AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

June 6, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-NC2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1345-NC2

Dear Dr. Berwick:

On April 7, 2011, the Centers for Medicare and Medicaid Services (CMS) proposed waivers of certain fraud and abuse laws as necessary to implement the provisions of the Medicare Shared Savings Program (MSSP), and asked for comments. On behalf of the Association for Medical Device Reprocessors (AMDR), thank you for the opportunity to provide input into Medicare's cutting-edge reimbursement model that will incentivize healthcare providers to enhance the quality of healthcare in our country while simultaneously lowering costs.

As further discussed below, AMDR would like CMS to consider the following specific comments:

1. FDA-regulated reprocessed medical devices are safe and effective.
2. As a result, CMS should clearly state that use of FDA-regulated reprocessed medical devices will not implicate civil monetary penalties, insofar as reprocessed devices are used as part of accountable care organizations (ACO) to reduce costs.

In addition to this letter, AMDR submitted a letter under separate cover that provides comments on the MSSP proposed rules.

I. AMDR Background

AMDR promotes and protects the legal, regulatory and other trade interests of the nation's third-party medical device reprocessing industry. As part of that mission, AMDR supports:

- The proper reprocessing of medical devices labeled by the original equipment manufacturer for "single-use;"
- Reprocessed devices that are as safe and as effective as original devices;
- Reprocessing as a means of cutting healthcare costs while maintaining patient safety and quality of care; and
- Third-party reprocessing as an environmentally responsible practice.

AMDR defines "third-party reprocessor" as an entity that, at the request of a provider customer, inspects, cleans, refurbishes, function-tests, packages, and sterilizes medical devices originally labeled by the manufacturer as for "single-use" in such a manner that ensures:

- The quality, physical characteristics, and functionality of the devices are not adversely affected, or such characteristics are improved;
- The devices remain as safe and effective for an additional single-use; and
- The devices are reprocessed in full-compliance with FDA regulations.

The reprocessing industry has demonstrated an exemplary record of safety over the last decade, when FDA extended its medical device manufacturer requirements to reprocessors (*see* Section II, *infra*). Since that time, informed health care facilities and physicians have increasingly shown support of the practice of reprocessing. AMDR's members currently serve America's finest medical facilities, including all of institutions ranked by *U.S. News & World Report* as the nation's "Honor Roll" hospitals.[1] AMDR's members also serve all 10 of America's top heart hospitals and 9 of the top 10 orthopedic hospitals, as listed by *U.S. News & World Report.*[2]

However, there is ample opportunity for greater financial savings through the use of reprocessed medical devices. Hospitals are struggling to find solutions that reduce costs while continuing to provide excellent healthcare. AMDR and a majority of U.S. hospitals believe that reprocessed medical devices are one critical solution. Similarly, AMDR believes that ACOs are an important step in achieving high quality, cost-effective care for Medicare beneficiaries. By ensuring that hospitals and physicians have access to safe, effective and efficient means of serving their patients – including the use of reprocessed medical devices – CMS can further the movement toward a sustainable healthcare economy.

II. FDA-Regulation of Reprocessed Medical Devices

Reprocessed medical devices are regulated by FDA, and as such have been found to be "as safe and as effective as a new device."[3] Below we outline, in brief, the applicable federal law and regulatory requirements for reprocessed medical devices.

Since at least 1998, the U.S. Food and Drug Administration ("FDA") has considered third-party "reprocessors of devices labeled for single-use to be [medical device] manufacturers."[4] "A

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[1] *See http://health.usnews.com/sections/health/best-hospitals;* AMDR (2011).

[2] *See http://www.amdr.org/news/2010/10/americas-top-hospitals-reprocess/:* AMDR (2011).

[3] Testimony of Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA), before the U.S. House Committee on Government Reform (26.9.2006) [hereinafter Schultz Testimony]. For a more detailed discussion of FDA's requirements for medical device reprocessors, the "single-use" label, and the safety record of reprocessed devices, *see* AMDR's Best Clinical Practice Background paper.

[4] Letter from Melinda K. Plaisier, Associate Commissioner for Legislation, FDA, to The Honorable Thomas J. Bliley, Jr. (November 29, 2000), at 2 [hereinafter Plaisier letter]. *See also* Letter from D. Bruce Burlington, M.D., Director, Center for Devices and Radiological Health (CDRH), FDA, to Nancy Singer, Special Counsel, Health Industry Manufacturers Association (HIMA, now AdvaMed) (July 15, 1998), stating "reprocessors are inspected in accordance with the current Quality System regulation [QSR], Title 21, Code of Federal Regulations (CFR), Part 820, and they are subject to the labeling requirements of 21 CFR part 801. . . . In fact, FDA has considered such reprocessing firms to be manufacturers under the GMP regulations [which preceded the QSR] . . ." (emphasis

manufacturer can market a device for one more single use from a raw material that was a previously-used, [single-use device] if that device meets the specifications of the device described in the market clearance."[5] A device that complies with all of the applicable requirements of the FDCA is not misbranded or adulterated, and may be marketed legally in the United States. Therefore, a reprocessed device that complies with all of the applicable requirements of the federal Food, Drug, and Cosmetic Act ("FDCA") is lawful and may be marketed legally in the United States.[6]

Specifically, like all medical device manufacturers, reprocessors are subject to establishment registration and medical device listing;[7] medical device reporting;[8] medical device tracking;[9] reports of corrections and removals;[10] the quality system regulation ("QSR");[11] and labeling requirements.[12]

Perhaps most importantly, just like an original equipment manufacturer, a reprocessed device is subject to premarket review by FDA, unless the agency has, by regulation, declared the device to be exempt from premarket requirements. Unless exempt, the lower risk "Class I" and "Class II" devices, whether "original" or reprocessed, are required to have cleared premarket notification submissions ("510(k)s").[13] With regard to premarket review, reprocessors are subject to *more stringent* regulation by FDA than are OEMs[14] because, pursuant to provisions added to the FDCA in 2002 by the Medical Device User Fee and Modernization Act ("MDUFMA"), FDA has withdrawn the exemptions from the premarket notification requirement for a significant number of previously exempt reprocessed devices, although the "original" devices remain exempt from premarket review.[15]

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added). *See also,* CDRH, FDA, *Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Medical Devices* (Sept. 25, 2006), at 15. *See also, Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (August 14, 2000), at 1 [hereinafter FDA Guidance of 2000].

5 Plaisier letter, *supra* note 4, at 2.

6 *See* 21 U.S.C. §§ 351, 352, 360, and 360c-360e.

7 21 U.S.C. § 360 and 21 C.F.R. Part 807, subpart B.

8 21 U.S.C. § 360i(a) and 21 C.F.R. Part 803.

9 21 U.S.C. § 360i(e) and 21 C.F.R. Part 821.

10 21 U.S.C. § 360i(f) and 21 C.F.R. Part 806.

11 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820.

12 21 U.S.C. § 352 and 21 C.F.R. Part 801.

13 21 U.S.C. § 360(k).

14 *See* Schultz Testimony, supra note 3. "Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the agency that exceeded the requirements for the original manufacturers (OEMs)" (emphasis added).

15 Title III of MDUFMA amended the FDCA (Public Law 107-250). The law required FDA to identify "critical" and "semi-critical" 510(k)-exempt devices for which the exemptions should be terminated when the devices are reprocessed, "in order to provide a reasonable assurance of the safety and effectiveness of the devices" (21 U.S.C. § 360(o)). For devices that lost exemption from the premarket notification, reprocessors had to submit a 510(k) within 15 months of FDA's publication of a notice terminating the exemption, or the device in question could no longer be legally marketed. 21 U.S.C. § 360(o)(2)(B)*; see also* 68 Fed. Reg. 38071 (June 26, 2003).

Further, reprocessors must, in many cases, include in their premarket submissions a whole category of data that OEMs are not required to submit.[16] Specifically, reprocessors are, in many cases, required to include "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended."[17] By contrast, OEMs, who also must validate their processes, are not required to submit such data on a premarket basis.

The reprocessing of medical devices originally labeled for "single use" is subject to a stringent, comprehensive regulatory scheme. In short, "FDA believes that reprocessed [single-use devices] that meet FDA's regulatory requirements are as safe and effective as a new device."[18]

III. Competitive Benefits of Reprocessing

In the U.S., a number of different sources have confirmed the significant cost-savings hospitals achieve through reprocessing. Hospitals not only save about 50% for every reprocessed device they purchase and spend less on waste disposal, they also save money when original equipment manufacturers (OEMs) lower their prices to compete with third-party reprocessors, thus lowering the overall cost of healthcare.

a. Reprocessed Devices Cost Less

FDA-regulated reprocessed devices are as safe and effective as original equipment, but much less costly - typically about half of the cost of an original device.[19] This 50% savings incorporates all of the third-party reprocessors' costs, including research and development, equipment and materials, staff, and the cost of recycling devices when they have reached the end of their life, among many other operational costs.

As far back as 2000, the U.S. Government Accountability Office (GAO) found that facilities using reprocessed devices saved between $200,000 and $1 million annually, on average.[20] Currently, reprocessors estimate that a typical 200 bed hospital, if taking advantage of a reprocessors' full product line, can save between $600,000 and $1 million dollars a year, and

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[16] MDUFMA requires that the labeling of reprocessed devices bear the reprocessor's name and state that the device was reprocessed. 21 U.S.C. § 352(v), effective January 25, 2004. The law also requires that, in many instances, reprocessors include validation data in their premarket submissions. 21 U.S.C. § 360(o)(2)(B)*; see also* 68 Fed. Reg. 38071 (June 26, 2003).

[17] 68 *Fed. Reg.* 23139 (April 30, 2003), *citing* 21 U.S.C. § 360(o) (emphasis added). For a full description of the validation data reprocessors must submit on a premarket basis, including more particular guidance on cleaning, functional testing, and sterilization data requirements, *see* *Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Medical Devices* (Sept. 25, 2006), at 15.

[18] Schultz testimony, *supra* note 3. "FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device."

[19] 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 5 [hereinafter 2000 GAO Report].

[20] *Id*, at 19.

divert between 5,000 and 15,000 pounds of waste from landfills.[21] The savings enable hospitals to hire additional nurses, upgrade technology, provide indigent care, and make other necessary improvements.

America's third-party reprocessors currently save U.S. hospitals over a quarter of a billion dollars a year and independent analysts project double digit year-over-year growth for the reprocessing industry (and thus savings to the healthcare system) through 2013.[22]

b. Reprocessing Promotes Competition

Medical device reprocessing creates price competition that has been shown to decrease the price of new devices. As the GAO explained, "the competitive alternative offered by SUD reprocessing has affected negotiations between manufacturers and purchasers and may have caused some manufacturers to lower their prices to some purchasers."[23]

Over the years, AMDR has also collected evidence of dramatic OEM price reductions to compete with reprocessors. Consistent with the GAO's findings, AMDR has collected evidence that some OEMs will drop their costs, by as much as one-half, in order to undercut the competition from reprocessing. Other OEMs have offered free equipment in exchange for a hospital's commitment *not* to reprocess the OEM's SUDs.[24] But, in nearly all cases, hospitals are not given lower pricing from OEMs *unless* they first agree not to engage the services of a third-party reprocessor. While these unwelcomed and potentially anticompetitive tactics do, unfortunately, discourage numerous hospitals from fully realizing the potential benefits of a reprocessing program, it simply underscores the influence of reprocessing on market competition.

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[21] Individual hospital results will vary. Savings and waste reduction estimates are based on averages achieved by actual customers using the full line of reprocessed devices. Contact a third-party reprocessor to complete a facility analysis and get a more accurate estimated savings potential based on your facility's device usage data.

[22] *See*, Millennium Research Group, *US Markets for Reprocessed Devices 2009 (*May 2009), Reprocessed Device Market Booming During the Economic Crisis ("According to Millennium Research Group's (MRG's) *US Markets for Reprocessed Devices 2009*, hospitals are under significant pressure to lower spending due to the global economic crisis and the rising cost of health care within the US. Health care providers are therefore increasingly purchasing lower-priced products, such as reprocessed devices, which cost approximately 40 to 60% less than original equipment manufactured goods. As a result, market growth for reprocessed devices will exceed 12% annually through 2013."); *see also Caris & Company, Medical Device Reprocessing Accelerating, 10% Penetrated* (August 6, 2009) ("Unprecedented hospital budget constraints and the eco-friendly recycling movement are driving 20-25% YoY equipment reprocessor revenue growth from a $250-300 MM industry revenue base." Further, Caris expects continued year-over-year reprocessing revenue growth of 25% through 2012 with "20%+ annual growth prospects for the next 5-10 years.").

[23] 2000 GAO Report, *supra* note 19, at 19-20. GAO went on to say, "for example, we found evidence that manufacturers sometimes offer lower prices to facilities that agree not to reprocess. We obtained copies of marketing materials from a manufacturer of single-use sequential compression devices offering to reduce prices if the purchasing hospital signed a contract stipulating that it would not reprocess the devices. For two hospitals we contacted, manufacturers offered to reduce the price of new EP catheters by as much as one-half, matching the price of third-party reprocessing, if the facilities would agree to not reprocess the devices. A major third-party reprocessing firm told us that some hospitals stopped using its services when offered this arrangement by manufacturers."

[24] AMDR 2011. Information on file and available upon request.

c. Reprocessed Devices Reduce Waste and Waste Disposal Costs

Regulated medical waste (RMW), also known as "red bag waste," costs hospitals 5 to 10 times more to dispose than regular solid waste. Many medical devices that end up in a hospital's RMW are actually eligible to be reprocessed multiple times, eliminating the needless generation of more RMW and also reducing unnecessary waste disposal costs. Ninety-five percent (95%) of the reprocessed devices that have reached the end of their life are recycled versus sent to landfills. AMDR's members recycle a variety of raw materials from devices that cannot be reprocessed or have reached their maximum number of reprocessing cycles, including stainless steel, aluminum, titanium, gold, polycarbonate and polyurethane parts.

Reprocessing has allowed some hospitals to divert over 8,000 pounds of RMW from landfills each year, while larger systems can divert more than 50,000 pounds. Groups like the American Nursing Association, the Association of periOperative Registered Nurses, and Practice Greenhealth have recognized or endorsed reprocessing as a way to reduce waste.[25]

d. The Bottom Line on Reprocessing and Cost-Savings

As CMS, insurers and hospitals look for ways to manage and reduce healthcare costs, AMDR hopes each will take a closer look at reprocessing. Reprocessing is a vehicle for improving our healthcare system by providing the same standard of care, at half the cost. We believe that AMDR's mission to provide less costly, safe and effective medical devices is consistent with CMS's goals to provide "better care for individuals, better health for populations, and lower growth in expenditures."[26]

IV. Savings to CMS

AMDR understands that CMS pays for medical devices in a variety of ways. Most directly, as a part of the prospective payment system for hospital outpatient department services, new medical devices may be categorized for transitional pass-through payment.[27] With respect to reprocessed devices, in past agency commentary, CMS explained that "we expect those hospitals' charges for reprocessed single-use devices will reflect the costs, just as in the case of the first-use devices."[28] As a result, if hospitals use reprocessed devices that fall into a transitional pass-through category, CMS will receive direct savings through smaller pass-through payments because reprocessed devices typically cost half as much as original medical devices.

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[25] American Nursing Association, Resolution: Safety and Efffectiveness of Reprocessed Single-Use Devices in Healthcare (2010); Association of peri-Operative Registered Nurses, AORN Position Statement on Environmental Responsibility (2006); Practice Greenhealth, Regulated Medical Waste.

[26] 76 Fed. Reg. 19531 (April 7, 2011).

[27] 42 U.S.C. § 1395l(t)(6); 42 C.F.R. § 419.66. In general, if a medical device is medically necessary, approved by the FDA, and is not insignificant, then CMS will provide pass-through payments for a period of at least two years, but not more than three years, beginning on the date that CMS establishes a category of devices.

[28] 66 Fed. Reg. 59897 (Nov. 30, 2001). Note, to date, AMDR is not aware of any reprocessed devices that are eligible for CMS *pass-through* payments. All reprocessed devices, like most of their original equipment manufacturer counterparts, are reimbursed as part of a global payment under the DRG system.

However, under Medicare Part A, hospitals are paid for inpatient admission cases on a per-case reimbursement basis according to the appropriate diagnosis-related group (DRG), which is a global payment that does not itemize the amount a hospital pays for a specific device. Because Medicare pays a flat rate per case for inpatient hospital care, efficient hospitals are rewarded for their efficiency, and inefficient hospitals have an incentive to become more efficient. Moreover, under Medicare Part B, aside from the pass-through transitional payments described above, devices are reimbursed on a fixed fee-schedule basis, that does not take into account the cost to the supplier for a medical device. Hence, 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. As a result, all direct savings will accrue to the physician practice or hospital that chooses to use a reprocessed device.

However, over time, these savings will also benefit healthcare payers, including CMS. As hospitals increase their use of reprocessed devices, and CMS continues to collect device pricing data (as part of updating its DRG payments), AMDR expects that reprocessed devices will help drive down or, at a minimum, mitigate increases to overall procedure costs. Devices are a significant part of an overall surgical DRG and reprocessed devices can help to reduce that portion of the procedure cost, resulting in savings most immediately to the healthcare provider, but ultimately to CMS.

But while an incentive currently exists under the DRG system for healthcare institutions to use reprocessed devices, physicians do not share the same incentive. CMS' ACO initiative is a prime opportunity to align physician and provider incentives to encourage greater use of safe, effective and lower-cost technologies, such as reprocessed medical devices. Thus, it is our hope that CMS will identify and encourage the use of reprocessed medical devices as a tool ACOs can use as part of shared savings programs.

V. Civil Monetary Penalties Waiver

If an ACO participating in MSSP chooses to require or incentivize use of FDA-regulated reprocessed devices as a cost-saving measure, we encourage CMS to confirm that such pro-reprocessing policies will not implicate civil monetary penalties laws.

The civil monetary penalties statute prohibits hospitals from compensating physicians to withhold necessary care from a patient.[29] The OIG has in the past found that gainsharing arrangements, or arrangements that incentivize physicians to limit spending on patients, are in violation of the civil monetary penalties statute. The OIG was specifically concerned about limiting patient care and treating healthier patients preferentially by steering sicker patients elsewhere. The civil monetary penalties statute seeks to ensure that patient care is not being compromised to improve the financial performance of the hospital.

FDA has found that reprocessed devices are as safe and as effective as original equipment. Reprocessed devices are fully regulated by FDA, as any other medical device, and reprocessed devices are fully interchangeable with original equipment for all patients. Therefore, the use of reprocessed medical devices does not constitute the limiting of patient care when such products

[29] 42 U.S.C. § 1320a-7a(b).

are chosen over an original device counterpart. We ask CMS to confirm that inclusion of reprocessing in an ACO incentivizing plan will not be interpreted as an improper form of gainsharing, or otherwise violative of the civil monetary penalties statute.

We recommend that CMS clearly state that ACO policies that promote the use of lower-cost, FDA-regulated reprocessed devices will never be considered compensation for withholding care or subject to civil money penalties (so long as such reprocessing is conducted by an FDA-regulated vendor).

VI. Conclusion

We would like to reiterate that AMDR shares many of the MSSP's goals, most important of which are improving patient care and reducing costs. We appreciate this opportunity to introduce AMDR, as well as provide our thoughts on the MSSP proposed rules, specifically with regard to a waiver from civil money penalties for reprocessed device used as part of an ACO. We look forward to working with you on MSSP implementation and regulation of ACOs.

Sincerely,

Daniel J. Vukelich, Esq.
President and CEO
Association of Medical Device Reprocessors