Comments to Council on Environmental Quality;
Federal Agency Climate Adaption and Resilience Plans

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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We are pleased to have the opportunity to comment on select federal agency climate adaptation and resilience plan submissions to the Council on Environmental Quality. The Association of Medical Device Reprocessors (AMDR) provides comments specifically in response to the U.S. Veterans Health Administration, the Department of Health and Human Services, and the Department of Defense to address climate change by reducing greenhouse gas emissions in the health sector.

AMDR is the global trade association representing the interests of regulated, commercial medical device reprocessors. We write with a simple, evidence-based solution that reduces greenhouse gas emissions from the supply chain at hospitals, reduces costs and improves supply chain resiliency – a solution that is not addressed in the climate adaptation and resilience plans from the noted departments.

"Reprocessing" refers to the collection, shipment, tracing, cleaning, testing, disinfecting/sterilization, and repackaging of a medical devices originally labelled for "single-use." Commercial reprocessors are professional, FDA-regulated companies. Over 300 single-use products have been cleared or regulatorily approved for reprocessing in the United States, Canada, Japan, the UK, and the European Union.

More than 9,200 US hospitals, including the Cleveland Clinic, Mayo Clinic, and most U.S. military hospitals use reprocessed single-use devices (SUDs), according to our members. Unfortunately, due to policy restrictions, none of the VA hospitals use reprocessed SUDs, instead preferring to throw out these assets after a single use, resulting in a completely avoidable wasteful practice that, as evidenced below, spikes greenhouse gas emissions from the supply chain.

Health Care Without Harm (HCWH) estimates that "if the global health care sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet." U.S. based studies indicate that the country's health care emissions "have reached 8.9% and 9.8% of the

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national total respectively, with the latter estimate comprising 655 million metric tons of carbon dioxide equivalent (CO2e)," according to the HCWH report.[1]

Their report notes that most emissions from hospitals – **are derived from the supply chain through the production, transport, and disposal of goods and services including medical devices.**

A second study by researchers from Yale, Northeastern, and the University of British Columbia – among other institutions – took a deeper dive into the environmental emissions from the U.S. health sector and found that **Scope 3 emissions, those largely from the supply chain required to treat patients, accounts for 82% of the problem**. Therefore, urgent attention is need to supply chain solutions that are less toxic, such as reprocessing.

Recently, a study published in the Journal Sustainability compared the environmental and public health impacts of reprocessed electrophysiology (EP) catheters to original or "virgin" EP catheters. The life cycle assessment looked at the environmental impact across 16 major measures. The results were remarkable: the researchers found that reprocessing cut the products' global warming impact – a metric that measures relevant factors such as greenhouse gas emissions and resource consumption – by more than 50%. Use of reprocessed catheters had cut ozone depletion by over 90% and had reduced incidences of cancer and other diseases caused by pollution from healthcare waste by over 60%.

Regrettably, despite the overwhelming evidence that greenhouse gas emissions from the health sector are heavily concentrated in the supply chain, each of the climate adaptation reports from VHA, HHS, and DoD – the three departments with oversight over hospitals – fail to commit to specifically looking for evidence-based methods to reduce greenhouse gas emissions from the supply chain. The reports concentrate on making sure their supply chains are safe from interruption caused by climate change, but that is different from committing to reduce emissions from the largest cause of the emissions.

Interestingly, reprocessed SUDs strengthen the supply chain because reprocessed devices become local devices, and are more readily available, lessening hospital dependence on a global supply chain. Reprocessing is also 30 to 40% less expensive.

Although AMDR member companies reprocessed over 31 million such devices and returned them to over 10,300 hospitals worldwide for reprocessing, our data shows that this represents only a tiny fraction of the FDA-cleared SUDs that could be reprocessed. We

[1] HCWH references the following for this data: Eckelman MJ, Sherman J (2016) Environmental Impacts of the U.S. Healthcare System and Effects on Public Health. PLoS ONE 11(6): e0157014. doi:10.1371/journal.pone.0157014

specifically call on HHS to add to its plan ways to ensure that hospitals in the US create a preferential use pathway for FDA-cleared, commercially reprocessed SUDs.

AMDR and our members are pleased to answer any questions, provide a virtual plant tour, or support this initiative to significantly reduce greenhouse gas emissions from the health sector through FDA-regulated reprocessing of SUDs.

In closing, we share that the UK's National Health Service has reviewed its Scope 3 emissions and committed to use reprocessed SUDs (called remanufactured SUDs in the UK) to reduce greenhouse gas emissions – the action we hope our government will take.

An interview reprinted below with Alan Wain, Chief Operating Officer for Supply Chain Coordination, National Health System UK offers a look into the Scope 3 commitments we would like to see from these three U.S. departments.

Q: Tell us about the National Health System's (UK) interest in the use of remanufactured[2] single-use devices.

Remanufacturing is quite sophisticated. Most of these devices cannot simply be put through a sterilizer; you have to take them apart; you have got to reprocess them put them back together and make sure they are clinically safe to use again.

Just to put remanufacturing into context, if we examine our strategy to net-zero carbon emissions, the NHS needs to take out something like 16.5 million tonnes of carbon dioxide equivalent per year just from the supply chains.

One of the biggest contributors [of emissions in the NHS] is down our supply chains, our suppliers' own carbon footprints, and that that accounts for about 4.5 million tonnes. Of that, 157,000 tonnes could be removed by using remanufactured or reprocessed devices, and another 202,000 tonnes from reused and refurbished devices.

To achieve our objectives, the NHS needs to be working with our strategic suppliers to achieve a major, seismic shift in carbon footprint reduction. We have been working with Vanguard as a strategic supplier, and we are doing a lot of engagement around the NHS for uptake of remanufactured devices.

It starts with the collection of the original device and sending it off to Vanguard's remanufacturing unit to remanufacture them for reuse by the NHS. The next step is to get a bigger uptake of these devices within the NHS. There is, now, a small amount of uptake, but the ambition is to get to a much larger footprint wherein 40–50% of the devices being used are remanufactured.

[2] In Europe, reprocessing is referred to as "remanufacturing"

> Remanufacturing is an important part of our strategy – though it is not the only part of our strategy – and we are looking forward to working with our strategic suppliers to drive down the carbon footprint across the whole NHS.

FDA-regulated reprocessing represents a rare triple win for America's hospitals. They reduce greenhouse gas emissions, strengthen the supply chain and lower costs. Reprocessors currently work with U.S. military hospitals, all of the *US News & World Report* "Honor Roll Hospitals," including the Mayo Clinic and Cleveland Clinics, and at the majority of hospitals in the country. We do not understand why they are not used at VHA facilities and ask that the Administration strongly advocate that VHA adopt SUD reprocessing as part of its climate change adaptation plans.

Please do not hesitate to reach us if you have questions.

Sincerely,

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