

MAINE STATE LEGISLATURE

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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.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator CARNEY of Cumberland.

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

2 **Sec. 1. 38 MRSA §1612, sub-§1, ¶B**, as enacted by PL 2021, c. 94, §2, is repealed.

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

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

11 "Covered drug" does not include:

- 12 (1) Vitamins or supplements;
- 13 (2) Herbal-based remedies and homeopathic drugs, products or remedies;
- 14 (3) Cosmetics, soap with or without germicidal agents, laundry detergent, bleach,
15 household cleaning products, shampoo, sunscreen, toothpaste, lip balm,
16 antiperspirant or other personal care products that are regulated as both cosmetics
17 and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;
- 18 (4) Pet pesticide products contained in pet collars, powders, shampoos, topical
19 applications or other forms and prescription pet food;
- 20 (5) Drugs that are biological products, as defined in 21 Code of Federal
21 Regulations, Section 600.3(h), if the manufacturer provides a program to take back
22 that drug;
- 23 (6) Drugs for which a manufacturer provides a program to take back those drugs
24 as part of a United States Department of Health and Human Services, Food and
25 Drug Administration managed risk evaluation and mitigation strategy;
- 26 (7) Emptied syringes or emptied medical devices or the component parts or
27 accessories of those products or devices;
- 28 (8) Drugs that are used solely in a clinical setting; and
- 29 (9) Dialysate drugs required to perform home kidney dialysis.

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

32 K. "Manufacturer" means:

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

35 (1-A) Except as provided in subparagraph (2), a manufacturer of a covered drug
36 that is sold or offered for sale in or into the State; or

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

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

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

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

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

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

16 **SUMMARY**

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