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S.P. 15

In Senate, January 13, 2021

An Act To Support Collection and Proper Disposal of Unwanted Drugs

Received by the Secretary of the Senate on January 11, 2021. 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", is positioned above the printed name of the Secretary of the Senate.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator CARNEY of Cumberland.
Cosponsored by Representative HYMANSON of York.

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

2 **Sec. 1. 22 MRSA §2700, sub-§8** is enacted to read:

3 **8. Drug take-back stewardship program participation.** Nothing in this section
4 prohibits a law enforcement agency from participating as an authorized collector in a drug
5 take-back stewardship program implemented under Title 38, section 1612.

6 **Sec. 2. 38 MRSA §1612** is enacted to read:

7 **§1612. Drug take-back stewardship program**

8 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
9 following terms have the following meanings.

10 A. "Authorized collector" means:

11 (1) A person, company, corporation or other entity registered with the United
12 States Department of Justice, Drug Enforcement Administration to collect
13 controlled substances and noncontrolled substances for the purposes of safe
14 disposal and destruction;

15 (2) A law enforcement agency; or

16 (3) A person, company, corporation or other entity authorized by the department
17 to provide alternative collection methods for covered drugs that are household
18 pharmaceutical waste and that are noncontrolled substances.

19 "Authorized collector" includes a mandatory pharmacy collector.

20 B. "Brand" means a name, symbol, word or mark that identifies a covered drug, rather
21 than its components, and attributes a covered drug to the owner of the brand.

22 C. "Collection receptacle" means a secure box, kiosk or other container:

23 (1) Into which a person may deposit for disposal covered drugs that are household
24 pharmaceutical waste and that is prominently labeled in a manner indicating that
25 only such types of covered drugs may be deposited for disposal;

26 (2) That meets applicable federal standards for the use described in subparagraph
27 (1); and

28 (3) That is located on the premises of an authorized collector participating in a
29 stewardship program under this section.

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

36 "Covered drug" does not include:

37 (1) Vitamins or supplements;

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

39 (3) Cosmetics, soap with or without germicidal agents, laundry detergent, bleach,
40 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;

(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.

E. "Drug take-back stewardship organization" or "stewardship organization" means a corporation, nonprofit organization or other legal entity created by one or more manufacturers to implement a stewardship program under this section.

F. "Drug take-back stewardship plan" or "plan" means a plan designed by a manufacturer or stewardship organization for the establishment of a stewardship program.

G. "Drug take-back stewardship program" or "stewardship program" means a system implemented under this section for the collection, transportation and disposal of covered drugs that are household pharmaceutical waste.

H. "Household pharmaceutical waste" means useless, unwanted or discarded drugs generated by a household.

For the purposes of this paragraph, "household" includes, but is not limited to, a single residential unit, a multifamily residential unit, an apartment and an independent living community. "Household" does not include a hospital, health clinic, hospice facility, skilled nursing facility or other long-term care facility, physician's office, pharmacy or veterinary office or clinic.

I. "Mail-back envelope" means a prepaid, preaddressed mailing envelope, as authorized by federal law and regulation, that is provided by or through a company or organization licensed or otherwise authorized to dispose of covered drugs that are household pharmaceutical waste received in such mailing envelopes and that is made available through a stewardship program to persons seeking to dispose of covered drugs that are household pharmaceutical waste.

J. "Mandatory pharmacy collector" means a pharmacy licensed by the Maine Board of Pharmacy pursuant to Title 32, section 13751.

For the purposes of this paragraph, "pharmacy" has the same meaning as in Title 32, section 13702-A, subsection 24, except that "pharmacy" does not include a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population.

1 K. "Manufacturer" means:

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

4 (2) If the person to which subparagraph (1) applies has no physical presence in the
5 United States, a person that imports a covered drug that is branded by the person
6 to which subparagraph (1) applies.

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

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

13 L. "Operator" means a manufacturer or a stewardship organization that implements
14 and operates a stewardship program.

15 M. "Proprietary information" means information that is a trade secret or production,
16 commercial or financial information the disclosure of which would impair the
17 competitive position of the submitter and would make available information not
18 otherwise publicly available.

19 **2. Manufacturer responsibility.** A manufacturer shall:

20 A. Individually or jointly with one or more manufacturers, implement, administer and
21 operate a stewardship program pursuant to a plan that has been approved by the
22 department; or

23 B. Enter into an agreement with a stewardship organization to implement, administer
24 and operate a stewardship program pursuant to a plan that has been approved by the
25 department.

26 **3. Submittal of plan.** A manufacturer, individually or jointly with one or more
27 manufacturers, or a stewardship organization contracted by one or more manufacturers,
28 shall submit to the department for approval a proposed plan. The plan must include, at a
29 minimum:

30 A. A certification that the stewardship program will accept all covered drugs that are
31 household pharmaceutical waste regardless of who manufactured the covered drugs;

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

37 C. A description of how the stewardship program will make available free, convenient
38 and ongoing collection opportunities for covered drugs that are household
39 pharmaceutical waste to all persons seeking to dispose of such covered drugs and how
40 the collection opportunities will be geographically distributed in a way to ensure access
41 in rural and underserved areas, as determined based on geographic information systems
42 modeling. The plan must include a list of authorized collectors and collection
43 locations;

1 D. A description of the collection methods to be used to ensure that only covered drugs
2 that are household pharmaceutical waste will be collected by authorized collectors
3 under the stewardship program and a description of how separation of those covered
4 drugs from packaging by consumers will be encouraged to reduce transportation and
5 disposal costs. The plan must ensure that collection methods used under the program
6 include mail-back envelopes and collection receptacles and do not include home
7 disposal methods involving packets, bottles or other containers that a person may use
8 to render nonretrievable or destroy a covered drug that is household pharmaceutical
9 waste by means of a chemical process;

10 E. A certification that, upon implementation of the plan, the operator will post on a
11 publicly accessible website:

12 (1) A list of authorized collectors, collection locations and the collection methods
13 available at each collection location, updated as necessary;

14 (2) General information regarding the purpose and scope of the stewardship
15 program and the opportunities available to consumers under the program for the
16 safe disposal of covered drugs that are household pharmaceutical waste; and

17 (3) A statement that the stewardship program is designed for the collection of
18 covered drugs that are household pharmaceutical waste only;

19 F. Information on how covered drugs that are household pharmaceutical waste will be
20 safely and securely tracked, handled and transported from collection through final
21 disposition and policies to ensure security and compliance with all applicable federal
22 and state laws, rules and regulations including, but not limited to, 21 Code of Federal
23 Regulations, Section 1317.90 and 40 Code of Federal Regulations, Sections 239 to 282;

24 G. A description of how the collection system will be designed and monitored to
25 prevent tampering;

26 H. A description of how the stewardship program will measure the amount of collected
27 and disposed of covered drugs that are household pharmaceutical waste;

28 I. A description of the education and outreach materials that will be used by the
29 stewardship program to encourage consumer awareness and participation and to meet
30 the performance goals established pursuant to paragraph J, including, but not limited
31 to, a publicly accessible website with the information described in paragraph E and
32 printed materials, including brochures and signage, containing similar information for
33 use by authorized collectors and at collection locations. The plan must ensure that the
34 program provides education and outreach materials to authorized collectors for
35 distribution to consumers in accordance with subsection 8, paragraph E;

36 J. A description of the performance goals to be established under the stewardship
37 program to measure the success of the program and a description of how the program
38 will be designed to achieve or exceed those goals. Performance goals must include,
39 but are not limited to, the implementation of education and outreach efforts designed
40 to:

41 (1) Ensure awareness of the program by 60% of residents of the State after one
42 year of stewardship program implementation, by 70% of residents of the State after
43 2 years of implementation and by 90% of residents of the State after 4 years of
44 implementation; and

(2) Discourage the use of improper disposal methods for covered drugs that are household pharmaceutical waste, such as flushing the drugs or placing them in the garbage;

K. A description of how the manufacturer or stewardship organization will fund a representative survey of residents of the State by an independent 3rd party prior to implementation of the stewardship program to assess baseline public awareness regarding proper disposal methods for unwanted drugs; and

L. Information on how the stewardship program will be financed in accordance with subsection 5.

4. Approval of plan; amendments to plan; program audits. Within 120 business days of receipt of a plan submitted under subsection 3, the department shall review the plan and approve, approve with conditions or reject the plan. The department may hold a public hearing prior to deciding whether to approve, approve with conditions or reject a submitted plan. The department shall notify the person or persons that submitted the plan in writing of the department's determination and, if the plan is approved with conditions or rejected, include in the notification the basis for the department's determination.

A. A manufacturer or stewardship organization whose plan is rejected shall submit a revised plan to the department within 60 days after receiving a notice of rejection. If the department rejects the revised plan, the manufacturer or manufacturers that submitted the plan or that would have been participating under the plan are considered noncompliant with the requirements of this section.

B. A manufacturer that begins to sell or offer for sale in the State a covered drug after the date that an approved plan is first implemented under subsection 6 shall, within 30 days after the manufacturer's initial sale or offer for sale in the State of that covered drug, demonstrate to the department that it is participating in an existing stewardship program under this section or submit a proposed plan consistent with subsection 3 for a new stewardship program to the department for approval.

C. Prior to implementing an amendment to an approved plan, an operator shall submit the proposed amendment to the department for review. If the amendment is not substantive, such as the addition of or a change to a collection location or the addition of a manufacturer to the stewardship program, approval by the department is not needed, but the operator shall inform the department of the amendment within 14 days of implementing the amendment. The department shall review plan amendments in accordance with paragraphs A and B.

D. At any time, the department may require an operator to implement amendments to its approved plan or to submit to an independent financial audit of its stewardship program.

5. Costs. A manufacturer, individually or jointly with one or more manufacturers, shall pay all costs associated with the implementation, administration and operation of the manufacturer's stewardship program, including, but not limited to:

A. Costs of installing, managing and servicing collection receptacles at and collecting covered drugs that are household pharmaceutical waste from participating authorized collectors, transporting such covered drugs for disposal, disposing of such covered drugs and providing mail-back envelopes;

1 B. Costs related to the development of, with input from authorized collectors and the
2 department, a readily recognizable, consistent design for collection receptacles, as well
3 as clear, standardized instructions for consumers regarding the use of collection
4 receptacles;

5 C. Costs incurred by the department in accordance with subsection 11 in the review of
6 submitted plans and plan amendments, the review of annual reports and the
7 administration and enforcement of this section; and

8 D. Costs associated with the stewardship program assessments required under this
9 section.

10 When 2 or more manufacturers participate in a stewardship program, the costs of
11 implementing, administering and operating the program must be fairly and reasonably
12 allocated between each participating manufacturer so that the share of the costs that is
13 allocated to each manufacturer is reasonably related to the market share of covered drugs
14 that the manufacturer sells in the State.

15 **6. Implementation of plan.** A manufacturer or stewardship organization that
16 submitted a plan under subsection 3 that was approved by the department under subsection
17 4 shall implement that plan no later than 180 days after the date the plan was approved.

18 **7. Confidential information.** Proprietary information submitted to the department in
19 a drug take-back stewardship plan under this section, in an amendment to a plan or pursuant
20 to the reporting requirements of this section that is identified by the submitter as proprietary
21 information is confidential and must be handled by the department in the same manner as
22 confidential information is handled under section 1310-B.

23 **8. Authorized collectors; collection locations.** This subsection governs the activities
24 of authorized collectors and the operation of collection locations.

25 A. A mandatory pharmacy collector shall participate in a stewardship program and
26 shall provide for the safe collection of covered drugs that are household pharmaceutical
27 waste under that program through the use of:

28 (1) Mail-back envelopes made available to consumers of covered drugs upon
29 request;

30 (2) Collection receptacles; or

31 (3) Any other method of collection that complies with applicable United States
32 Department of Justice, Drug Enforcement Administration regulations under 21
33 Code of Federal Regulations, Part 1300, 1301, 1304, 1305, 1307 or 1317 and that
34 has been approved by the department as a method of collection for use in the
35 stewardship program, except that the department may not approve for use in any
36 stewardship program under this section a method of home disposal involving
37 packets, bottles or other containers that a person may use to render nonretrievable
38 or destroy a covered drug that is household pharmaceutical waste by means of a
39 chemical process.

40 A mandatory pharmacy collector that is a pharmacy not located in the State that
41 provides covered drugs to residents in the State by mail shall provide for the safe
42 collection of covered drugs that are household pharmaceutical waste through the use
43 of mail-back envelopes and shall ensure that consumers in the State purchasing covered
44 drugs from the pharmacy are provided with information regarding the availability of

1 such envelopes upon request and instructions regarding how the customer can request
2 an envelope.

3 B. An operator shall notify all authorized collectors that are not mandatory pharmacy
4 collectors of the opportunity to serve on a voluntary basis as a collection location under
5 the stewardship program and shall ensure that any such authorized collector that
6 requests to participate in the program is added to the program within 90 days of the
7 operator's receipt of the request. A participating authorized collector that is not a
8 mandatory pharmacy collector may use any of the collection methods described under
9 paragraph A.

10 C. The operator shall ensure that all collection receptacles located at a collection
11 location under the stewardship program are emptied and serviced as often as necessary
12 to avoid the receptacles reaching storage capacity and to ensure proper operation.

13 D. A mandatory pharmacy collector participating in a stewardship program shall
14 provide information on covered drug collection and safe drug disposal options to a
15 consumer upon dispensing a covered drug, including the availability of mail-back
16 envelopes upon request. An authorized collector that is located in the State that is
17 providing for the collection of covered drugs that are household pharmaceutical waste
18 through the use of mail-back envelopes shall ensure that information regarding the
19 availability of such envelopes upon request is prominently posted, displayed or
20 otherwise provided to consumers purchasing covered drugs.

21 E. As part of a stewardship program, all collection mechanisms, program information
22 and other program services must be provided by the operator free of charge to
23 authorized collectors, including, but not limited to, the installation, maintenance and
24 emptying of collection receptacles; the provision of mail-back envelopes, educational
25 materials, brochures and signage; and drug-disposal-specific surveillance.

26 F. Collection of covered drugs that are household pharmaceutical waste at collection
27 locations under a stewardship program must be made available to consumers free of
28 charge. An operator and an authorized collector may not charge a point-of-sale fee to
29 consumers, a fee that could be passed on to consumers or any other fee relating to the
30 collection and disposal of covered drugs that are household pharmaceutical waste.

31 **9. Education and outreach assessment.** During the 2nd and 3rd years of
32 implementation of a stewardship program, and every 2 years after that 3rd year, the operator
33 of the program shall fund an independent 3rd-party assessment of the effectiveness of the
34 program's education and outreach efforts, including, but not limited to, progress achieving
35 the consumer awareness goal described in subsection 3, paragraph J, subparagraph (1) and
36 efforts under the program to discourage the use of improper disposal methods for covered
37 drugs that are household pharmaceutical waste, as described in subsection 3, paragraph J,
38 subparagraph (2). The methods and scope of the assessment under this subsection must be
39 developed with input from the department. The operator shall implement changes as
40 necessary to the stewardship program's education and outreach efforts if demonstrated by
41 the results of the assessment.

42 **10. Annual stewardship program reporting.** Within 90 days after the first full year
43 of implementation of a stewardship program, and annually thereafter, the operator of the
44 program shall submit to the department a report describing the activities of the program
45 during the prior calendar year, which must include, at a minimum:

1 A. A list of manufacturers participating in the stewardship program, including contact
2 information;

3 B. The amount by weight of material collected under the stewardship program in the
4 prior calendar year, including the amount by weight from each collection method used,
5 both in total and by county;

6 C. Details regarding the stewardship program's collection system, including a list of
7 authorized collectors and associated collection locations with addresses; a list of
8 locations where mail-back envelopes were provided under the program; a list of
9 collection locations where collection receptacles were made available under the
10 program; dates and locations of collection events held under the program; and a list of
11 the transporters and disposal facilities used under the program for the transportation
12 and disposal of collected covered drugs that are household pharmaceutical waste;

13 D. Information regarding any safety or security issues encountered in the collection,
14 transportation or disposal of covered drugs that are household pharmaceutical waste
15 under the program during the prior calendar year and, if such issues occurred, a
16 description of completed or anticipated changes to program policies, procedures or
17 tracking mechanisms to address those issues;

18 E. A description of the public education, outreach and evaluation activities
19 implemented in accordance with the approved plan pursuant to subsection 3, paragraph
20 I. For the 2nd year and 3rd year of stewardship program implementation, and every 2
21 years after that 3rd year, the report must include the results of the 3rd-party assessment
22 required under subsection 9;

23 F. A description of how packaging collected under the program was recycled, to the
24 extent feasible;

25 G. A description of the methods used under the stewardship program to collect,
26 transport and dispose of covered drugs that are household pharmaceutical waste,
27 including information regarding efforts by the operator to ensure that only covered
28 drugs that are household pharmaceutical waste were collected, and how the methods
29 are consistent with the federal hazardous waste regulations identified in subsection 3,
30 paragraph F;

31 H. A summary of the stewardship program's achievement of its performance goals as
32 set forth in the approved plan pursuant to subsection 3, paragraph J. If any performance
33 goals were not achieved, the report must include a description of the efforts that will
34 be made to achieve those goals the following year;

35 I. An analysis of the convenience of the collection system under the stewardship
36 program for people living in various regions of the State, as determined based on
37 geographic information systems modeling;

38 J. The total cost of implementing, administering and operating the stewardship
39 program in the prior calendar year, which must include an accounting of the program's
40 expenditures in the prior calendar year, as verified through an independent 3rd-party
41 audit; and

42 K. Any recommendations for changes to the stewardship program to improve the
43 convenience of the collection system, to increase consumer awareness and education
44 or to better evaluate program performance.

1 **11. Administration and enforcement; rulemaking; fees.** The department shall
2 administer and enforce this section and may adopt rules as necessary to implement this
3 section. Rules adopted pursuant to this subsection are routine technical rules as defined in
4 Title 5, chapter 375, subchapter 2-A.

5 The department shall charge a reasonable fee to be paid by a manufacturer or stewardship
6 organization for review of a plan or amendments to an approved plan submitted under
7 subsection 4. The department may establish a reasonable annual fee to cover the
8 department's actual costs for annual report review, oversight, administration and
9 enforcement of a stewardship program, except that the fee may not exceed the greater of
10 \$100,000 per year and 1% of total stewardship program costs, as verified through the
11 independent 3rd-party audit required under subsection 10, paragraph J.

12 **12. Private right of action.** A manufacturer or stewardship organization
13 implementing an approved plan under this section that is in compliance with all applicable
14 requirements of this section may bring a civil action against a manufacturer for damages
15 when:

16 A. The plaintiff manufacturer or stewardship organization has incurred more than
17 \$3,000 in actual, direct costs in collecting, handling and disposing of covered drugs
18 that are household pharmaceutical waste sold or offered for sale in the State by a
19 defendant manufacturer or manufacturers that are not in compliance with all applicable
20 requirements of this section;

21 B. The defendant manufacturer or manufacturers can be identified as the manufacturer
22 or manufacturers of the covered drugs described in paragraph A from a brand or
23 marking on the covered drugs or from other information available to the plaintiff
24 manufacturer or stewardship organization;

25 C. The plaintiff manufacturer or stewardship organization has submitted a
26 reimbursement request for the costs described in paragraph A to the defendant
27 manufacturer or manufacturers; and

28 D. The plaintiff manufacturer or stewardship organization has not received
29 reimbursement for the costs described in paragraph A within:

30 (1) Sixty days after the request for reimbursement under paragraph C, if the
31 plaintiff manufacturer or stewardship organization did not request an independent
32 audit under subparagraph (2); or

33 (2) Thirty days after completion of an independent audit, if the plaintiff
34 manufacturer or stewardship organization requested an independent audit and the
35 audit verified the validity of the reimbursement request.

36 As used in this subsection, "damages" means the actual, direct costs a plaintiff
37 manufacturer or stewardship organization incurs in collecting, handling and disposing of
38 covered drugs that are household pharmaceutical waste reasonably identified as having
39 originated from a defendant manufacturer or manufacturers that are not in compliance with
40 all applicable requirements of this section; punitive or exemplary damages not exceeding
41 3 times those incurred costs; and the plaintiff manufacturer's or stewardship organization's
42 attorney's fees and costs of bringing the action under this subsection.

43 **13. Annual report to Legislature.** The department shall annually report to the joint
44 standing committee of the Legislature having jurisdiction over environment and natural
45 resources matters on the status of stewardship programs established pursuant to this section

1 and shall recommend amendments to the provisions of this section as necessary. After
2 reviewing the report under this subsection, the committee may report out legislation related
3 to the report. The report under this subsection may be included in the report required
4 pursuant to section 1772, subsection 1.

5 **14. Preemption.** To ensure maximum effectiveness through uniform statewide
6 application, the State intends to occupy the whole field of regulation of
7 government-mandated, manufacturer-funded drug take-back, collection or disposal
8 programs. A local government may not adopt an ordinance mandating a
9 manufacturer-funded drug take-back, collection or disposal program and any ordinance or
10 regulation that violates this subsection is void and has no force or effect.

11 **Sec. 3. 38 MRSA §1776, sub-§11,** as enacted by PL 2013, c. 315, §7, is amended
12 to read:

13 **11. Exceptions.** This section does not apply to products subject to section 1610, 1612,
14 1665-A, 1665-B, 1672, 2165 or 2166.

15 **Sec. 4. Submittal of drug take-back stewardship plan.** Within 180 days after
16 the effective date of this Act, a manufacturer of a covered drug under the Maine Revised
17 Statutes, Title 38, section 1612, individually or jointly with one or more manufacturers, or
18 a drug take-back stewardship organization contracted by one or more manufacturers, shall
19 submit to the Department of Environmental Protection for review a proposed drug take-
20 back stewardship plan that meets the requirements of Title 38, section 1612, subsection 3.

21 SUMMARY

22 This bill provides for the establishment of drug take-back stewardship programs. It
23 requires certain drug manufacturers, as defined in the bill, to operate a drug take-back
24 stewardship program to collect and dispose of certain drugs.