Action Tip

Topic	Addressing Misinformation About CMS Reimbursement & Hospital Billing for FDA-Regulated, Commercially Reprocessed Single-Use Devices
Market Area	U.S. Hospital Finance, Revenue-Cycle, Compliance & Supply-Chain Teams
Product(s)	All FDA-regulated, commercially reprocessed single-use devices (SUDs)
Date	August 22, 2025

Issue

Issue 1: Some original equipment manufacturer (OEM) representatives claim that Medicare will not reimburse procedures when commercially reprocessed devices are used, or that special billing modifiers are required.
Issue 2: Confusion may still persist in value-analysis committees over whether and how to list reprocessed devices on patient bills, leading some hospitals to under-utilize cost- and carbon-reducing reprocessing programs.
Issue 3: CMS policy and GAO findings confirm that reprocessed devices are reimbursed exactly like new devices; CMS lacks the means—or intent—to differentiate.
Issue 4: Transparent but straightforward billing practices (e.g., blended pricing) free up resources for quality-of-care initiatives, yet not all hospitals have adopted them.

Technical Background

- Any device legally marketed under the FDCA—including FDA-regulated, commercially reprocessed SUDs—qualifies for Medicare reimbursement when "reasonable and necessary" for patient care.
- CMS reimburses procedures, not individual devices; thus, according to GAO, it "currently lacks the means to determine whether it is paying for a new or a reprocessed device."
- CMS has affirmed that "reprocessed devices will be subsumed under the same categories as the original device" and rejected calls to create special modifiers or categories.
- Reprocessors must meet the same FDA Quality System and 510(k) clearance requirements as OEMs, ensuring devices are as safe and effective as a new device.

- Hospitals commonly handle patient billing either by continuing device-diagnostic charge practices or by using a blended price that averages OEM and reprocessed acquisition costs—both fully compliant.

Recommendations

1. **Dispel OEM myths.** Share this Alert with clinical, procurement, and other hospital leaders; remind stakeholders that CMS reimburses procedures containing commercially reprocessed devices with no special codes.
2. **Audit charge masters.** Verify that no device-level modifiers or unique CPT/HCPCS codes have been added that could inadvertently flag reprocessed devices.
3. **Adopt transparent pricing.** Use existing billing practices or a blended-cost methodology to reflect actual acquisition expenses in a transparent and predictable manner and reinvest savings in patient-care projects.
4. **Educate clinicians and procurement.** Emphasize that commercial reprocessors are FDA-regulated manufacturers subject to identical quality and compliance standards as OEMs and that reprocessed devices are not subject to special rules in reimbursement or billing.
5. **Report misinformation.** Document and forward OEM materials that misrepresent reimbursement policy to Compliance and AMDR for corrective action and monitoring, respectively.

For Further Information

Contact your AMDR-member commercial reprocessing partner.

If you are aware of false and misleading claims about FDA-regulated reprocessing with respect to reimbursement and billing, please write to info@amdr.org. If requested, your anonymity will be honored.