Healthcare Distribution Alliance

HEALTH DELIVERED

December 22nd, 2022

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

HDA Comments re: Rulemaking for Maine's Packaging Stewardship Law, § 2146

The Healthcare Distribution Alliance (HDA) appreciates the opportunity to provide comments during this stakeholder listening period in advance of rulemaking for the Packaging Stewardship Law § 2146. While HDA supports the intent of the law, we respectfully request the Department further clarify the definition of "producer" in the final rulemaking to ensure it clearly captures the actual manufacturer of a product. The clarification we respectfully propose below would help alleviate any ambiguity around the definition while also following the precedent of Maine's Drug Take-Back Stewardship Law and other recycling programs across the country.

HDA is the national trade association representing healthcare wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 customers, including but not limited to pharmacies, hospitals, long-term care facilities, clinics and others nationwide. In Maine, our members serve approximately 261 customers.

HDA's distributor members do not research, develop, manufacture or market specific 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 purchase pharmaceutical products from manufacturers, securely store, and safely deliver them to state and federally licensed healthcare providers. HDA members operate 24 hours a day, 365 days a year, shipping approximately 15 million products across the nation every day. Simply put, wholesale distributors are logistics experts that ensure pharmacies and hospitals keep their shelves stocked with medications and healthcare products their patients need.

On behalf of our member companies, we are concerned that the definition of "producer" in § 2146 may unintentionally capture other entities within the supply chain outside of the actual manufacturer of the product, which would create unnecessary complexity within the law as well as additional administrative burden for the state. Below is the definition of "producer" from § 2146, **with our redlined rulemaking request:**

> *O. "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 that is branded by a person that meets the requirements of subparagraph (1) and has no physical presence in the United States.*

"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:

(i) a nonprofit organization exempt from taxation under the United States Internal Revenue Code of 1986, Section 501(c)(3)

(ii) a wholesaler that sells or offers for sale in the State at wholesale a covered drug if the covered drug is manufactured by a manufacturer who participates in a recycling or drug stewardship program.

We believe the above clarification would remove any ambiguity and better achieve the legislative intent of the law. Furthermore, the above recommended amendment would better align the Packing Law § 2146 with the state's Drug Take- Back Stewardship Program, § 1612, where the definition of "manufacturer" is very similar to the definition of "producer"- however with clarifying language similar to what we are proposing be included in § 2146 already incorporated. § 1612 states:

K. "Manufacturer" means: (1) A person that has legal ownership of the brand of a covered drug sold in or into the State; or (2) If the person to which subparagraph (1) applies has no physical presence in the United States, a person that imports a covered drug that is branded by the person to which subparagraph (1) applies.

"Manufacturer" does not include a wholesaler that sells or offers for sale in the State at wholesale a covered drug if the covered drug is manufactured by a manufacturer that is a participant in a stewardship program.

"Manufacturer" does not include a retailer that sells or offers for sale in the State at retail a covered drug under the retailer's brand or store label if the covered drug is manufactured by a manufacturer that is a participant in a stewardship program.

Simply put, HDA believes that the original manufacturers of a pharmaceutical product are in the best position to manage product stewardship activities and to reduce waste, rather than those entities in the middle of the pharmaceutical supply chain that "handle" products, such as wholesalers, private label distributors, repackagers, retailers etc. Failing to add this clarifying exemption could create misalignment between the EPR and Stewardship laws and open the door to creating redundancies and administrative burdens for the state, as it could unintentionally cause a single product to be taxed or tracked multiple times as it passes through the healthcare supply chain.

In summary, we respectfully request the Department follow the precedent of § 1612 and add the outlined explicit exclusion when implementing the rules for Packaging Stewardship Law. Thank you for your consideration, and please contact me for any further discussion at kmemphis@hda.org or 443.375.6541

Sincerely,

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