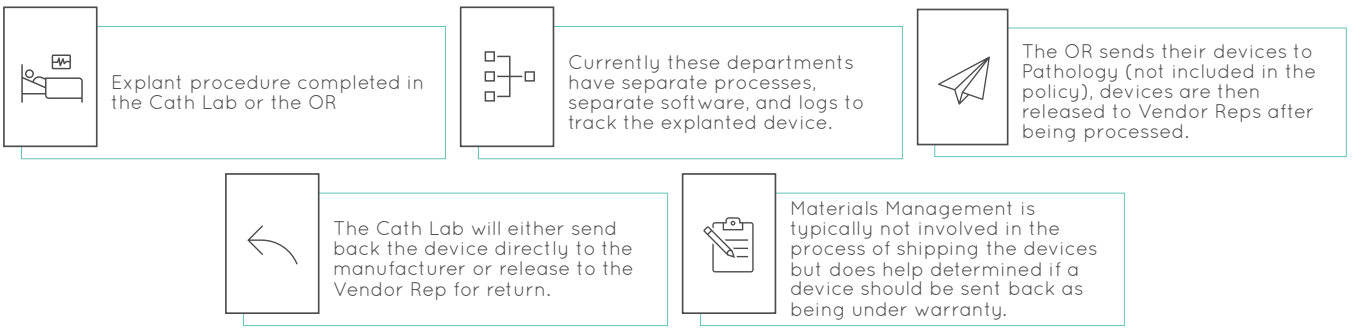
A typical flow for managing medical device credits falls roughly along the following 5 steps:



Unfortunately, this preceding process flow faces many challenges and as demonstrated in the OIG report the process can fail frequently. Healthcare Systems need to be aware of the typical areas of failure represented in the following list:

1. Clinical Areas Product Collection

- Device discarded or given to patient Device improperly cleaned/sterilized
- Device not recognized as requiring return under warranty program
- Vendor rep wrongly indicates that item no under warranty
- Vendor rep takes device and fails to properly initiate claim
- Non-standard workflows

2. Shipment Process

- Vendor box or kit used, but tracking number not captured
- Vendor rejects item because past the 30-45-day return window warranty is expired
- Return Merchandise Form not completed.

3. Vendor Process

- Vendor unable to obtain sufficient info
- Device evaluation not requested
- Product analysis report not requested
- Vendor never processes warranty claim

4. Credit and Finance Process

- Patient name and device serial number not documented
- Credit memo is not detected as explant and applied to outstanding invoice
- 50% rule not calculated correctly
- Explant returns and credits not reconciled
- Patient Accounts never notified of credit received
- Patients claim not adjusted via the UB-04

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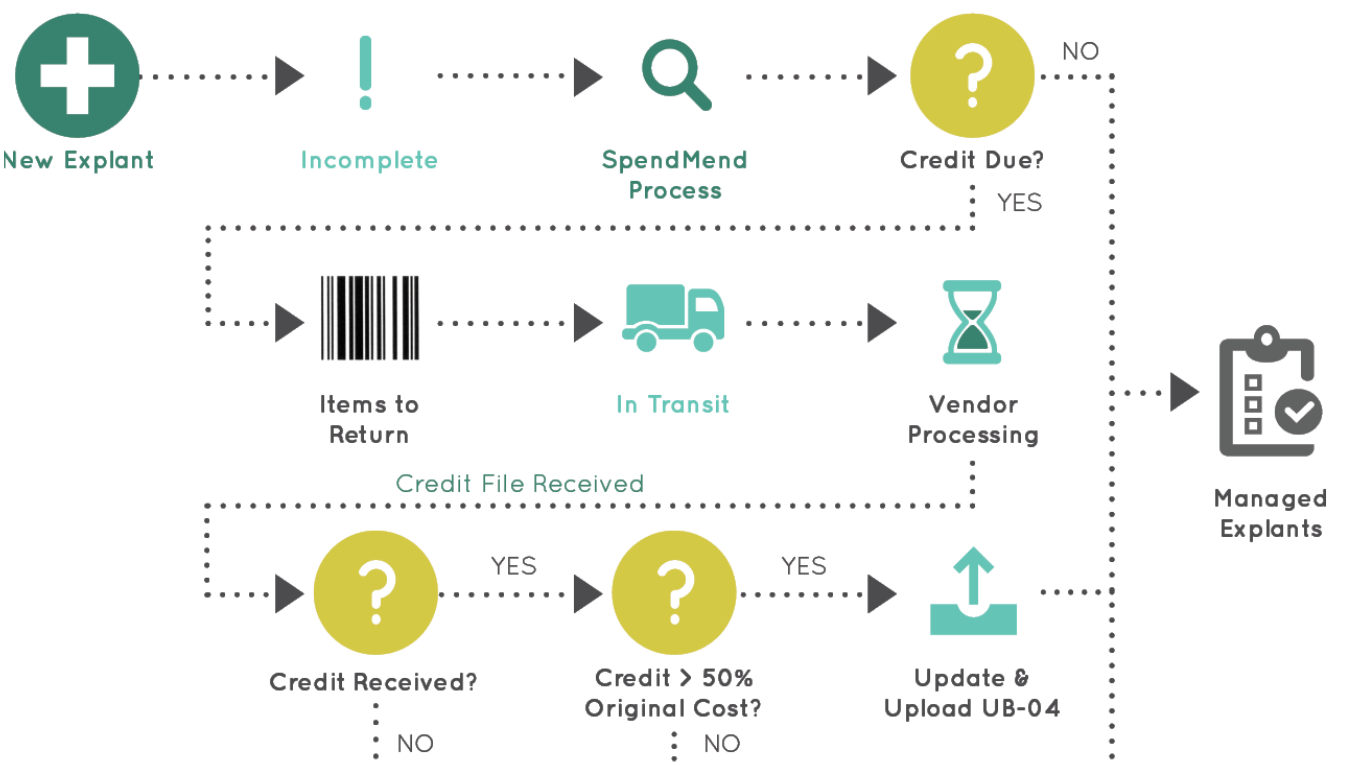
SpendMend's Solution

SpendMend will provide both a tracking software and service component to standardize and provide insight into the Medical Device Explant Warranty Process for our health system. This process is a low frequency high risk process that requires consistent execution from multiple departments. As part of their solution SpendMend will audits the last four years to assess past or current risk. This will allow our Health System to self-report any past monies owed to CMS which mitigates and possibly eliminates the potential fines and penalties that could enforce if the OIG would uncover them in an audit.

1. The software is a HIPPAA and HITECH compliant cloud-based portal designed to standardize workflow, communication, and visibility into the process across the health system. The workflow (screen shot below) follows and meets all CMS and OIG standards. . The tool provides a single point of access and data repository eliminating department specific logs, spread sheets and the FTE hours to fill and maintain them. All explants are entered into the software, significantly reducing errors in clinical or vendor rep decision making and leading to improved resource allocation.



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2. The Service component of SpendMend's solution is critical to hospital compliance. An Integral part of the software, SpendMend stays involved as an ongoing partner in the process. Every Medical Device Explant is reviewed by the SpendMend team to assess for complete documentation and warranty eligibility. If there is missing documentation or documents our Health System will be notified via a task in the system. SpendMend has an extensive data base of vendor and product warranties. The hospital is notified with in 24 business hours if an explant is under warranty. A warranty summary along with applicable RMA forms and shipping label is created in the system for our staff to print off and use to send back the explant. The explant is tracked to the vendor validating that the item is received with in the required time frame. The software notifies the hospital when a credit is issued and assess if the credit meets the 50% threshold of repayment. The system notifies and emails both hospital finance and patient billing alerting them of the issued credit. The system notifies patient billing contacts for any needed billing revisions on the UB-04.

3. SpendMend's solution will also help with ongoing compliance and provide and annual audit as they will aggregate warranty information from the various departments SpendMend will alert the hospital if a department is out of compliance. SpendMend's solution will also provide reporting from the Portal which is essential for internal compliance reviews. This will also be the complete source of data should our health system be audited by the OIG.

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Financials and ROI

The solution is delivered as an annual subscription that includes the Mock OIG audit to identify non-compliance and risk, along with the software solution to standardize the process going forward. There are one-time fees for the implementation, training, and the audit.

The Mock OIG audit typically identifies $500,000-$3,000,000 in liability and $50,00-$250,000 in lost opportunity for not returning explants. Credits for the hospital range between $0-$100,000 depending on credit age and vendor claim restrictions.

Operational efficiencies are realized by eliminating multiple spread sheets and data entry. The solution creates a single data base that all departments can use to track and communicate through the process.

The system provides an ROI annually and provides peace of mind that the organization will be prepared should the OIG want to audit your facility.

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