Healthcare Distribution Alliance

HEALTH DELIVERED

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

HDA Comment Letter
Maine EPR Chapter 428 Proposed Rule, Updated

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 the products they need to treat their patients.

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. 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. Wholesale distributors' role is to serve as the logistical experts who purchase pharmaceutical products from manufacturers, securely store them, and then 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, operating on less than one percent annual profit margin on average.

HDA would respectfully like to share our ongoing view that certain exemptions should be added to the rules in order to achieve the stated intentions of the program, streamline operations for the state, and avoid adding disruptive burden to the supply chain. Further, such exemptions are critical to ensuring that distributors do not face undue barriers in their ability to safely and efficiently delivering over 93% of all products to Maine. Specifically:

1.) The packaging of products regulated by FDA as drug or medical devices should be exempted from the definition of "packaging materials" in the Chapter 428 Final Rules.

The rules as stated are designed to provide an incentive for packaging that meets certain environmental standards regarding material, recyclability, and labeling. However, due to stringent federal laws, regulations, and standards[i] governing the packaging of drugs, distributors would be limited or precluded from switching to packaging materials to increase the recyclability or reduce the volume of packaging material. Accordingly, the content and construction of packaging for U.S. Food and Drug Administration (FDA) regulated drugs and medical devices meet the requirements for exclusion and should be exempted via rulemaking from the final rules. Requiring each and every drug product to go through the application process will create voluminous and duplicative reporting resulting in an unnecessary burden for the state and the

pharmaceutical supply chain. Due to these concerns, HDA requests that the Department add the following exemption language, which is included in several other state's EPR statutes:

> 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.

2.) **Drugs already covered under Maine's Drug Stewardship Program should be exempted from the final Chapter 428 rules to prevent products from being fined multiple times, adding undue burden and strain to the critical pharmaceutical supply chain which keeps Maine shelves stocked with essential medication.**

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. HDA believes that 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 best resolve this conflict and avoid harmful duplications between the programs-** however should the Department choose not to approve such FDA exemption language, we would further urge the Department 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

3.) **The final rules should make it explicit that distributors are not producers.**

It is HDA's view that the original manufacturer 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. Clarifying that distributors,

who temporarily own manufacturer products before fulfilling pharmacy orders and deliver the product, are not producers will reduce redundancies and administrative burdens for the state, further ensuring that single products are not fined or tracked multiple times as it passes through the healthcare supply chain.

> V. 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; (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 branded by a person that meets the requirements of Section 2(VW)(1) and has no physical presence in the United States; or (3) Adds packaging material to another producer's product for distribution directly to a consumer. This person is only the producer for the packaging material it adds. Producer includes a low-volume producer, as defined in 38 M.R.S. § 2146(1)(G), 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). Producer 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 who participates in a recycling or drug stewardship program.

Should the Department choose not to incorporate this clarifying exemption language, HDA would like to express our support for this line currently included in the definition of producer remaining in any final rules:

> This person is only the producer for the packaging material it adds.

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 again continues to urge the final rules to include appropriate and necessary exemption for the packaging of drugs and medical devices. Thank you for any further consideration that may be provided to these exemption requests, and please contact HDA for any further discussion at kmemphis@hda.org.

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance

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[i] ***Specific laws, regulations, and standards which HDA requests the Department consider as grounds for exemption via rulemaking:***

- ***The United States Pharmacopeia*** *(a standard setting body)* ***Code 659*** *precludes and prevents distributors' ability to increase the recyclability or reduce the volume of packaging material for certain cold controlled products, such as certain essential vaccines. This code, which is*

referenced by the FDA, establishes standards critical to patient safety regarding the packaging, storage, and shipping of controlled cold products regarding protection from moisture, freezing, heat, and light- standards which can exclusively be met through the use of Styrofoam containers. Therefore, failing to incorporate an exemption in the rules for all pharmaceutical products, ***but especially for Styrofoam containers****, would unduly penalize distributors for utilizing the highest product and patient safety guidelines on behalf of Maine patients.*

- ***Federal Code*** ***21 CFR 205.50-*** *HDA encourages the Department to reconsider their view that this code does not establish content or construction standards which preclude or significantly diminish a producer's ability to increase the recyclability or reduce the volume of packaging material. Specifically, this code establishes that drugs must be packaged in specific ways to meet federal standards and ensure drug stability and inform patients. Failing to exempt the packaging of FDA-regulated medical and drug products would create conflict with federal requirements, adding undue strain to the healthcare supply chain providing critical products to Maine patients.*

- ***Federal Code 21 CFR Part 211*** ***Subpart G*****;** ***Subpart E****- Again, HDA encourages the Department to reconsider their view that this code does not establish content or construction standards which preclude or significantly diminish a producer's ability to increase the recyclability or reduce the volume of packaging material. These codes establish container construction standards for control of components, labeling requirements, and other packaging requirements for drug products.*

- ***Federal Code*** ***21 CFR Part 1302****- This code establishes specific requirements for the packaging and labeling of controlled substances. Due to the highly regulated and highly sensitive nature of controlled substances, HDA requests that the Department assess this regulation as grounds for exemptions.*

- ***FDA Guidance for Specific Products-*** *HDA requests that the Department thoroughly review and assess the following FDA guidance which establishes packaging and labeling requirement for specific products:*

    - *FDA Guidance on Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use*
    - *FDA Guidance on Container Closure Systems for Packaging Human Drugs and Biologics*
    - *FDA Guidance on Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors*
    - *USP Chapter <659> (Packaging and Storage Requirements) – Provides definitions for packaging, package type terms for injectable medical products, noninjectable packaging containers, measuring devices (e.g., dosing cup, dosing spoon, medicine dropper, oral syringe), temperature, and storage.*