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AMDR Policy Agenda – Reducing Cost and Environmental Impact Through Greener Medical Devices

The Association of Medical Device Reprocessors (AMDR) advocates for policies that promote the use of reprocessed ("remanufactured" in some jurisdictions outside the U.S.) single-use devices (SUDs) to reduce costs, waste, and greenhouse gas emissions while strengthening the supply chain. The following policy objectives aim to drive systemic and cultural changes in healthcare purchasing and regulatory oversight for SUD reprocessing globally.

1. Grow the Circular Economy: Shift Away from Volume Based Purchasing

AMDR wants governments and healthcare systems to prioritize the considerable environmental and cost benefits associated with reusable and reprocessed products rather than short-term, more carbon emitting and wasteful purchasing of disposable products in high volumes. As reprocessed devices are both less polluting and less expensive than their disposable counterparts, their use in health systems should be encouraged. To this end, we advocate for the development of payment incentives that reward hospitals for promoting a circular economy, such as by prioritizing the use of reprocessable devices. We support stand-alone incentive payments to hospitals meeting reprocessing benchmarks to quickly achieve measurable reductions in carbon emissions, waste, and costs, and propose adjusting rewards, over time, to encourage increasingly ambitious reprocessing targets.

2. Focus on Reducing Emissions from Healthcare Supply Chains

While AMDR supports accrediting group prioritization of sustainability programs (e.g. the Joint Commission and Joint Commission International's voluntary sustainability accreditation), we would like to see regulatory authorities and payors require hospitals to report on emission reductions. These should specifically target supply chain (Scope 3) emissions, which constitute 60 to 80% of healthcare sector emissions. Regulators and payors should establish goals and reporting requirements, inclusive of reprocessing, that can be updated to drive significant reductions in greenhouse gas emissions, waste, and costs.

3. Fund Life Cycle Assessments and Cost Research

Governments should promote funding independent Life Cycle Assessments of healthcare products to inform purchasers about the environmental impact of disposable vs. reprocessable SUDs. Specifically, they should encourage research on:

- Price differences between disposable and reprocessable products.

- Differences in carbon emission impact between disposable and reprocessed products.
- Lifetime or "cost per use" expenses.
- Waste disposal costs for healthcare institutions.
- How supply chain savings can improve care for underserved populations.

Additionally, research should investigate how reprocessing savings could fund beneficial activities such as expanded surgical and other medical interventions, environmental initiatives, and staff compensation. Finally, researchers should aim to scrutinize greenwashing. Existing recycling and other end-of-life programs should be carefully evaluated to determine their real impact in comparison with alternatives, such as reprocessing.

4. Identify and Overcome Barriers While Promoting Successful Models

Regulators and payors should partner with stakeholders such as group purchasing organizations, healthcare staff, and reprocessors to identify and overcome barriers to the adoption of circular economic business models. They can also showcase easy-to-adopt, successful, working models, including reprocessing "best practices" to address healthcare emissions. Government funded or reimbursed institutions should be required to participate in regulated reprocessing programs to capitalize on immediate sustainability and emission reducing opportunities.

5. Address Forced Obsolescence and Other Anti-Reprocessing Practices

Some original equipment manufacturers (OEMs) engage in practices to inhibit or discourage the use of reprocessed devices, such as by intentionally limiting device usability or outright prohibiting reprocessing in contracts. AMDR calls on regulators to aggressively investigate and put a stop to these practices. Regulators should, for example, prepare reports to help healthcare buyers make informed decisions and push back against linear sales models that hinder sustainability efforts. We appreciate the existing efforts by some U.S. federal agencies to examine this serious problem, and we hope to see these efforts turn into concrete action.

6. Educate Stakeholders on Available Reprocessing Opportunities

Regulatory authorities can empower healthcare procurement staff by creating a webpage listing devices cleared for reprocessing in their jurisdictions. We urge authorities to alert healthcare systems about regulated reprocessing options, especially for devices with anticipated shortages due to supply chain issues or other disruptions.

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7. Promote Global Harmonization of Reprocessing Standards

AMDR envisions a harmonized global market where reprocessing is governed by the same regulatory standards as OEMs, and where these standards are the same or similar across international boundaries. We urge all nations to adopt regulations building towards a consistent, global standard for medical device reprocessing. In countries that lack the resources to provide regulatory oversight, we encourage officials to accept or allow US or EU compliant reprocessed devices to be placed on their markets.

Finally, AMDR has specific policy concerns in the following jurisdictions:

- **United States:**
    - **Federal Oversight:** The U.S. Food & Drug Administration (FDA) began regulating SUD reprocessing in 2000. AMDR seeks continued, rigorous federal oversight to ensure the safety and efficacy of reprocessed devices. Moreover, we want federal agencies such as the Federal Trade Commission to monitor and address the anti-reprocessing business practices of some OEMs and CMS to favorably reimburse reprocessing to induce more reprocessed device usage.
    - **Overturning Veterans Affairs Restrictions:** Currently, the only major health system in the U.S. to prohibit the use of reprocessed SUDs is the Veterans Health Administration (VHA). This senseless policy seems to be based on little more than inertia and outdated assumptions of risks, and costs taxpayers, the planet, and American veterans. While the Department of Veterans Affairs has taken this policy under review, it is AMDR's position that it should be overturned as soon as possible.
    - **The "Single-Use" Label:** For decades, the "single-use" label has promoted the mistaken belief that SUDs cannot be safely reprocessed. As the FDA has explained, this label merely means the OEM has chosen not to perform the validation tests necessary to label a device "reusable" and does not mean it cannot be cleared for reprocessing. AMDR urges FDA to examine and address the underlying causes behind the proliferation of this label and consider establishing a new framework for the labelling of reprocessable devices.
- **European Union**:
    - **Eliminating the "Opt-In" Model:** Under Article 17 of the current EU Medical Device Regulation (MDR), medical device reprocessing (referred to in Europe as "remanufacturing") is permitted, but individual member states must proactively

"opt-in" in order for it to be allowed in their jurisdictions. This unnecessary, additional step required of national-level regulators needlessly complicates the adoption of a circular economic practice. Instead, the EU should amend the MDR such that reprocessing will be allowed across the continent, if the reprocessed device meets CE marking requirements. To learn more about AMDR's recommended amendments to Article 17, please see our position paper.

- **CE Mark Adoption**: Absent EU action above, AMDR urges EU member states to harmonize a consistent regulatory approach for reprocessing and ensure that all reprocessed products that obtain a CE mark are entitled to be placed on the entirety of the EU market. With the availability of CE-marked, remanufactured SUDs, hospitals have access to lower-priced devices that provide competitive downward pricing pressure on manufacturers for new devices, and lower waste and emission options while building supply chain resilience.

By advancing these policy initiatives, AMDR aims to create a more sustainable, cost-effective, and resilient healthcare supply chain that benefits providers, patients, and the planet.