131st MAINE LEGISLATURE

SECOND REGULAR SESSION-2024

Legislative Document **No. 2021**

S.P. 849 In Senate, December 13, 2023

An Act to Clarify the Laws Regarding Pharmaceutical Product Stewardship

Submitted by the Department of Environmental Protection pursuant to Joint Rule 203.

Received by the Secretary of the Senate on December 11, 2023. Referred to the Committee on Environment and Natural Resources pursuant to Joint Rule 308.2 and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator CARNEY of Cumberland.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 38 MRSA §1612, sub-§1, ¶B, as enacted by PL 2021, c. 94, §2, is repealed.

Sec. 2. 38 MRSA §1612, sub-§1, ¶D, as enacted by PL 2021, c. 94, §2, is amended to read:

D. "Covered drug" means any substance recognized as a drug under 21 United States Code, Section 321(g)(1), as amended, and any regulations adopted pursuant to that provision, that is sold, offered for sale or dispensed in the State, whether directly or through a wholesaler, in any form, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, brand name and generic drugs and drugs for veterinary use.

"Covered drug" does not include:

(1) Vitamins or supplements;

(2) Herbal-based remedies and homeopathic drugs, products or remedies;

(3) Cosmetics, soap with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirant or other personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;

(4) Pet pesticide products contained in pet collars, powders, shampoos, topical applications or other forms and prescription pet food;

(5) Drugs that are biological products, as defined in 21 Code of Federal Regulations, Section 600.3(h), if the manufacturer provides a program to take back that drug;

(6) Drugs for which a manufacturer provides a program to take back those drugs as part of a United States Department of Health and Human Services, Food and Drug Administration managed risk evaluation and mitigation strategy;

(7) Emptied syringes or emptied medical devices or the component parts or accessories of those products or devices;

(8) Drugs that are used solely in a clinical setting; and

(9) Dialysate drugs required to perform home kidney dialysis.

Sec. 3. 38 MRSA §1612, sub-§1, ¶K, as enacted by PL 2021, c. 94, §2, is amended to read:

K. "Manufacturer" means:

~~(1) A person that has legal ownership of the brand of a covered drug sold in or into the State; or~~

(1-A) Except as provided in subparagraph (2), a manufacturer of a covered drug that is sold or offered for sale in or into the State; or

(2) If the ~~person to which subparagraph (1) applies~~ manufacturer of a covered drug that is sold or offered for sale in or into the State has no physical presence in the United States and is not a participant in a stewardship program, a person that

imports a covered drug that is ~~branded by the person to which subparagraph (1) applies~~ sold or offered for sale in or into the State.

"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.

Sec. 4. 38 MRSA §1612, sub-§3, ¶B, as enacted by PL 2021, c. 94, §2, is amended to read:

B. Contact information for the person submitting the plan to whom the department shall direct all related inquiries, a list of participating manufacturers and their ~~brands~~ covered drugs, contact information for each participating manufacturer and a list of the covered drugs manufactured by any participating manufacturer that are ~~branded or~~ labeled for sale in the State by a retailer under the retailer's own ~~brand or~~ store label;

SUMMARY

This bill clarifies that the entity that manufactures a drug is the regulated entity under the drug take-back stewardship program and that retailers are not regulated as manufacturers of generic drugs.