CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1509	**Date: May 16, 2008**
	Change Request 5860

NOTE: Transmittal 1498, dated May 2, 2008 is rescinded and replaced by Transmittal 1509, dated May 16, 2008. The instruction was removed from the July 2008 release to October 2008 release. It was inadvertently misstated in the policy in Chapter 3, Section 100.8 reflecting the incorrect date. This instruction has been revised. All other information remains the same.

SUBJECT: Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit

I. SUMMARY OF CHANGES: This CR provides instructions for billing replaced devices that are received without cost or with a credit. It also includes contractor instructions for how to reduce IPPS payment based on the amount of the credit received by the hospital for the replaced device.

New / Revised Material
Effective Date: October 1, 2008
Implementation Date: October 6, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N	3/100.8/ Replaced Devices Offered Without Cost or With a Credit
R	32/67.2.1/Billing No Cost Items Due to Recall, Replacement, or Free Sample

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1509	Date: May 16, 2008	Change Request: 5860

NOTE: Transmittal 1498, dated May 2, 2008 is rescinded and replaced by Transmittal 1509, dated May 16, 2008. The instruction was removed from the July 2008 release to October 2008 release. It was inadvertently misstated in the policy in Chapter 3, Section 100.8 reflecting the incorrect date. This instruction has been revised. All other information remains the same.

SUBJECT: Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

I. GENERAL INFORMATION

A. Background:

In recent years, there have been several field actions and recalls with regard to failure of implantable cardiac defibrillators (ICDs) and pacemakers. In many of these cases, the manufacturers have offered replacement devices without cost to the hospital or credit for the device being replaced if the patient required a more expensive device. In some circumstances, manufacturers have also offered, through a warranty package, to pay specified amounts for un-reimbursed expenses to persons who had replacement devices implanted.

Nonetheless, CMS believes that incidental device failures that are covered by manufacturer warranties occur routinely. Though device malfunctions may be inevitable as medical technology grows increasingly sophisticated, CMS believes that early recognition of problems would reduce the number of people who would be potentially adversely affected by these device problems.

In addition to concerns for overall public health, CMS also has a fiduciary responsibility to the Medicare Trust Fund to ensure that Medicare pays only for covered services. Therefore, CMS believes it is appropriate to reduce the Medicare payment in cases in which an implanted device is replaced at reduced or no cost to the hospital or with partial or full credit for the removed device.

To address the issue, CMS issued CR 4058 on November 4, 2005. This CR provided instructions for billing and processing claims with the following condition codes:

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.

50 Product Replacement for Known Recall of a Product—Manufacturer or FDA has identified the product for recall and therefore replacement.

The use of condition codes 49 and 50 allow CMS to identify and track claims billed for replacement devices.

B. Policy:

Medicare is not responsible for the full cost of the replaced device if the hospital is receiving a partial or full credit, either due to a recall or service during the warranty period. Therefore, effective for discharges on or

after October 1, 2008, hospitals are required to bill the amount of the credit in the amount portion for value code, FD, "Credit Received from the Manufacturer for a Replaced Medical Device," when the hospital receives a credit for a replaced device that is 50% or greater than the cost of the device.

Medicare shall reduce the hospital reimbursement, for one of the applicable Medical Severity Diagnosis Related Groups (MS-DRGs) listed below, by the full or partial credit a provider received for a replaced device. This adjustment is consistent with section 1862(a)(2) of the Act, which excludes from Medicare coverage an item or service for which neither the beneficiary, nor anyone on his or her behalf, has an obligation to pay.

DRGs Subject to Final Policy		
MDC	**MS- DRG**	**Narrative Description of DRG**
PRE	1 & 2	Heart Transplant or Implant of Heart Assist System with and without MCC, respectively (former CMS-DRG 103, Heart Transplant or Implant of Heart Assist System)
1	25 & 26	Craniotomy and Endovascular Intracranial Procedure with MCC or with CC, respectively (former CMS-DRG 1, Craniotomy Age > 17 With CC)
1	26 & 27	Craniotomy and Endovascular Intracranial Procedure with CC or without CC/MCC, respectively (former CMS-DRGs 2, Craniotomy Age > 17 Without CC)
1	40 & 41	Peripheral & Cranial Nerve & Other Nervous System Procedure with MCC; or with CC or Peripheral Neurostimulator, respectively (former CMS-DRG, 7 Peripheral & Cranial Nerve & Other Nervous System Procedures With CC)
1	42	Peripheral & Cranial Nerve & Other Nervous System Procedure without CC/MCC (former CMS-DRG 8, Peripheral & Cranial Nerve & Other Nervous System Procedures without CC)
1	23 & 24	Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant; and without MCC [or Chemotherapy Implant], respectively (former CMS-DRG 543, Craniotomy With Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis)
3	129 & 130	Major Head & Neck Procedures with CC/MCC or Major Device; or without CC/MCC, respectively (former CMS-DRG 49, Major Head & Neck Procedures)
5	216, 217, & 218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization With MCC; or with CC; or without CC/MCC, respectively (former CMS-DRG 104, Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization)
5	219, 220, & 221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC; or with CC, or without CC/MCC, respectively (former CMS-DRG 105, Cardiac Valve & Other Major Cardiothoracic Procedures Without Cardiac Catheterization)
5	237	Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair (former CMS-DRG 110, Major Cardiovascular Procedures With CC)
5	238	Major Cardiovascular Procedures without MCC (former CMS-DRG 111, Major Cardiovascular Procedures without CC)
5	260, 261, & 262	Cardiac Pacemaker Revision Except Device Replacement with MCC, or with CC, or without CC/MCC, respectively (former CMS-DRGs117, Cardiac Pacemaker Revision Except Device Replacement)
5	258 & 259	Cardiac Pacemaker Device Replacement With MCC, and Without MCC, respectively (former CMS-DRG 118, Cardiac Pacemaker Device Replacement)

DRGs Subject to Final Policy		
MDC	**MS- DRG**	**Narrative Description of DRG**
5	226 & 227	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC and without MCC, respectively (former CMS-DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization)
5	215	Other Heart Assist System Implant (former CMS-DRG 525, Other Heart Assist System Implant)
5	222 & 223	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRGs 535, Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock)
5	224 & 225	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRG 536, Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock)
5	242, 243, & 244	Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (MS-DRG 551, Permanent Cardiac Pacemaker Implant with Major Cardiovascular Diagnosis or AICD Lead or Generator
5	242, 243, & 244	Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (former CMS-DRG 552, Other Permanent Cardiac Pacemaker Implant without Major Cardiovascular Diagnosis)
5	245	AICD Lead and Generator Procedures (this is a new MS-DRG, created from AICD and generator codes moved out of CMS DRG 551)
8	461 & 462	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC, or without MCC, respectively (former CMS-DRG 471, Bilateral or Multiple Major Joint Procedures of Lower Extremity)
8	469 & 470	Major Joint Replacement or Reattachment of Lower Extremity with MCC or without MCC, respectively (former CMS-DRG 544, Major Joint Replacement or Reattachment of Lower Extremity)
8	466, 467, & 468	Revision of Hip or Knee Replacement with MCC, with CC, or without CC/MCC, respectively (former CMS-DRG 545, Revision of Hip or Knee Replacement)

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	**Requirement**	**Responsibility (place an "X" in each applicable column)**									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5860.1	Medicare Standard Systems shall accept the new value code, FD, "Credit Received from the Manufacturer for a Replaced Medical Device."						X			X	NCH COBC
5860.2	Medicare Standard Systems shall create edits to ensure that IPPS claims report condition code 49 or 50 when value code FD is present. Note: This requirement is only applicable to IPPS providers (11X Type of Bills from provider's with a provider range of 0001-0979), excluding Maryland waiver hospitals and Cancer hospitals.						X				

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5860.3	Medicare Standard Systems shall deduct 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 listed in the policy section above.						X				
5860.4	CMS shall create a line on the cost report for the amount associated with value code FD.	X		X							Cost-Report
5860.4.1	Contractors shall deduct the amount entered on the claim for value code FD from the final IPPS reimbursement amount.	X		X							Cost-Report
5860.5	CMS shall create a line on the PS&R report for the amount associated with value code FD.	X		X							PS&R
5860.5.1	Contractors shall deduct the amount entered on the claim for value code FD from the final IPPS reimbursement amount, for Provider Statistical and Reimbursement (PS&R) report purposes.	X		X							PS&R

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5860.6	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Joe Bryson at joseph.bryson@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*, use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual

Chapter 3 - Inpatient Hospital Billing

100.8 – Replaced Devices Offered Without Cost or With a Credit

100.8 – Replaced Devices Offered Without Cost or With a Credit

(Rev.1509, Issued: 05-16-08, Effective: 10-01-08, implementation: 10-06-08)

Background

To identify and track claims billed for replacement devices, CMS issued CR 4058 on November 4, 2005. This CR provided instructions for billing and processing claims with the following condition codes:

- ***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.*
- ***50 Product Replacement for Known Recall of a Product****—Manufacturer or FDA has identified the product for recall and therefore replacement.*

Policy

Beginning with discharges on or after October 1, 2008, CMS reduces Medicare payment when a replacement device is received by the hospital at a reduced cost or with a credit, and when the assigned MS-DRG for the claim is one of the MS-DRGs applied to this policy.

For a list of MS-DRGs for which this policy applies to, please see the IPPS Final Rule.

This adjustment is consistent with section 1862(a)(2) of the Act, which excludes from Medicare coverage an item or service for which neither the beneficiary, nor anyone on his or her behalf, has an obligation to pay.

Billing Procedures (Discharges on or after October 1, 2008)

To correctly bill for a replacement device that was provided with a credit or no cost, hospitals must use the combination of condition code 49 or 50, along with value code FD. The condition code 49 or 50 will identify a replacement device while value code FD will communicate to Medicare the amount of the credit, or cost reduction, received by the hospital for the replaced device.

Payment (Discharges on or after October 1, 2008)

Medicare 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.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample

(Rev.1509, Issued: 05-16-08, Effective: 10-01-08, implementation: 10-06-08)

Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes will be used to identify and track medical devices that are provided by a manufacturer at no cost. The no-cost device may be provided due to warranty, replacement, recall or defect issues.

Table 1: New Condition Codes and Descriptions		
Condition Code		**Description**
49	Product Replacement within Product Lifecycle	A medical device is replaced before "end-of-life" because there is an indication that the device is not functioning properly. (This is a warranty situation.)
50	Product Replacement for Known Recall of a Product	A medical device is replaced because of a manufacturer or FDA recall.

Providers must use the *above condition* codes to identify medical devices that are provided by a manufacturer at no cost. These condition codes will be used to track no-cost recalled or replacement devices.

Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no-cost device when conditions of replacement or recall are met.

Outpatient Hospital Billing

Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS), bill the device HCPCS with a token charge to bypass device and device insertion procedure edits. Effective January 1, 2006, modifier -FB will be used to indicate that a device used in a procedure was furnished without cost to the provider and; therefore, it is not being charged to Medicare or the beneficiary. Also, effective January 1, 2008, modifier –FC will be used to indicate that a hospital *received a partial credit of 50 percent or more of the cost of the new replacement device.* More information on the billing HCPCS *modifiers* –FB *and –FC* can be located in Sections 20.6.9 *and 61.3* of the Medicare Claims Processing Manual, Chapter 4.

NOTE: Outpatient hospitals billing “no cost” devices must append the -FB modifier to the procedure code for implanting the “no cost” device, along with the appropriate condition code (in Table 1 above). The modifier will identify the procedure code line for

the “no cost” device, while the condition code will explain the reason why the device was provided free of cost.

Billing under the Inpatient Prospective Payment System (IPPS)

For instructions on how to bill for replaced devices received without cost or with a credit under the IPPS, please see Chapter 3, Section 100.8 of The Claims Processing Manual.