# Memo

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To Washington State Department of Ecology Solid Waste Management Program

From Cardinal Health

Cc recyclingreform@ecy.wa.gov

Subject Recycling Reform Act Rulemaking (Chapter 173-950 WAC) Feedback

To Whom It May Concern,

We appreciate the opportunity to comment on the draft rule language for Chapter 173-950 WAC implementing Washington's Extended Producer Responsibility (EPR) program. As a manufacturer of medical devices and other FDA-regulated healthcare products, we support the program's environmental goals; however, we strongly recommend that the Department adopt explicit exclusions or significantly streamlined requirements for these product categories due to their unique regulatory, scientific, and patient safety constraints.

As drafted, the definition of "covered material" broadly includes primary, secondary, and tertiary packaging introduced into the state, which would unintentionally capture packaging used for medical devices and similar healthcare products. This packaging is not discretionary. It is integral to product safety and performance. Medical device packaging must comply with FDA Quality System Regulation requirements (21 CFR Part 820) and internationally recognized standards such as ISO 11607, which require validated sterile barrier systems, packaging integrity testing, and stability through distribution. These requirements are supported by scientifically validated testing, including microbial barrier testing, transportation simulation (ASTM D4169), and shelf-life validation. Any modification to packaging materials; even minor reductions, can compromise sterility assurance levels, require full revalidation, and often necessitate regulatory submissions to FDA. As a result, this packaging cannot be redesigned for recyclability or reduction without introducing potential risks to patient safety and disrupting product availability.

Additionally, medical device packaging frequently consists of specialized, multi-material systems (Tyvek®, foil laminates, and high-barrier polymers) designed specifically to maintain sterility and protect against contamination, moisture, and oxygen ingress. These materials are typically incompatible with conventional municipal recycling systems and cannot be readily substituted with recyclable alternatives without compromising performance. This fundamental technical limitation distinguishes healthcare packaging from typical consumer packaging and significantly undermines the environmental effectiveness of applying EPR requirements to these products.

We also have significant concerns regarding the reporting obligations under Section 173-950-100, which require producers to provide detailed packaging data, recycling metrics, and supporting records upon request. For medical device manufacturers, this requirement is disproportionately burdensome due to globally integrated supply chains, complex product configurations, and regulatory controls that do not align with state-level tracking. Packaging data is typically managed at a global or product family level, not at a state-specific level, and segregating this data would require substantial system redesign without producing meaningful environmental benefits. In addition, many devices are distributed through healthcare systems where packaging disposition is controlled by regulated medical waste streams, further limiting the relevance of traditional recycling metrics.

While Section 173-950-510 provides a process for temporary exclusion where federal requirements make inclusion infeasible or inadvisable, the process as drafted is resource-intensive, duplicative, and ill-suited for FDA-regulated products that are already subject to rigorous federal oversight. It requires extensive technical analysis, ongoing reporting, and periodic resubmission, even where the underlying constraints; such as sterility and biocompatibility requirements, are well established and unlikely to change. Requiring individual petitions for each product or packaging type creates unnecessary administrative burden without advancing the program's objectives.

Given these considerations, we strongly urge the Department to adopt a clear, categorical exclusion for medical devices, combination products, dietary supplements requiring protective packaging, and other FDA-regulated healthcare products where packaging is necessary to ensure sterility, safety, or efficacy. At a minimum, the rule should explicitly recognize that packaging subject to federal safety and sterility requirements is exempt or subject to significantly reduced reporting and compliance obligations. This approach is consistent with the statutory allowance for exclusion where federal requirements make inclusion infeasible, and it reflects well-established scientific and regulatory realities.

Excluding these product categories will avoid unintended consequences, including potential conflicts with federal law, risks to patient safety, supply chain disruption, and increased healthcare costs, while allowing the EPR program to focus on materials with meaningful potential for redesign and improved recyclability. We believe this targeted approach will better align with the program's environmental goals and ensure practical, effective implementation.

Please direct any questions or requests for further information to Alexzandra.Bour@cardinalhealth.com.

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Thank you!