Healthcare Distribution Alliance

HEALTH DELIVERED

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Maine Department of Environmental Protection
17 State House Station
32 Blossom Lane
Augusta, Maine 04333-0017

HDA Comments on EPR Conceptual Draft Rules, Part 2
Rulemaking for Maine's Packaging Stewardship Law, § 2146

On behalf of the Healthcare Distribution Alliance (HDA), we greatly appreciate the opportunity to comment on the EPR Conceptual Draft Rules, Part 2, which Maine Department of Environmental Protection has published in advance of Maine's Packaging Stewardship Law, § 2146.

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 15 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 them to state and federally licensed healthcare providers. Pharmaceutical distribution is a high-volume, high-value, yet very low margin industry.

As the logistical experts in the pharmaceutical supply chain, our members are concerned about the negative impact Maine's Packaging Stewardship Program would have on healthcare and prescription medications in Maine. 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 requests that any final rules implementing the program incorporate important exemptions not currently included in the Department's EPR Conceptual Draft Part 2, as outlined below.

<u>Explanation of HDA Exemption Requests</u>

- **Include Exemption Language for FDA Approved Products Already Covered Under the Maine Drug Stewardship Program:**
  As exemplified through the architectural paint exemption, the Maine Packaging Stewardship law should be specific to products and packaging that are currently not covered under another state stewardship program, since their inclusion would result in administrative complexity as well as unnecessary and added costs onto specific products. HDA requests language be incorporated into the final rule exempting products already covered under Maine's Drug Stewardship Program, as outlined in *Title 38 Chapter 16 §1612.*

Maine's Drug Stewardship Program law is already underway, 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, there is no need for them to be included in the Packaging Program as well.

Requiring these products to also be covered under the Packaging Material Stewardship Program would result in the same drug packaging material being assessed multiple fees paid by multiple entities, which would create confusion for both programs and add disruptive burden to the supply chain, resulting in added costs to healthcare and pharmaceutical products for Maine consumers.

Furthermore, HDA continues to encourage the Department to consider a full exemption 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. Stewardship and EPR programs across the country often include this exemption due to the added costs these programs would have on patients within their states.

Recommended Exemption Language: I. "Packaging material" means a discrete type of material, or a category of material that includes multiple discrete types of material with similar management requirements and similar commodity values, used for the containment, protection, delivery, presentation or distribution of a product, including a product sold over the Internet, at the time that the product leaves a point of sale with or is received by the consumer of the product. "Packaging material" does not include a discrete type of material, or a category of material that includes multiple discrete types of material, that is:

(1) Intended to be used for the long-term storage or protection of a durable product and that can be expected to be usable for that purpose for a period of at least 5 years;

(2) A beverage container, as defined in section 3102, subsection 2, subject to the requirements of chapter 33;

(3) A container for architectural paint, as defined in section 2144, subsection 1, paragraph A, as long as a paint stewardship program is in operation, has been approved by the department pursuant to section 2144 and the stewardship organization operating that program:

(a) Has demonstrated to the department's satisfaction that it recycles at least 90% of the containers of architectural paint 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 containers of architectural paint collected under the program; or

(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

(5) Excluded from the definition of "packaging material" by the department by rule adopted pursuant to subsection 13, paragraph D. [PL 2021, c. 455, §2 (NEW).]

- **Ensure Clarity in the Definitions:**
  HDA is concerned the definition of "producer" contains room for multiple interpretations, and thus could inadvertently include many entities under the definition of producer, potentially causing the same packaging material to be assessed multiple times and adding unnecessary costs in the system. This would be the case for the pharmaceutical distribution industry, with multiple entities involved in the safe and efficient delivery of products. As the pharmaceutical distribution is a low-margin industry with a less than a 1% net profit margin, having distributors arbitrarily assessed a fee best paid by the manufacturer of the product would disproportionally impact and disrupt the pharmaceutical distribution chain. Similarly, adding these costs to the pharmacy would undoubtedly impact their operations. Clarifying that the producer is whoever owns the product's labeling code would avoid these complications and better fit the unique nature of the pharmaceutical supply chain. The clarifying language below would ensure that the entity responsible for the product would also be responsible for its recycling, rather than other entities within the supply chain who act as conduits for the safe delivery of the manufacturer's product.

A. Producer. "Producer" means a person that:

(1) Has legal ownership of the brand of a product sold, offered for sale or distributed for sale in or into the State contained, protected, delivered, presented or distributed in or using packaging material; or

(2) Is the sole entity that imports into the State for sale, offer for sale or distribution for sale in or into the State a product contained, protected, delivered, presented or distributed in or using packaging material is branded by a person that meets the requirements of subsection (1) and has no physical presence in the United States and

(3) Adds packaging material to another producer's product for distribution directly to a consumer.

Producer includes a low-volume producer and a franchisor of a franchise located in the State but does not include the franchisee operating that franchise.

Producer does not include a nonprofit organization exempt from taxation under the United States Internal Revenue Code of 1986, Section 501(c)(3).

For FDA-approved products, the producer shall mean the holder of the product's labeling code.

In summary, HDA respectfully urges the Department to revisit § 2146 subparagraph (13) (D) of the statute by adding an explicit exemption to the definition of "packaging material" for packaging used in products regulated as a drug by the FDA, and for packaging materials already covered by Maine's Drug Take- Back Stewardship Program, §1612. Such exemptions are critical to the success of the program and to ensuring the stability of the drug supply chain in Maine.

Thank you again for your consideration, and please contact me for any further discussion at kmemphis@hda.org or 443.375.6541

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance