Medical Device Replacements

Compliance Insights for Device Warranty Credits and No Charge Devices

Brenda Mickow, Revenue Compliance Officer
Jesse Schafer, Explant Control Manager
Mayo Clinic

Mayo Clinic Scottsdale, AZ

Mayo Clinic Rochester, MN

Mayo Clinic Jacksonville, FL

Mayo Clinic Health System

What We Will Cover

- History: the risk associated with Medicare's device warranty credit and no charge device requirements

- Process: how a large multi-site, multi-specialty academic medical center improved processes around cardiac and surgical device returns

- Metrics: tracking and trending to monitor device returns and credits

Implantable Medical Device

- Devices surgically implanted that are designed to remain in the patient after the conclusion of the procedure for one or more of the following benefits:
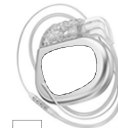

| Limb or joint replacement | Medication delivery | Organ support | Monitoring and Therapy |

Medicare Regulation

- All eligible explanted medical devices must be pursued for warranty credit and no-charge replacement. If the discounted replacement device cost is lower than half of the cost of the device, it must be reported on the claim.

Warranty

Problem device

Product Recall

≥50%

Medicare
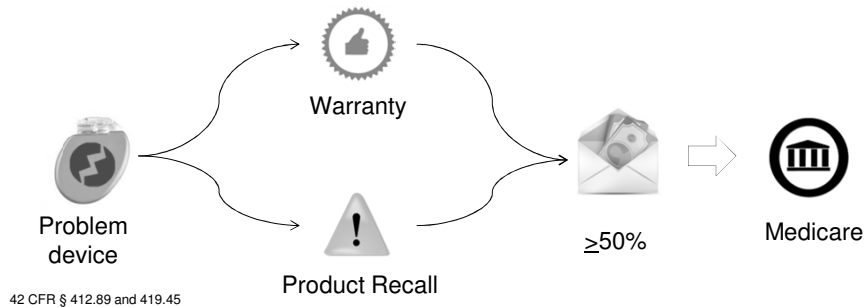
42 CFR § 412.89 and 419.45

Office of Inspector General (OIG) Audit Findings

- 2018 national cardiac audit
  - OIG pulled list of cardiac credits reported by vendors 2008-2013
  - Five devices targeted due to recalls/failures
  - 300 'at risk' claims from 210 hospitals
  - 4.4M in credits paid by vendors never routed to Medicare

OIG (2018, March). *Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits.* Retrieved from www.oig.hhs.gov

Office of Inspector General (OIG) Audit Findings

- 2016 national cochlear audit
  - Audit period 2012 - 2014
  - Estimate $2.7M in Medicare overpayments due to devices replaced with reduced cost
- 2010-2017 general and cardiac audits
  - Medical device overpayments of $30-300k <u>per</u> hospital

OIG (2016, Nov 22). *Hospitals Did Not Always Comply With Medicare Requirements for Reporting Cochlear Devices Replaced Without Cost.* Retrieved from www.oig.hhs.gov
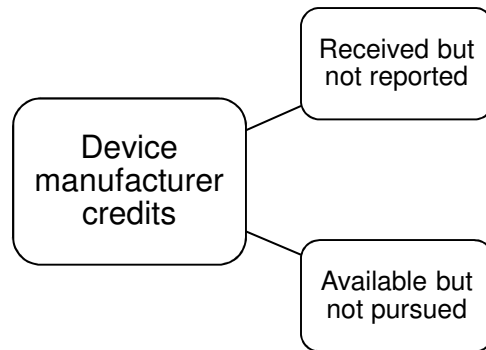

OIG Recommendations

- Require up-front use of condition codes 49 and 50 for certain cardiac replacement procedures due to recall and premature failure prior to vendor credit outcome. Medicare contractor follows up with hospitals to confirm outcome of potential credits and claim adjustment.

- Consider studying alternatives to implementing edits in order to eliminate the current Medicare requirements for reporting device credits, for instance, by reducing IPPS and OPPS payments for device-intensive procedures.

OIG (2018, March). *Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits.* Retrieved from www.oig.hhs.gov

OIG Recommendations

• Hospitals accountable for …

```
          ┌──────────────┐
          │ Received but │
          │ not reported │
          └──────────────┘
┌──────────────┐
│    Device    │
│ manufacturer │
│    credits   │
└──────────────┘
          ┌──────────────┐
          │ Available but│
          │  not pursued │
          └──────────────┘
```

What Got Us Where We Are Today?

• Observed industry

• Performed self-evaluation

• Requested internal audit

• Recognized opportunity

• Support of a dedicated resource

Our Initial Approach

- Performance improvement project
  - Existing stakeholders
- Hired dedicated resource
  - Required close coordination across clinical practice, supply chain, and revenue cycle
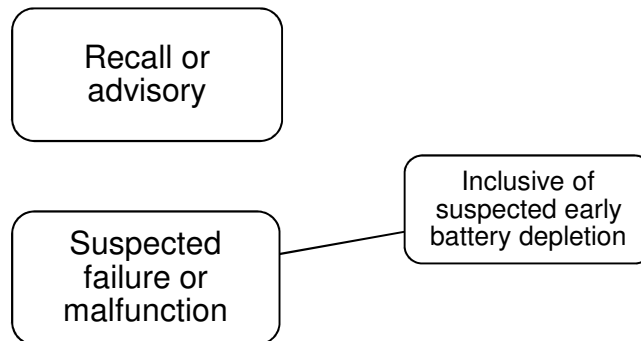- Significant effort and time invested
- Required human engagement

Strategy for Implementation

- Project Charter
- Approvals
- Face-to-face
- Policy/Procedure/Workflows
- Scope
- Tools
- Continuity

Explant Policy Should Contain

- Return all explanted devices replaced due to …

Recall or advisory

Suspected failure or malfunction

Inclusive of suspected early battery depletion

Explant Policy Should Contain

- Pursue warranty credits based upon Medicare and other payer requirements

- Consider all devices related to the required procedural codes with emphasis on battery-operated devices

Cardiac Cochlear Neuro More …
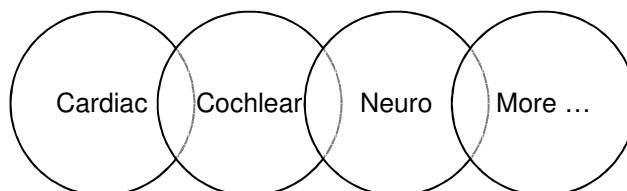
Disclosure

- As is the case for all products in which Mayo Clinic has provided intellectual property or know how, Mayo Clinic has financial interest in Warranty Tracker (offered by Champion Healthcare Technologies). The conflict of interest does not apply for services utilized by Mayo Clinic.

- Commercial Software to be used as future reference

Explant Return Workflow

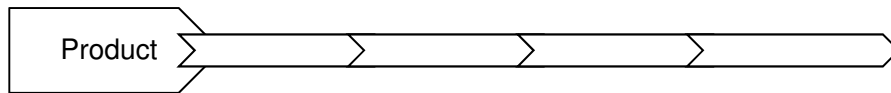| Product | Ship | Vendor analysis | Credit memo | Patient accounts |
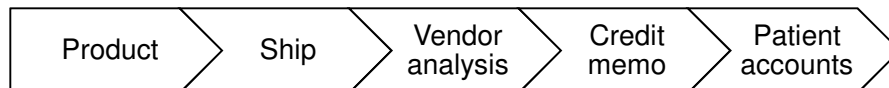
Mayo's Process for Eligible Devices

- Electronic Medical Record (EMR) identifies product type

- Procedural staff document explant reason from dropdown

- If both type and reason qualify, on-screen guidance prompts activation of return to vendor workflow

Product

Mayo's Process for Shipping

- EMR printout summarizes key patient and device details necessary to initiate product return

- Internal web form prompts clinical user to populate key patient and device information

- If vendor return approval required, returns team contacts vendor and forwards limited patient and device details
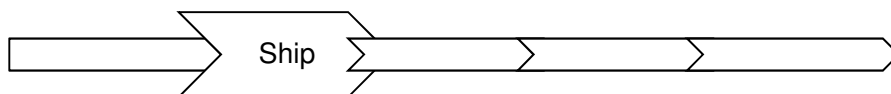

Ship

Mayo's Process for Shipping

- All returns logged in Enterprise Resource Planning (ERP) tool for credit reconciliation (e.g. Lawson)

- Cardiac returns and credit requests are communicated via commercial software

- Physical shipment and tracking managed by hospital

- Vendor allowed to assist with out-of-service details only

Ship
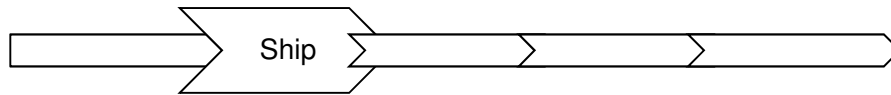
Mayo's Process for Vendor Analysis

- Standardized patient and device details decreases claims delayed or rejected due to incompleteness

- Cardiac credit outcomes received via commercial software

- Surgical credit outcomes requested for relevant device suppliers (we call and ask for a credit report)

Vendor analysis
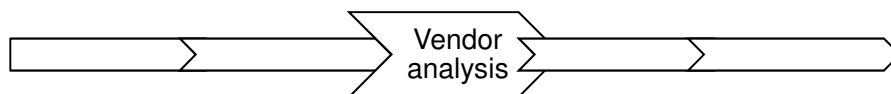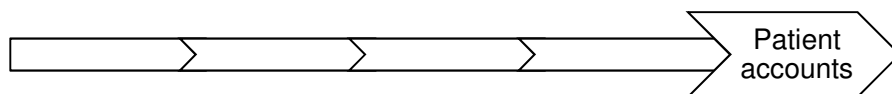
Mayo's Process for Credit Memo

- Explant related credit memos detected through character recognition scanning of incoming documents

- Vendor return approval (RMA) and/or explanted device serial number applied as positive match

- ERP report merged with commercial software report to identify credits $\geq$ 50%
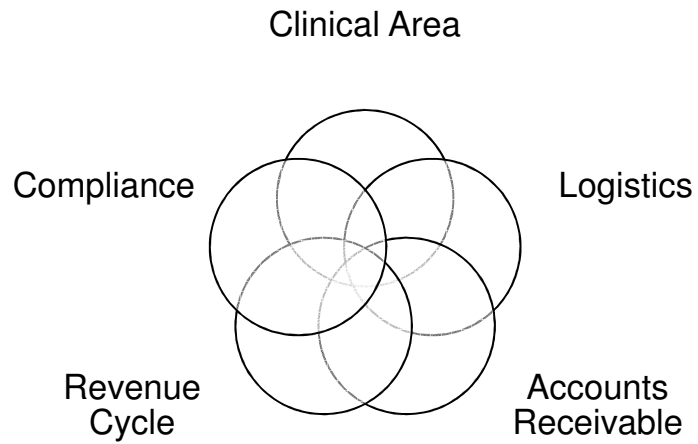
Credit memo
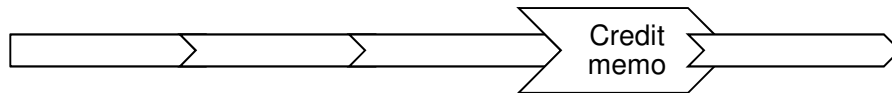
Mayo's Process for Revenue Cycle

- Explant credit outcome updated in EMR and ERP

- Automated 50% calculation performed in EMR

- Report periodically run to aggregate qualifying credits

- Revenue Cycle processes the affected claims with appropriate value and condition codes

Patient accounts

It Takes a Village

Clinical Area

Compliance

Logistics

Revenue
Cycle

Accounts
Receivable

How We Enhanced Our Workflow

Enterprise resource assigned

Dedicated in-person outreach

Buy-in across Practice, Compliance and Supply Chain leadership

Policy/Procedure

Current and future state flow diagrams

Site champions
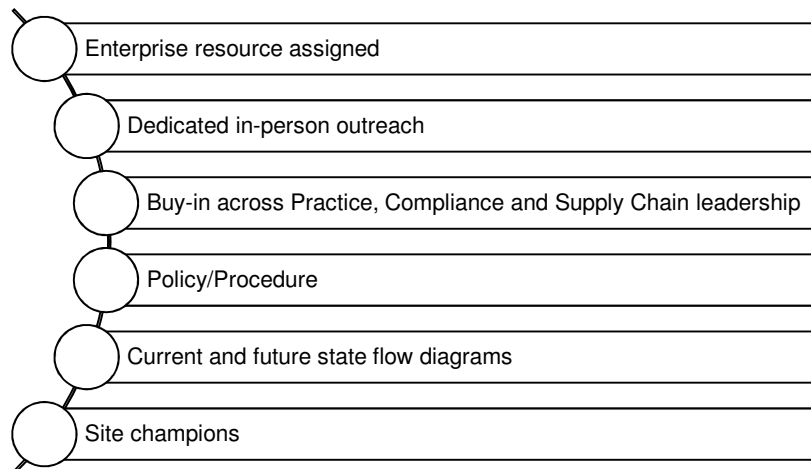
Potential Risks

- Lack of policy, procedure, training and local buy-in may inhibit standardized workflows

- Limited physician awareness may contribute to improper discard of defective devices

- Lack of system tools may inhibit consistent tracking and detection of credits related to explant returns

- Undefined roles may inhibit consistent pursuit of unresolved credit claims and accurate processing of credits received

Solutions

- Capture explant type and reason in EHR

- Build alerts to prompt clinical area to route item for shipment

- Add report to EHR that provides key patient and device information

- Develop standard data sheet to allow direct send of patient/device info to vendor to initiate complaint/return

Solutions

- Ensure appropriate documentation in ERP returns record

- Consider automated scanning of credit memos to detect key explant identifiers (RMA, serial #)

- Develop reconciliation process to close all explant returns as approved or denied by vendor

- Develop process to notify billing of all credits ≥50% of replacement device cost

Solutions

- Run ERP reporting to monitor explant return status

- Reconcile with monthly vendor claim reports

- Require explant credit memos in contracting language to assist hospital compliance

- Provide constructive feedback to vendors regarding claim response time

- Consider warranty outcomes as part of vendor performance and product value

Compliance Tracking Metrics

% Eligible vs. Returned	% Vendor Response	% Claims Adjusted

1. # of devices flagged for return in EMR vs. Logged as returned in ERP
2. # of vendor credit outcome responses over time
3. # of claims adjusted for credits $\geq$50% prior to internal checks

---

An Effective Device Explant Strategy

- Policies and procedures
- Workflow
- Staff engagement
- Assessing risk and removing barriers
- Metrics
- Compliance committee oversight

Q&A