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Mr. Chris Fredley
SWM Program Rule Coordinator
Washington Department of Ecology
Solid Waster Management Program
300 Desmond Drive SE
Lacey, WA 98503

**RE: Comments on the Proposed Chapter 173-950 WAC – Recycling Reform Act**

Dear Mr. Fredley,

On behalf of AdvaMed, the Medtech Association, I am writing with concerns regarding the Washington Department of Ecology draft rulemaking implementing the Recycling Reform Act.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 650 members include the full spectrum of medical technology companies, including diagnostic and imaging tools to digital health technology companies.

While we share the overarching goal of reducing plastic pollution and achieving a circular economy, the proposed regulations present significant legal, operational, and economic concerns that disproportionately impact Washington's medical technology industry, and more importantly, the patients who rely on these products. AdvaMed strongly urges the Department to maintain the full exemption for medical devices and medical device packaging enacted by the Washington legislature in SB 5284.

The enacting legislation (SB 5284) explicitly exempts all packaging for products regulated as a medical device by the FDA. The law defines packaging as "a material, substance, or object that is used to protect, contain, transport, serve, or facilitate delivery of a product and is sold or supplied with the product to the consumer for personal, noncommercial use." The statute is clear that medical devices regulated by the FDA and their packaging are exempt from the law. The

scope and merits of this exemption were thoroughly debated and resolved as part of the legislative process and the regulation should reflect that.

The proposed regulation narrows this exemption to primary packaging alone. This interpretation is inconsistent with the straightforward exemption in statute. The exemption was crafted transparently in the legislature's established policy committee framework.

We believe the Department's interpretation in this draft regulation exceeds statutory authority, as the law does not impose any qualifiers on the medical device exemption. Medical device and medical product companies already operate within strict regulatory frameworks for their products and packaging. This is a highly regulated and multilayered system, designed to protect product sterility and patient safety. Restricting the exemption jeopardizes compliance with federal safety standards and risks disrupting the supply chain for life-saving products.

The proposed regulation creates a potential conflict with federal requirements, particularly for packaging that safeguards public health. The U.S. Food and Drug Administration (FDA) requires packaging that ensures the sterility, safety, and efficacy of medical devices. Any regulation that impedes compliance with these federal mandates not only threatens patient health but also creates liability and operational uncertainty for medical device companies.

Disruptions to these frameworks caused by regulatory uncertainty risks reducing access and increasing cost. These costs ultimately impact Washington's healthcare system, increase the price of critical medical products, create barriers for companies seeking to operate and innovate within the state, and reduce access to novel treatments.

Further, medical devices and products often remain in service with the end user for the product lifespan. Some hospitals operate recycling programs or participate in partnerships with manufacturers and other organizations to recycle or repurpose constituent materials. There is also a market for refurbished equipment, which reduces the amount of materials used.

We urge the Department to modify its proposed regulation to adhere to the clear language of SB 5284 and maintain the clear exemption for medical device packaging and other critical products as provided in the law. This not only ensures consistency across states, but will also align with legislative intent, ensure

regulatory compliance, and avoid unnecessary disruptions to patient care and public health.

AdvaMed remains committed to partnering with the Department to achieve the goals of the Recycling Reform Act within the enacted language.

Thank you for your consideration. We welcome the opportunity to engage further on this matter, please feel free to contact me at dgottlieb@advamed.org.

Sincerely,

Darbi Gottlieb
Senior Director, State Government & Regional Affairs
AdvaMed