Healthcare Distribution Alliance

HEALTH DELIVERED

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Maine Department of Environmental Protection
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HDA Comment Letter
Maine EPR Chapter 428 Proposed Rule

On behalf of the Healthcare Distribution Alliance (HDA), thank you for the opportunity to continue engaging in the rule making process for Maine's Packaging Stewardship Law, § 2146 on behalf of our wholesale distributor members who ensure that over 1,500 points of care in Maine are physically stocked with products. **Respectfully, we would like to share our ongoing view that packaging materials for drugs be explicitly exempted from the definition of "packaging material" by being added through this major substantive rulemaking process to the Chapter 428 Proposed Rules.**

HDA is the national trade association representing healthcare wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide, including over 260 pharmacies and other sites of care across Maine. Healthcare wholesale distributors are unique entities in the supply chain operating 24 hours a day, 365 days a year, shipping approximately 10 million products across the nation every day. Distributors do not research, develop, manufacture or market pharmaceutical products. Wholesalers also do not prescribe or dispense medications to patients or have any impact on a patient's pharmacy benefit design. Wholesale distributors' role is to serve as the logistical experts who purchase pharmaceutical products from manufacturers, securely store, and safely deliver manufacturer's products to state and federally licensed healthcare providers. Pharmaceutical distribution is a high-volume, high-value, yet very low margin industry.

HDA appreciates the consideration and work that the Department of Environmental Protection has put into the rules draft, such as including a section to allow for producers to petition for fee exemption. We also understand and appreciate that the staff plans to shortly initiate a process that would allow producers to apply for exclusions via rulemaking for packaging material with content or construction standards that preclude or significantly diminish its ability to increase the recyclability or reduce the volume of packaging material. **However, we would like to take this opportunity to share our ongoing view that the Department reduce the burden on both the state and businesses by incorporating into the Chapter 428 Rules an exemption for the packaging materials of products regulated by the FDA as a drug or medical device.**

Due to stringent federal regulations, HDA believes that pharmaceutical packaging materials content and construction already meet the requirements for exclusion, and requiring each and every drug product to go through the application process will create complications and burden

for the state and the pharmaceutical supply chain. For example, the rules are stated as being designed to provide incentive for packaging that meets certain environmental standards regarding material, recyclability, and labeling- options not widely available for FDA-regulated drug products, which must be packaged in ways that meet federal standards, including labels that inform patients and dispensers of certain information, and ensure drug stability.

These complications and burden will be further exacerbated by the definition of "producer", which contains language which in some cases may capture wholesale distributors, who are not the manufacturers of drug products, which could result in a single product being taxed multiple times, and place a disproportionate burden on distributors due to their thin net profit margins of under 1%. Adding the FDA exemption language below, which is included in several state EPR laws such as Oregon and Maryland, will avoid such complications.

Finally, Maine's Drug Stewardship Program law is already underway, as outlined in *Title 38 Chapter 16 §1612,* with the selected drug stewardship organization being tasked by the statute to report how packaging collected by the program was recycled, and manufacturers being required to make payments to fund the program based on weight, volume, and type of packaging material. Since the packaging for these products is already being funded and recycled under Maine's Drug Stewardship program, including such covered drugs in the Packaging Program or requiring them to undergo individual application process will add unnecessary duplication in fees, efforts, and strain on the pharmaceutical supply chain. **We believe the final rules should exempt products covered under this law, as is the case in the current rules draft for other products also covered by other stewardship programs, such as architectural paint. HDA believes that adding the FDA exemption language would resolve this conflict- however should the Board choose not to approve such FDA exemption language, we would further urge the Board to add an exemption for covered drugs under this program as follows:**

> "Packaging material" does not include a discrete type of material, or a category of material that includes multiple discrete types of material, that is:
>
> (4) Packaging used for a covered drug, as defined in *Title 38 Chapter 16, section 1612, subsection 1, paragraph D, as long as the drug stewardship program is in operation, has been approved by the department pursuant to section 1612 and the stewardship organization operating that program:*
>
> (a) Has demonstrated to the department's satisfaction that it recycles at least 90% of the packaging of a covered drug collected under the program; or
>
> (b) Subject to the approval of the department, if unable to satisfy the requirements of division (a), has demonstrated to the department's satisfaction that it recycles at least 80% of the packaging of a covered drug collected under the program; or

In summary, the pharmaceutical supply chain is unlike any other and must be regulated appropriately and precisely to avoid disrupting patient access to essential medications. Accordingly, HDA continues to urge the final rules include a full exemption as follows:

> Packaging material does not include packaging used for products regulated as a drug or medical device by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., sec. 3.2(g)(1) of U.S. Code of Federal Regulations.

Thank you again for any further consideration that may be provided to these exemption requests, and please contact me for any further discussion at kmemphis@hda.org.

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance