

Medicare's New Policy For Recalled, Replaced Devices

Thursday, Nov 08, 2007 --- Inpatient hospitals are subject to a new Medicare policy regarding payment for procedures involving medical devices that are recalled or replaced at no cost or reduced cost to the hospital, effective Oct. 1, 2007. The provision is included in the Center for Medicare & Medicaid Services' ("CMS") sweeping final Medicare inpatient prospective payment system ("IPPS") rule for fiscal year 2008, which was published Aug. 22, 2007 (the "Final Rule").

The new policy was adopted in response to a number of recalls of implantable medical devices in recent years in which the manufacturers offered replacement devices without cost to the hospital or provided credit to the hospital for the device being replaced if the patient required a more expensive device.

CMS seeks to ensure that Medicare does not pay a hospital for the full cost of the replacement if the hospital is receiving a partial or full credit, and that Medicare retains any credit that is being provided to the hospital for service to a Medicare beneficiary.

Provisions of the Final Rule

Under current rules, Medicare payment is not reduced for a second procedure involving an implantable device, even if the hospital acquires the device for free or at reduced cost, such may be provided under certain recalls or other product failures or under the terms of manufacturer warranties.

Under the Final Rule, CMS will reduce Medicare payment in certain situations in which an implanted device is replaced at reduced or no cost to the hospital, or with partial credit to the hospital.

Specifically, CMS will provide a reduced payment to a hospital when the hospital received a credit equal to 50 percent or more of the cost of the device (compared to a 20 percent threshold under the proposed rule). CMS is limiting this policy only to diagnosis related groups ("DRGs") where the implantation of the device determines the base DRG assignment.

Hospitals will be required to identify when they receive a replacement device, and CMS will reduce the DRG payment to reflect the reduced cost to the hospital. Specific reporting requirements are set forth in the Final Rule, and CMS will issue additional claims processing instructions to Medicare contractors and hospitals regarding implementation of this policy.

The new IPPS rules parallel rules that have applied under the outpatient prospective payment system (“OPPS”) since Jan. 1, 2007, although the OPPS rules currently apply only to situations in which the hospital received a replacement device at no cost or at full credit for the replacement device. Note that CMS also has proposed expanding the OPPS policy to reduce the OPPS payment when partial credit for the device cost is received by the hospital for a failed or otherwise replaced device.

In addition to ensuring that Medicare does not pay inappropriately for implantable devices obtained at reduced costs, CMS believes that routine identification of Medicare claims involving certain replacement implantable devices can promote more timely recognition of device related problems.

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