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By electronic submission via www.regulations.gov

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Cohen Building
330 Independence Ave. NW
Washington DC, 20201

Re: **Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements**

Dear Acting Inspection General Chiedi:

The Association of Medical Device Reprocessors (AMDR) appreciates this opportunity to provide comments to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) on proposed rulemaking to revise the anti-kickback statute (AKS) regulations and beneficiary inducements under the civil monetary penalty rule (CMP). AMDR appreciates OIG's efforts in proposing changes to these regulations to better promote better value in healthcare.

AMDR is the international trade association representing the legal, regulatory and trade interests of professional, commercial "single-use" device (SUD) reprocessing companies.[1] Our mission is to promote the proper reprocessing of SUDs, ensure safety and efficacy standards with robust regulation on par with all other medical device manufacturers, and to highlight SUD reprocessing as a cost-saving and waste-reducing practice.

AMDR members perform most of the commercial SUD reprocessing in the United States and AMDR members serve nearly 7,400 hospitals and surgical centers in all 50 states and all of the *U.S. News & World Report* "Honor Roll" hospitals[2]. AMDR members provide reprocessed SUDs to hospitals at up to half the price of new devices. This enables hospitals to save hundreds of thousands, in many cases millions of dollars per year – resources that hospitals use to improve patient care, expand access or invest in new technologies.

Reprocessed devices are regulated by the Food and Drug Administration (FDA). AMDR members in the U.S. meet all FDA medical device manufacturer requirements, including

1 For more information, see www.amdr.org
2 See, Reprocessing by the Numbers, **AMDR.org**.

additional regulatory requirements unique to reprocessors.[3] FDA began its full regulatory oversight in 2000,[4] and, since that time, U.S. hospital savings provided by professional, commercial reprocessing firms has been substantial. Last year, AMDR members saved US hospitals and surgical centers $471 million.[5] When health institutions reprocess their medical devices instead of throwing them away, they extend the value of existing medical devices assets which reduces procedure costs and reduces the need for hospitals to buy more new devices. In addition to costs-savings, US hospitals have championed reprocessing as one of the most impactful healthcare sustainability strategies available to them to reduce operating room waste.[6]

AMDR appreciates OIG's efforts to "accelerate the transformation of the healthcare system into one that betters pays for value and promotes care coordination." AMDR shares the goal of promoting greater value in healthcare. In fact, AMDR works to better align the medical device industry with the fundamental interests of hospitals and healthcare providers by making SUD reprocessing a key supply chain strategy for all hospitals. Reprocessing is aligned with hospital and healthcare interests in that both hospitals and reprocessors are interested in extending the lifespan of existing medical device assets and thereby lowering costs. Further, AMDR works towards better transparency and accountability in the healthcare supply chain for medical devices so that providers can better control their medical device assets and optimize value by increasing the lifespan of medical technology.

In today's environment, many incentives exist for medical device companies to provide volume-based, rather than value-based sales. The future requires the medical device industry to enter a new paradigm where the focus is on providing value to healthcare rather than volume. The reprocessing subset of the medical device industry is demonstrating the ability of medical device manufacturers to deliver on this goal.

Thus, AMDR applauds OIG for inclusion of medical devices in the proposed rulemaking and we strongly urge the Department to include medical devices – and specifically the value brought by reprocessing - in the final regulation. Medical device manufacturers, particularly reprocessors, in our view, are uniquely positioned to drive reduction in the overall cost of delivering healthcare by enabling efficiencies throughout the continuum of care. Inclusion of medical devices in the proposed rules would enable reprocessors, who have already demonstrated an ability to reduce the overall cost of SUDs without sacrificing patient care, to work more collaboratively with healthcare provider customers to better coordinate care, ensure the same or better patient outcomes, and help bend the overall cost curve by promoting better use of medical device assets.

AMDR awaits the final rulemaking and we hope to work constructively with OIG staff and healthcare providers to help better realize the incredible value from reprocessing. Thank you.

Sincerely,

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3 *See,* **U.S. Food and Drug Administration (FDA),** *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510K)s) for Reprocessed Single-Use Medical Devices: Guidance for Industry and FDA Staff,* June 2004 (final).

4 *See*, **FDA**, *Enforcement Priorities for Single-Use Devices Reprocessed by Third-Parties and Hospitals; Guidance for Industry and for FDA Staff,* August 2000.

5 *See*, *Reprocessing by the Numbers*, *supra*, note 2.

6 *See, e.g.,* **Practice Greenhealth**, *Implementation Module: Medical Device Reprocessing,"* 2011.

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