ahia

Assoc. of Healthcare Internal Auditors

MEDICAL DEVICE CREDIT AUDITS:

THESE AREN'T YOUR ORDINARY DEVICES

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CAROLINAS HEALTHCARE SYSTEM

Carolinas HealthCare System

Carolinas HealthCare System

is one of the leading healthcare organizations in the Southeast and one of the most comprehensive public, not-for-profit systems in the nation.

As 2015 drew to a close, the System owned or managed 39 hospitals, serving patients at 940 care locations including satellite emergency departments, outpatient surgery centers, physician practices, urgent care centers, imaging centers, nursing homes, laboratories, and pharmacies.

The System operated nearly 7,400 beds, employed more than 62,000 people and had an estimated 12.5 million patient encounters.

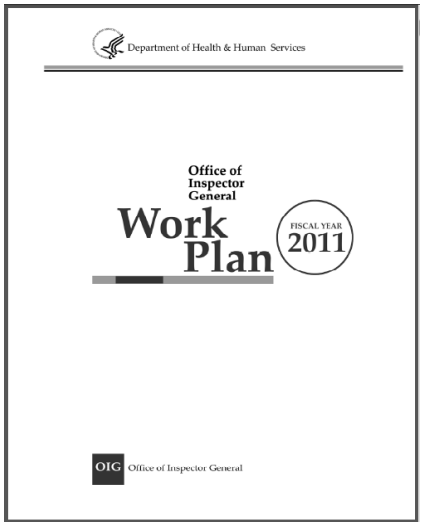
Carolinas HealthCare System's Mission

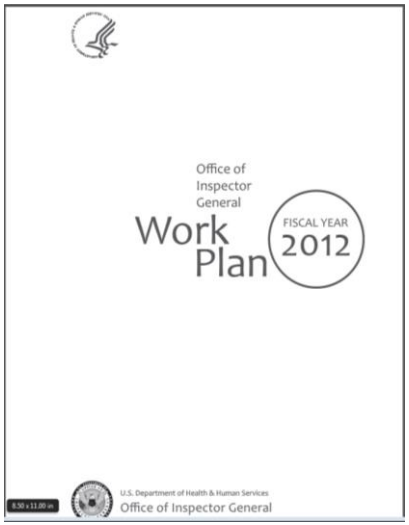
is to create a comprehensive system to provider healthcare and related services, including education and research opportunities, for the benefit of the people it serves.

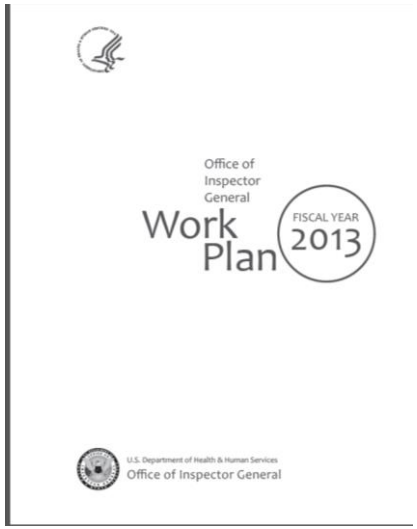
Objectives

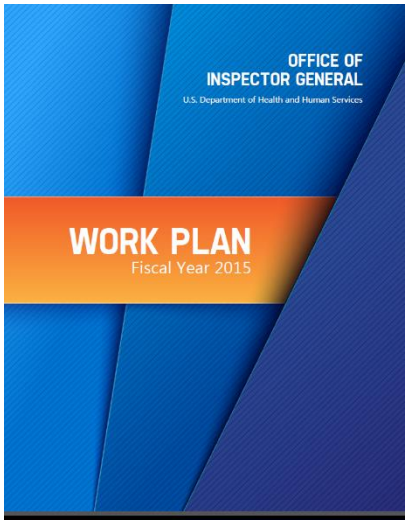
- To gain an understanding of the complex Medicare medical device credit billing rules.
- Discuss key elements of conducting a medical device credits review.
- Review examples of medical device credit process improvement opportunities and strategies for ongoing auditing and monitoring.

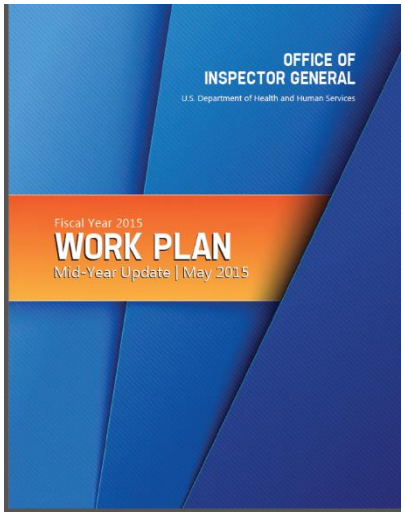
What is The Big Deal About Medical Device Credits?

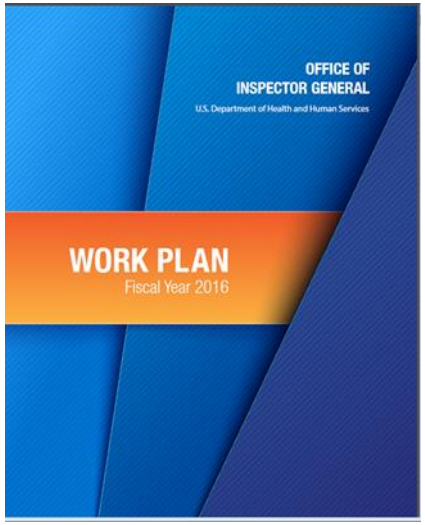


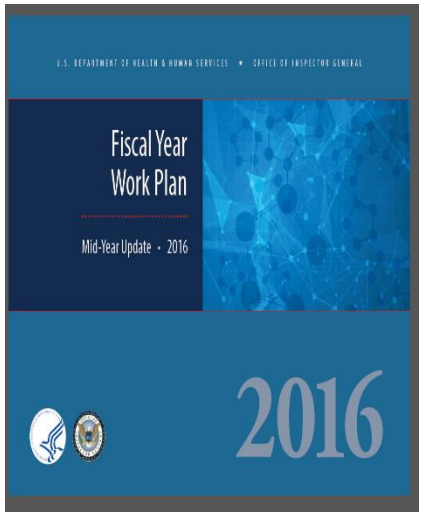




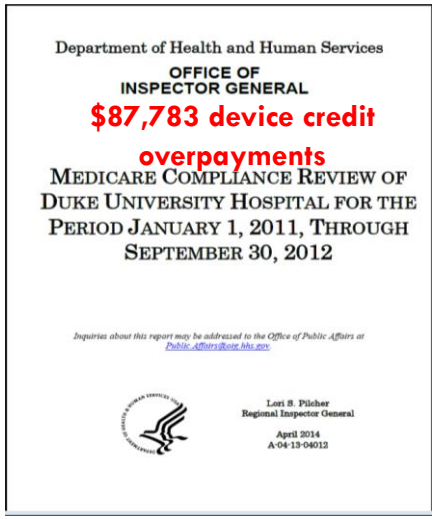


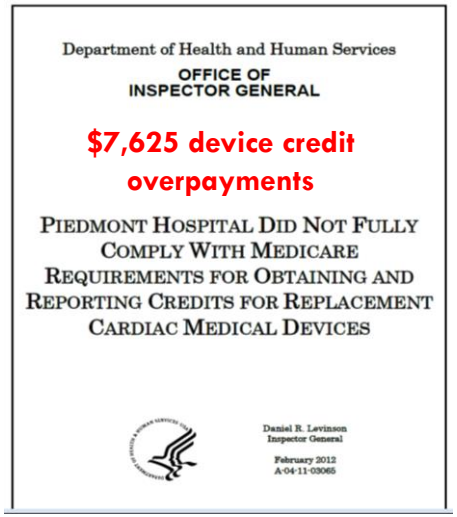


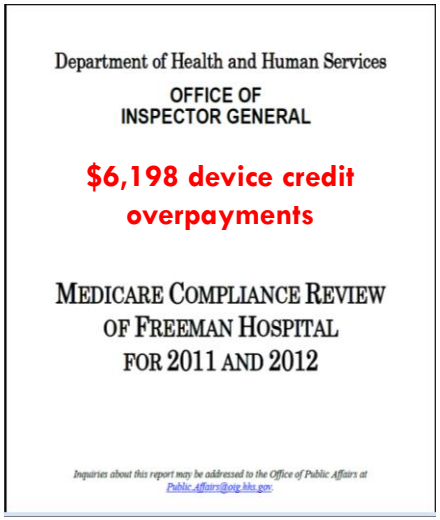


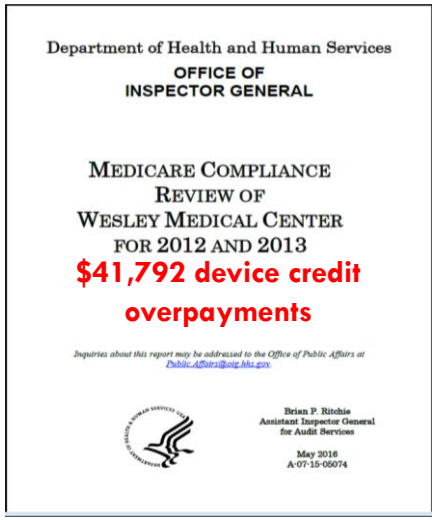


What Does That Mean-Overpayments?









Perspective on Medical Device Credits

- Medicare should not be held responsible for the full cost of the replaced medical device if the hospital received a partial or full credit from the manufacturer due to a recall or warranty credit.
- Device Credit regulations are complex and have changed over time since 2005.
- Requires interdisciplinary communication, processes, and controls between clinical service lines, billing, materials management, research, and compliance.

What risks should we audit?

- Determine whether facilities appropriately billed Medicare for medical device credits in accordance with Medicare regulations for warranty and recall credits as well as devices utilized in clinical trials and received for free.
- Validate processes and controls are present for accurate billing of claims when medical device credit rules apply.
- Existence of a timely tracking process of vendor device credit reports.

Understanding the Risks

- Requires knowledge of clinical operations and the day-to-day process of implanting medical devices within Cardiac Cath, Surgical Services, etc.
- In depth knowledge of the Medicare Billing Rules and their evolution.
- Requires verification of medical record documentation and accurate claims filing.
- Requires knowledge of the vendors supplying the organization with devices for procedures impacted by the Medicare device credit billing rules.

Medical Device Credits Medicare Billing Rules - Outpatient

Requirements - OUTPATIENT	2005	2006	2007	2008 - 2013	2014 -	2015 -
Must report HCPCS code for device when reporting procedure code for inserting device (**Effective 4/1/2005**)[1] "*Token Charge*"- For furnished device received no cost/full credit, report a charge of zero for the device, or, if the hospital's billing system requires that a charge be entered, the hospital must submit a token charge of less than $1.01 on the line with the device code.	X (eff. 4/1)	X	X	X		
Modifier -FB **(Effective 1/1/2006)**[2] - Report with procedure code when furnished device received at **no cost**		X (eff. 1/1)	X	X		
Modifier -FB **(Effective 1/1/2007)**[3] - Report with procedure code for device when **credit** received for device being replaced with more costly device			X (eff. 1/1)	X		
Modifier -FC **(Effective 1/1/2008)**[4,5] - Report with procedure code when receive **partial credit** of **50% or more** of the cost of replacement device				X (eff.1/1)		
Value Code "FD" **(Effective 1/1/2014)**[6] - Report amount of device credit in the amount portion for value code "FD" when furnished device received at no cost OR with a credit of 50% or more of the cost of replacement					X (eff. 1/1)	X
Condition Code 49 or 50 **(Effective 1/1/2014)**[7] - Report Condition Code 49 or 50 when Value Code "FD" is present on the claim and the credit is due to product replacement or a recall, respectively.					X (eff. 1/1)	X
Condition Code 53 **(Retro-Effective 1/1/2014)**[8] - Report Condition Code 53 when Value Code "FD" is present on the claim and the credit is for an initial medical device placement in a clinical trial or a free sample.						X (claims on or after 7/1/15)

[1] CMS Change Request (CR) # 3915 (2005 OPPS Update)
[2] CMS CR # 4250 (2006 OPPS Update); Modifier - FB (Item Provided Without Cost to Provider, Supplier or Practitioner (e.g., Covered Under Warranty, Replaced Due to Defect, Free Samples)
[3] CMS CR # 5263 (Reporting and Payment of No-Cost Devices Furnished - OPPS); Modifier - FB definition expanded to include credits; For credits, hospitals instructed to charge the difference between the hospital's usual charge for the replacement device, and the usual charge for the device being replaced when they receive credit for the device being replaced but implant a more costly device; Effective 1/1/2007, payment reduced by the full offset amount for specified procedure codes reported with Modifier -FB.
[4] CMS CR # 5860; Effective 1/1/2008, payment reduced by the partial offset amount for specified procedure codes reported with Modifier -FC.
[5] Effective 1/1/2009, payment only reduced for procedure codes that map to the APC groups on the list of APCs subject to the adjustment that are reported with Modifier -FB or -FC and that are present on claims with specified device HCPCS codes
[6] CMS CR # 8653 (2014 OPPS Update); Effective 1/1/2014, CMS will no longer recognize Modifiers -FB or -FC; The amount of the device credit should be specified in the amount portion for Value Code "FD" (Credit Received from Manufacturer for a Replaced Medical Device); Payment is reduced by the amount of the device credit for specified procedure codes, and the deduction is limited to the full device offset; Payment is only reduced for procedure codes that map to the APCs on the list of APCs subject to the adjustment that are reported with Value Code "FD" and that are present on claims with specified device HCPCS codes
[7] Condition Code 49 (Product Replacement within Product Lifecycle); Condition Code 50 (Product replacement for Known Recall of a Product)
[8] Condition Code 53 (Initial Placement of a Medical Device Provided as Part of a Clinical Trial or Free Sample); Implemented via CMS Change Request (CR) 8961 (CR Transmittal # 3181); Retroactive effective 1/1/2014 but for claims received on or after July 1, 2015.

Medical Device Credits Medicare Billing Rules - Inpatient

Requirements - INPATIENT	2005	2006	2007	2008 - 2015 -
Condition Code 49 or 50 **(Effective 4/1/2006)**[9] - Report Condition Code 49 or 50 to identify and track claims billed for replacement devices		X (eff. 4/1)	X	X
Value Code "FD" **(Effective 10/1/2008)**[10] - Report amount of device credit in the amount portion for value code "FD" when hospital receives a credit for replaced device that is ***50% or greater*** than the cost of the device				X (eff. 10/1/08)
Condition Code 53 **(Retro-Effective 1/1/2014)**[11] - Report Condition Code 53 when Value Code "FD" is present on the claim and the credit is for an initial medical device placement in a clinical trial or a free sample.				X (claims on or after 7/1/15)

[9] CMS CR # 4058 (New Condition Codes 49 and 50); Condition Code 49 (Product Replacement within Product Lifecycle); Condition Code 50 (Product replacement for Known Recall of a Product); CMS intends to use the condition codes for tracking purposes (to track replacements given to Medicare beneficiaries)

[10] CMS CR # 5860 (Adjusting IPPS Reimbursement for Replaced Devices Without Cost or With a Credit); Beginning with discharges on or after 10/1/2008, hospitals must use combination of Condition Code 49 or 50 AND Value Code "FD"; CMS deducts the partial/full credit amount, reported in the amount for Value Code "FD," from the final IPPS reimbursement when the assigned MS-DRG is one of the MS-DRGs applied to this policy ; The list of MS-DRGs for which the policy applies is included in IPPS Final Rule

[11] Condition Code 53 (Initial Placement of a Medical Device Provided as Part of a Clinical Trial or Free Sample); Implemented via CMS Change Request (CR) 8961 (CR Transmittal # 3181); Retroactive effective 1/1/2014 but for claims received on or after July 1, 2015.

Medical Device Credits Medicare Billing Rules

- "Prudent Buyer Principle"

  Federal regulations state, "All payments to providers of services must be based on the reasonable cost of services …". This is often referred to as the "prudent buyer principle." Excerpts in the CMS Provider Reimbursement Manual include additional interpretive information:

  - "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost conscious buyer pays for a given item or service. If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program."
  - "The prudent and cost-conscious buyer not only refuses to pay more than the going price for an item or service, he/she also seeks to economize by minimizing cost…Another way to minimize cost is to obtain free replacements or reduced charges under warranties for medical devices. Any alert and cost-conscious buyer seeks such advantages, and it is expected that Medicare providers of services will also seek them."

  Based on this prudent buyer principle, it is expected that providers follow Medicare medical device credit billing requirements, as applicable, for full or partial credits when a credit is actually received or **should have been received**.

Key Audit Program Areas

1. Identification of Vendors
2. Review of Warranty Credit Reports
3. Medical Record Review
4. Proper Billing of Devices
5. Establishment of a Device Credit Policy and Workflow
6. Implementation of Contractual Language for Increased Vendor Accountability

1. Identification of Vendors

- Analyzed charge data to identify the highest volume of vendors with implantable devices per the CMS listings of "devise-intensive" procedures and specific devices/HCPCS codes to which the rules applied. ***As of 1/1/2016, CMS will no longer publish a list of devices; rules apply to all medical device credit vendors.***
- Contacted each vendor to obtain vendor device credit information.

2. Review of Warranty Credit Reports

- Reviewed vendor device credit information reported and identified all Medicare accounts with reported credits greater than 50%
- Example of information reported by vendors

*Customer (Facility) Name	*Patient Last Name	*Patient First Name	*Original Product Model Number	Original Product Serial Number	Original Product Type	Original Implant Date	*Replacement Product Model Number	Replacement Product Serial Number	Replacement Product Type	*Replacement Date	Credit Type	*Warranty Credit Amount	*Date Issued	Invoice number	*Replacement Device Cost (Invoiced Price)	PO#
		*Fields with asterisk indicate minimum requirements.														

- Hospitals ***must*** return the implantable devices to the vendors. OIG report recently stated "should have known a credit was owed". This is evident on the vendor device credit reports.

3. Medical Record Review

- Reviewed each medical record to determine what activity occurred:
  - Product replacement within product lifecycle (condition code 49)
  - Product replacement for known recall of a product (condition code 50)
- Examples of common themes in medical record:
  - ICD change out (elective), generator change, device malfunction, lead fracture, change pacemaker due to ERI of battery, fidelis lead currently under advisory

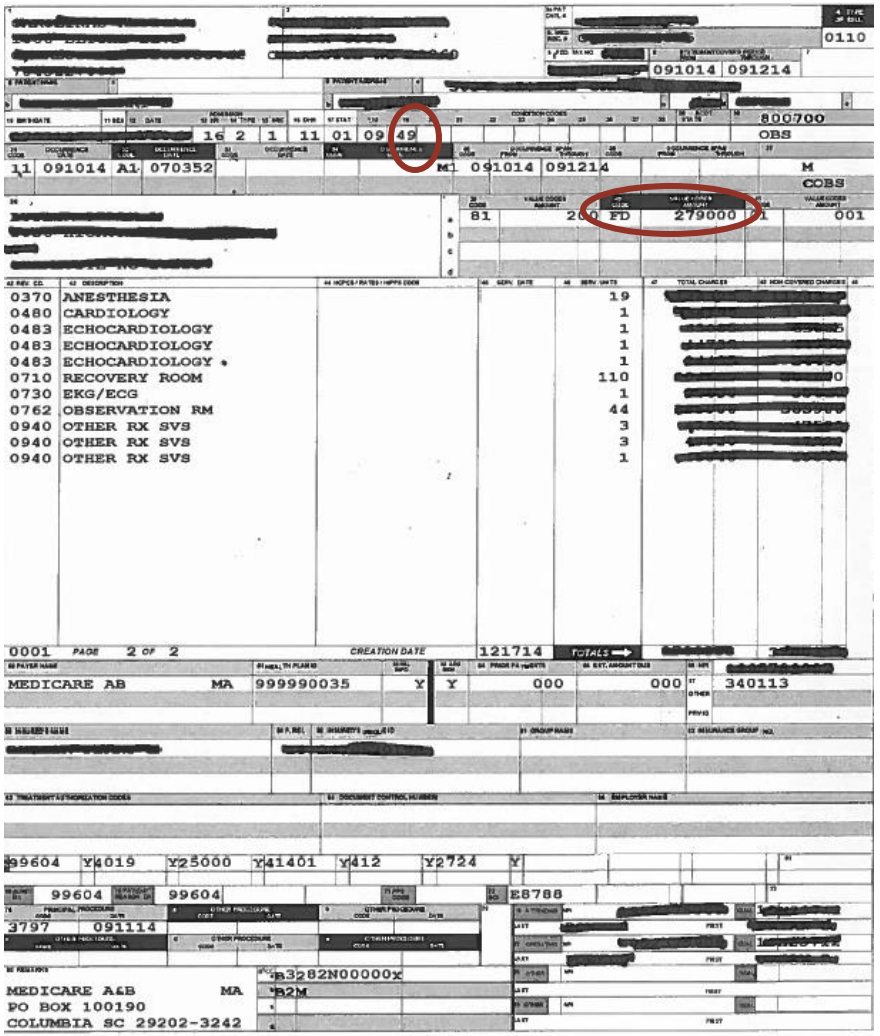
4. Billing of Devices

- Reviewed each claim to determine if the device credit was billed in accordance with the rules in effect at the time the claim was billed.
  - Condition Code 49, 50, or 53 (inpatient and outpatient rules)
  - Value Code FD – 50% or greater
  - Modifier FB or FC - applicable in prior years
- Identified claims that required corrections.

Medicare Rules Reference (slides 9 and 10).

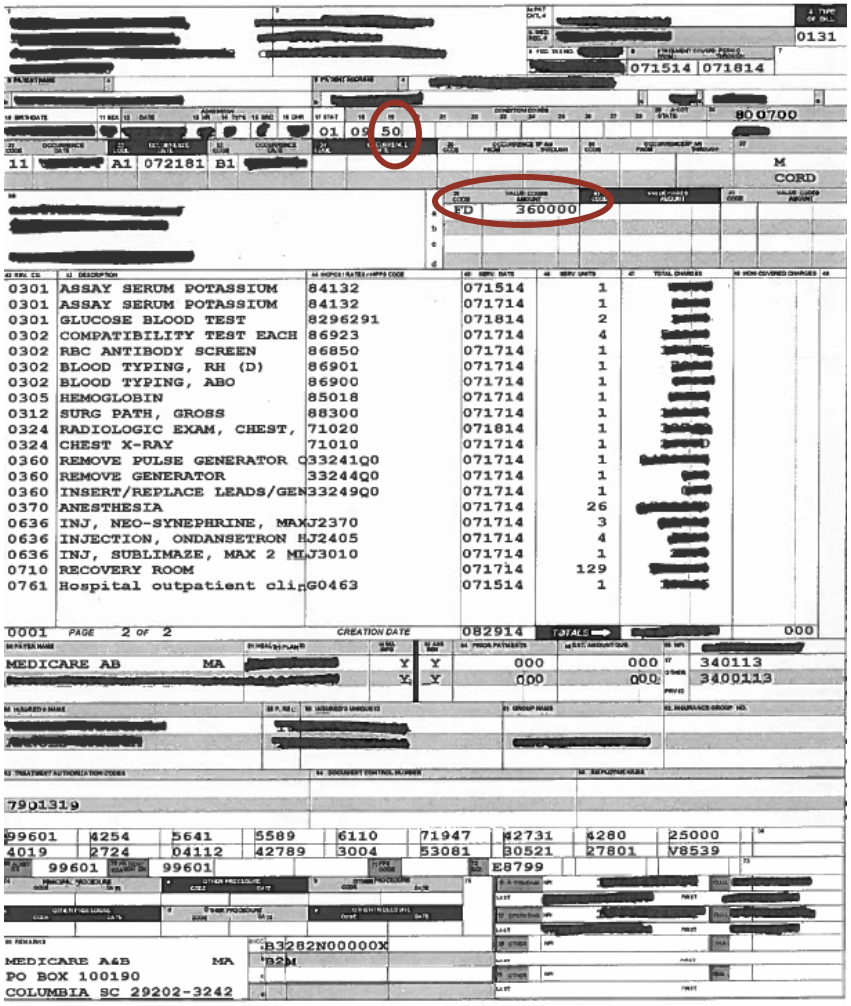
Billing of Devices – Example 1

- Lead was replaced under warranty advisory.
- Credit amount $2,790
- Value Code FD applied
- Condition Code 49 – within product lifecycle



Billing of Devices – Example 2

- Lead was replaced.
- Credit amount = $3,600
- Value Code FD applied
- Condition Code 50 – replacement for known product recall



0301	ASSAY SERUM POTASSIUM	84132	071514	1	
0301	ASSAY SERUM POTASSIUM	84132	071714	1	
0301	GLUCOSE BLOOD TEST	8296291	071814	2	
0302	COMPATIBILITY TEST EACH	86923	071714	4	
0302	RBC ANTIBODY SCREEN	86850	071714	1	
0302	BLOOD TYPING, RH (D)	86901	071714	1	
0302	BLOOD TYPING, ABO	86900	071714	1	
0305	HEMOGLOBIN	85018	071714	1	
0312	SURG PATH, GROSS	88300	071714	1	
0324	RADIOLOGIC EXAM, CHEST,	71020	071814	1	
0324	CHEST X-RAY	71010	071714	1	
0360	REMOVE PULSE GENERATOR	33241Q0	071714	1	
0360	REMOVE GENERATOR	33244Q0	071714	1	
0360	INSERT/REPLACE LEADS/GEN	33249Q0	071714	1	
0370	ANESTHESIA		071714	26	
0636	INJ, NEO-SYNEPHRINE, MAX	J2370	071714	3	
0636	INJECTION, ONDANSETRON H	J2405	071714	4	
0636	INJ, SUBLIMAZE, MAX 2 ML	J3010	071714	1	
0710	RECOVERY ROOM		071714	129	
0761	Hospital outpatient cli	G0463	071514	1	

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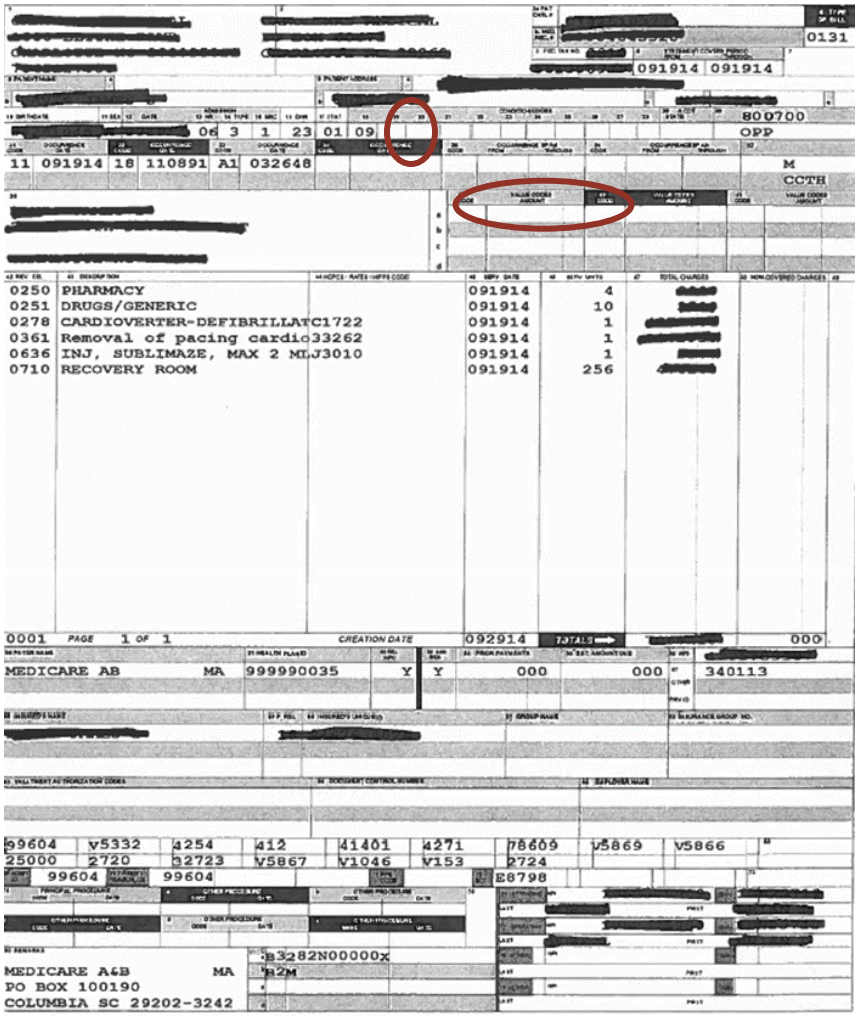
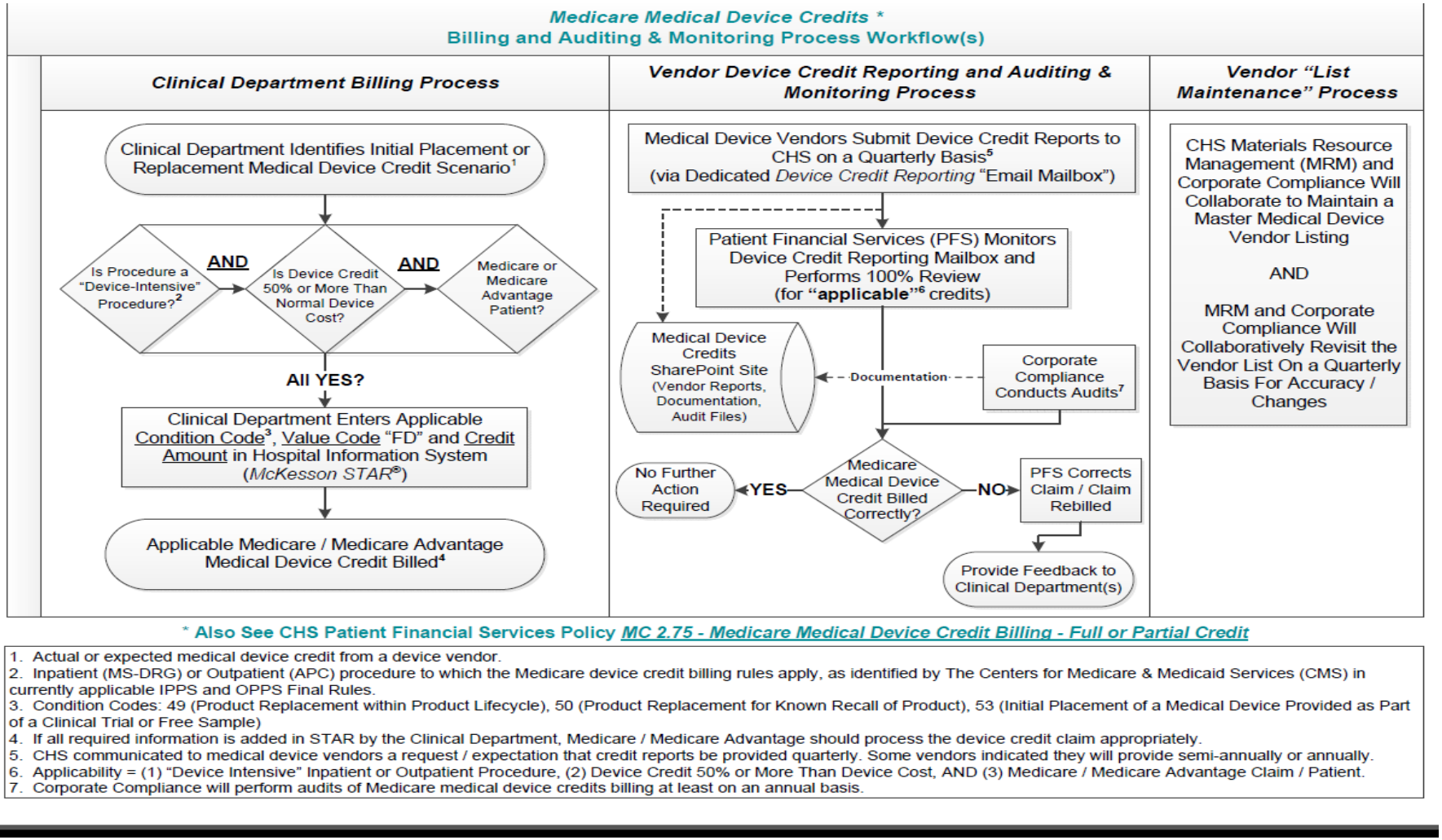
Billing of Devices – Example 3

- ICD malfunction w/ battery depletion.
- Credit amount = $10,320
- Value Code FD applied
- Condition Code 49 – within product lifecycle



5. Medical Device Credit Workflow

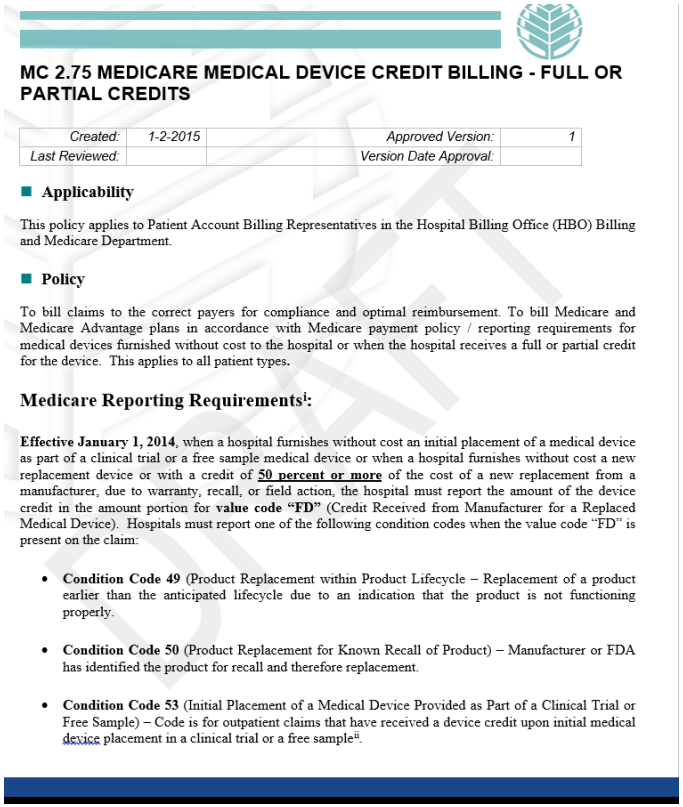


* Also See CHS Patient Financial Services Policy *MC 2.75 - Medicare Medical Device Credit Billing - Full or Partial Credit*

1. Actual or expected medical device credit from a device vendor.
2. Inpatient (MS-DRG) or Outpatient (APC) procedure to which the Medicare device credit billing rules apply, as identified by The Centers for Medicare & Medicaid Services (CMS) in currently applicable IPPS and OPPS Final Rules.
3. Condition Codes: 49 (Product Replacement within Product Lifecycle), 50 (Product Replacement for Known Recall of Product), 53 (Initial Placement of a Medical Device Provided as Part of a Clinical Trial or Free Sample)
4. If all required information is added in STAR by the Clinical Department, Medicare / Medicare Advantage should process the device credit claim appropriately.
5. CHS communicated to medical device vendors a request / expectation that credit reports be provided quarterly. Some vendors indicated they will provide semi-annually or annually.
6. Applicability = (1) "Device Intensive" Inpatient or Outpatient Procedure, (2) Device Credit 50% or More Than Device Cost, AND (3) Medicare / Medicare Advantage Claim / Patient.
7. Corporate Compliance will perform audits of Medicare medical device credits billing at least on an annual basis.

5. Medical Device Credit Policy

- Policy Outlines Key Medicare Reporting Requirements
  - Use of condition codes/value codes
  - No-cost device coding
  - Investigational Device Exemption (IDE) Studies
  - Medicare Payment Policies
  - Prudent Buyer Principle
- Includes required Clinical department actions and Billing staff actions



MC 2.75 MEDICARE MEDICAL DEVICE CREDIT BILLING - FULL OR PARTIAL CREDITS

Created:	*1-2-2015*	*Approved Version:*	*1*
Last Reviewed:		*Version Date Approval:*	

Applicability

This policy applies to Patient Account Billing Representatives in the Hospital Billing Office (HBO) Billing and Medicare Department.

Policy

To bill claims to the correct payers for compliance and optimal reimbursement. To bill Medicare and Medicare Advantage plans in accordance with Medicare payment policy / reporting requirements for medical devices furnished without cost to the hospital or when the hospital receives a full or partial credit for the device. This applies to all patient types.

Medicare Reporting Requirements[i]:

Effective January 1, 2014, when a hospital furnishes without cost an initial placement of a medical device as part of a clinical trial or a free sample medical device or when a hospital furnishes without cost a new replacement device or with a credit of **50 percent or more** of the cost of a new replacement from a manufacturer, due to warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for **value code "FD"** (Credit Received from Manufacturer for a Replaced Medical Device). Hospitals must report one of the following condition codes when the value code "FD" is present on the claim:

- **Condition Code 49** (Product Replacement within Product Lifecycle – Replacement of a product earlier than the anticipated lifecycle due to an indication that the product is not functioning properly.
- **Condition Code 50** (Product Replacement for Known Recall of Product) – Manufacturer or FDA has identified the product for recall and therefore replacement.
- **Condition Code 53** (Initial Placement of a Medical Device Provided as Part of a Clinical Trial or Free Sample) – Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample[ii].

6. Implementation of Contractual Language

- Vendor Agreement – Key Terms and Conditions
  - Include reference to the Medicare regulations for medical device credits.
  - Require ***all*** vendors to inform Facility of medical device credits.
  - Require a summary report of medical devices credits be provided on a monthly basis.
  - Specify minimum information requirements required on summary report (may be included as an Exhibit to contractual agreement). (refer to slide 6)
  - Include key stakeholders to receive summary reports and provide instructions on how reports should be submitted.

Findings/Observations – CURRENT STATE

- Current processes only focused on cardiac devices/manufacturers. *Expanded review to all vendors providing implantable medical devices.*
- Identified need to hold device vendors more accountable for timely, "up-front" communication of information. *Developed contractual language for inclusion in vendor contracts.*
- Lack of a formal process to track receipt of device credit reports. *Established internal email account and SharePoint site for tracking.*
- Clinical Departments involved had a lack of awareness of the Medicare device credit requirements. *Ongoing education provided to service lines.*
- Lack of a formal policy and procedure specific to medical device credits. *Patient Accounting policy established.*
- Lack of a defined workflow to clarify the flow of information and responsibilities. *Established workflow with clinical service line, Patient Accounting, and Materials Management.*

Lessons Learned

- Everyone needs to be involved: Physician and Clinical staffs, Patient Accounting, Materials Management, and Compliance.
- Several vendors are still establishing device credit reports; many do not have a monthly, routine reporting processes.
- Compliance is ongoing!

Questions?

Contact Information:

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Save the Date

August 27-30, 2017

36th AHIA Annual Conference

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Assoc. of Healthcare Internal Auditors