Related MLN Matters Article #: MM5860

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

Key Words

MM5860, CR5860, MM4058, CR4058, R741CP, R1509CP, IPPS, Prospective, Reimbursement, ICD, Devices

Provider Types Affected

Providers submitting claims to Medicare Fiscal Intermediaries (FIs) and Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries relating to replaced medical devices

Key Points

- The effective date of the instruction is October 1, 2008.
- The implementation date is October 6, 2008.
- 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 offered 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.
- The Centers for Medicare & Medicaid Services (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 identify and track claims billed for replacement devices, CMS issued Change Request (CR) 4058 (Transmittal 741, November 4, 2005). This CR provided instructions for billing and processing claims with the following condition codes:
  - 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; and
  - Condition Code 50: Product Replacement for Known Recall of a Product - Manufacturer or FDA has identified the product for recall and therefore replacement.
- 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 due to service during the warranty period.
- Therefore, hospitals are required to bill the amount of the credit in the amount portion for value code FD when the hospital receives a credit for a replaced device that is 50% or greater than the cost of the device.

New Policy Effective October 1, 2008

- Beginning with discharges on or after October 1, 2008, Medicare will reduce the hospital reimbursement by the full or partial credit a provider received for a replaced device for one of the applicable Medicare Severity Diagnosis Related Groups (MS-DRGs) listed in the table (Diagnostic Related Groups (DRGs) Subject to Final Policy) shown on pages 4 and 5 in MM5860.
- This adjustment is consistent with the Social Security Act (Section 1862(a)(2)), 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.
- For discharges on or after October 1, 2008:
  - Hospitals must use the combination of condition code 49 or 50, along with value code FD to correctly bill for a replacement device that was provided with a credit or no cost. 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.
  - Medicare will 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 applied to this policy.

Important Links

The related MLN Matters article can be found at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5860.pdf* on the CMS website.

The official instruction (CR5860) issued regarding this change may be viewed at *http://www.cms.hhs.gov/transmittals/downloads/R1509CP.pdf* on the CMS website.

CR4058 can be found at *http://www.cms.hhs.gov/Transmittals/downloads/R741CP.pdf* on the CMS website. Providers can find its corresponding MLN article at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4058.pdf* on the CMS website.

Section 1862 (a)(2) of the Social Security Act can be found at *http://www.ssa.gov/OP_Home/ssact/title18/1862.htm* on the internet.