CMS Reimbursement and Patient Billing for Reprocessed SUDs

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Overview

- The reprocessing of devices labeled by the original equipment manufacturer (OEM) as for "single-use" (SUDs) is lawful under the Federal Food, Drug, and Cosmetic Act (FDCA), if conducted in accordance with FDA's medical device manufacturer requirements.[1]
- Most U.S. hospitals contract with an FDA-regulated, third-party reprocessor in order to ensure that the reprocessed SUDs they purchase are FDA-compliant.
- In general, devices that are deemed by FDA to be legally marketed under the FDCA are reimbursable by Medicare. This includes reimbursement for use of legally marketed reprocessed SUDs.

Reprocessed SUDs are Eligible for Reimbursement by CMS Just as Non-Reprocessed Devices

A reprocessed device that complies with the regulatory requirements enforced by FDA is eligible for payment and coverage by Medicare to the same extent as non-reprocessed devices.

In general, devices that are deemed by FDA to be legally marketed under the FDCA are reimbursable by Medicare if they are "reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the functioning of a malformed body member."[2]

Specifically, pursuant to statements from CMS, reprocessed devices that meet FDA's requirements are eligible for coverage under Medicare Part B to the same extent as non-reprocessed devices. The same principles have been applied to procedures using reprocessed devices that are covered in other settings by Medicare.

It is important to note that CMS does not generally reimburse hospitals for the use of individual devices. Rather, CMS reimburses hospitals for entire procedures, without respect to whether reprocessed devices were used in a given procedure or not. As the General Accountability Office (GAO) has explained, "[CMS] currently lacks the means to determine whether it is paying for a new or a reprocessed device because it pays for the treatment of particular conditions, not for individual pieces of equipment that may be used in treatment."[3]

CMS reiterated that "reprocessed devices will be subsumed under the same categories as the original device." Further, CMS stated, "[w]e do not believe that it is practical or advisable to create special modifiers or categories" for reprocessed SUDs.[4] Thus, CMS stated, "[f]or the terms

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1 21 U.S.C. §§ 351, 352, 360, and 360c-360e. *See also, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (August 14, 2000).

2 42 U.S.C. § 1395y(a)(1)(A).

3 U.S. Government Accountability Office, GAO/HEHS-00-123, *Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted* (June 2000), at 24.

4 CMS, Final Rule, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, 66 Fed. Reg. 59855, 59897 (Nov. 30, 2001).

of participation, [CMS] ... has no plans to include requirements about the reuse of SUDs in any of its standards for Medicare conditions of participation for health care facilities."[5]

In short, reprocessed SUDs should be reviewed by CMS in the same manner and under the same criteria as non-reprocessed SUDs to determine whether they are "reasonable and necessary" for the diagnosis or treatment of an illness or injury. As is the case with non-reprocessed devices, CMS requires that reprocessed SUDs be manufactured and distributed in compliance with FDA's requirements before they are covered and reimbursed by Medicare.[6] A reprocessed device that complies with the regulatory requirements enforced by FDA is eligible for coverage and payment to the same extent as the non-reprocessed version of the device.

Hospital Billing Practices

The difference between what hospitals bill patients and what is actually submitted for reimbursement to Medicare/Medicaid or to third-party payers (*i.e.*, insurance companies), is something hospitals regularly encounter. AMDR cannot provide guidance to hospitals on patient billing practices, except to recommend, consistent with the above-described reimbursement principles, that reprocessed devices be billed to patients in the same transparent manner as non-reprocessed devices. Many variables contribute to a hospital's "cost" for a particular item, and AMDR encourages hospitals to transparently reflect those costs to patients – as they would for any other drug, device or procedure. For instance, a hospital may acquire a type of medical device from several different sources, including perhaps the manufacturer, a Group Purchasing Organization, or a third-party reprocessor, to name a few.

AMDR understands that hospitals most commonly address billing for these devices by either maintaining current billing practices (without distinguishing between reprocessed or OEM products), or taking the average cost of these products, creating a 'blended' price for each item (regardless of whether the devices are reprocessed or not) and relaying that cost to patients. Many hospitals believe that using these methods of patient billing allows them to redirect substantial financial resources to initiatives that significantly improve their quality of care.

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5 2000 GAO report, *supra* note 3, at 24.

6 42 U.S.C. § 1395y.