Response from AMDR to Request for Information

Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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Health and Human Services
Attention CMS-1771-P
PO Box 8013
Baltimore, MD 21244-1859

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The Association of Medical Device Reprocessors (AMDR) thanks CMS for the opportunity to comment and appreciates the agency's attention to addressing the adverse environmental impacts generated by the health sector.

AMDR is the global trade association representing the interests of regulated, commercial medical device reprocessing companies. Our members reprocess "single-use" medical devices (SUDs) cleared by FDA or parallel regulatory authorities in other countries. In 2020, our members reprocessed over 31.6 million devices for over 10,300 healthcare facilities in 13 countries.[1] AMDR members represent a regulated, safe environmental solution that reduces Scope 3 emissions, which drive 82% of all greenhouse gas emissions from U.S. hospitals.[2] The first of several anticipated well-designed, published life cycle assessments showed that a reprocessed EP catheter cut greenhouse gas emissions in half compared to using original devices with each patient.[3]

Use of commercially reprocessed SUDs improves supply chain resiliency by keeping devices circulating domestically. They typically cost 25 to 40% less than original devices, resulting in nearly $438M in savings to hospitals in 2020.[4] These substantial cost savings can be used to offset the costs for environmental remediation efforts.

We therefore specifically provide comments to questions posed in section (c), "understanding how to take action on reducing [healthcare provider] emissions and tracking their progress in this regard" (87 Fed Reg 28478), "Current Assessment of Climate Change Impacts on Health Outcomes, Care and Health Equity RFI."

We provide comments in response to the request for information's focus on "tools and supports that health systems and facilities most heavily rely on to support their efforts to reduce GHG emissions" and "how HHS and CMS can support hospitals…in their efforts to more fully prepare for …chronic impacts on their operations and the people they serve as well as what incentives might assist them in taking more action on climate… emissions reduction" (28478).

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Overview

A primary driver of Scope 3 emissions in healthcare is the "take-make-waste" thinking that underpins the predominantly linear economy for healthcare products – where materials are created, used once, then thrown in the trash. In AMDR's view, addressing climate change and reducing healthcare's outsized toll on the environment, requires shifting to circular economy solutions. For the medical device sector, that means designing for reuse or reprocessing, and incentivizing the uptake of reusable or reprocessed products.

Commercial SUD reprocessing provides a case study of a rare quadruple win for healthcare systems, patients, and the planet: they increase supply chain resiliency, and reduce waste, cost, and greenhouse gas emissions. The more devices are reprocessed and used, the more the benefits are realized. Most U.S. hospitals already have medical device reprocessing programs, but we believe there is considerable opportunity for increased GHG, waste and cost reductions. AMDR recently issued a report on the lost potential for U.S. hospitals when they don't use as many reprocessed devices as they could. AMDR's report is attached.

AMDR proposes CMS consider the following in line with the RFI:

Incentivize hospital purchasing of value and environmental benefits, not volume and wastefulness, in the healthcare supply chain

Current reward systems incentivize hospitals to buy MORE products, prioritizing volume in order to drive down prices. Fundamental changes are needed to move away from volume-based incentive structures, to value-based. Strong federal oversight is therefore needed to develop value-based payment incentives for the use of environmentally preferrable products. Given reprocessed SUDs already are regulated by FDA, eliminating safety or efficacy concerns, CMS could incentivize through payment or reward systems, greater hospital adoption of medical device reprocessing programs to reduce emissions, waste and cost.

As it stands now, reprocessed SUDs are reimbursable as part of a larger Diagnosis Related Group (DRG). Stand-alone payments to hospitals that participate and meet certain reprocessing benchmarks would rapidly incentive hospitals to make immediate carbon reduction, waste and cost reductions. In future years the rewards could be amended to adopt increasingly ambitious targets for reprocessing program compliance. Reprocessing is low-hanging fruit. As a test, and if rolled out as a condition of participation to incentivize more value-based and environmentally-sound purchasing behavior, AMDR believes other subsets of the healthcare supply chain will seek participation and will begin to offer more circular product offerings.

Incentivize or require hospital reporting on emission reductions, goals, and focus specifically on the healthcare supply chain

Given that we know over 80% of the emissions coming from healthcare are Scope 3, of from the supply chain, AMDR urges CMS to focus hospital GHG reduction efforts on the supply chain itself. Setting benchmarks, goals and reporting requirements that can be amended over time will make dramatic impacts on GHG reductions and, we believe, in

cost and waste reduction efforts as well, as evidenced by the reprocessing industry's commitment to healthcare over the last two decades.

Fund and disseminate Life Cycle Assessment (LCA) studies and research on cost savings

LCAs of healthcare products will better inform healthcare purchasers of the carbon emissions associated with disposable versus reusable or commercially reprocessable products. AMDR encourages funding for and use of these independent evaluations to assess supply chain vulnerabilities that may be associated with disposable medical equipment as compared to an alternative remanufactured/reprocessed product.

AMDR also encourages funding for research to evaluate cost comparisons, such as:

- Head-to-head prices for comparable disposable versus reusable or reprocessable products;
- Lifetime costs (or full life cycle or "cost per use") of products; and
- Disposal costs, incurred by health institutions, for the proper disposal of disposable equipment versus reusable or reprocessable version; and
- Assessments of how the lowering of supply chain costs associated with longer life cycle products may be used to provide more equitable, quality and affordable care to a wider array or underserved patient populations. We urge inquiry to investigate greater surgical intervention potential associated with cardiac ablation procedures, for example, if prices were lowered for the diagnostic medical devices. Further analysis could advise hospitals how savings from reprocessing could be used to offset the cost of additional environmental remediation efforts.

Collaborate to create Federal guidance on "best practices"

Identifying and sharing best practices will improve supply chain reliability, promoting products with preferential environmental outcomes, and lowering long-term cost. Suggestions include:

- Coordinate with group purchasing organizations (GPOs) or health plans to identify impediments for using more environmentally sustainable medical device options and advise on policies to help overcome roadblocks. Our members can also help to explain these barriers;
- Identify and highlight existing circular economy business models, including medical device reprocessing, to help address Scope 3 emissions in healthcare;
- Focus first on "wins" or easy-to-adopt supply chain "best practices" that will provide guidance to hospitals and health systems on reducing Scope 3 emissions; and
- For federally run or reimbursed health institutions, require participation in federally regulated reprocessing programs or other existing circular economy solutions, as a means of seizing "low hanging fruit," and to begin to move institutions into greater adoption of circular business models.

Incentivize development of apps and other handheld tools to help hospitals calculate real-time emissions reductions

AMDR is aware of at least three efforts (University of Brighton/UK, Mazzetti, and Practice Greenhealth) that are developing tools for hospitals to calculate supply chain waste reduction and/or greenhouse gas emission reduction. A perfect tool would calculate both. Involving CMS onto these projects will increase the likelihood of accurate and valuable tools. Further, HHS-OCCHE could incentivize use of these programs for hospitals.

Address "repair restriction" issues related to healthcare products

Through collaboration with FTC, HHS-OCCHE could catalyze change that would reduce emissions significantly by taking the following measures:

- Investigate forced obsolescence practices used by some healthcare manufacturers to intentionally limit device use and require greater healthcare acquisitions and source consumption; and
- Prepare a report to healthcare purchasers so they may make more informed purchasing decisions and to allow healthcare delivery organizations to exert counterpressure to linear sales models placed upon them by the current industry.

AMDR and our members are ready to assist in exploring these and Scope 3 emissions issues, particularly around SUDs. Should you have any questions, please do not hesitate to be in touch.

Thank you,

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[1] AMDR, "Hospitals Reprocessed over 31 Million "Single-Use" Medical Devices in 2020," December 28, 2021.

[2] Eckelman MJ, Haung K, et. al (2020) Healthcare Pollution and Public Health Damage in the United States: An Update, **Health Affairs** 39:12. 2071-2079.

[3] Schulte A, et. al., Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, *Sustainability,* 2021, *13*(2), 898.

[4] AMDR, op. cit.