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STATE OF MAINE
ONE HUNDRED AND THIRTIETH LEGISLATURE
COMMITTEE ON ENVIRONMENT AND NATURAL RESOURCES

TO: Senator Anne Carney, Chair
Representative Thom Harnett, Chair
Joint Standing Committee on Judiciary

FROM: Senator Stacy Brenner, Chair
Representative Ralph Tucker, Chair
Joint Standing Committee on Environment and Natural Resources

DATE: March 8, 2021

RE: Public records exception review of LD 8

The Joint Standing Committee on Environment and Natural Resources is requesting the Judiciary Committee's review of a portion of the majority report amendment to LD 8, *An Act To Support Collection and Proper Disposal of Unwanted Drugs* (Sen. Carney, sponsor) pursuant to Title 1, section 434.¹ For reference, attached to this memorandum is a copy of the original version of the bill as well as a copy of the majority and minority report amendments to the bill.²

The majority report amendment to LD 8, which replaces the bill, establishes a drug take-back stewardship program in the State. Under that program, manufacturers of so-called "covered drugs" are required to participate in a drug take-back stewardship program and, whether directly or through a drug take-back stewardship organization, are required to submit to the Department of Environmental Protection ("the department") certain information as part of the initial program setup and annually

¹ It should be noted that LD 8 is substantially similar to LD 1460, considered by ENR during the 129th Legislature and voted unanimously OTP-AM. LD 1460 contained the same proposed public records exception and by memo dated July 6, 2020, ENR requested a JUD FOAA review. By return memo dated July 29, 2020, JUD noted it had conducted such a review of the proposal and recommended no changes concerning freedom of access issues in the proposed language. A copy of that JUD memo is attached. LD 1460 was not enacted, however, as a subsequent special session was not held.

² There are 8 members on the majority report (Sens. Brenner and Carney; Reps. Tucker, Bell, Blume, Doudera, Gramlich and Zeigler). There are 3 members on the minority report amendment (Sen. Bennett; Reps. Hanley and Tuell). 2 members voted ONTP on the bill (Reps. Johansen and O'Connor).

It should be noted that the proposed public records exception contained in the majority report amendment is also included in the minority report amendment.

once the program is established. Section 2 of the amendment, in new 38 MRSA §1612, subsection 7, provides:

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

The term “proprietary information” is defined in section 2 of the amendment, in new 38 MRSA §1612, subsection 1, paragraph M as follows:

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

38 MRSA §1310-B, which is referenced in the above language, contains the standard process for management of confidential material within Title 38 (see attached statutory provision). That process, as described in statute, is generally as follows:

- If a submitter designates certain information submitted to the department as confidential, that information has to be segregated from other public department records;
- The department’s public records must indicate that such information has been submitted and designated as confidential and must describe the general nature of the information;
- If any entity submits a request to the department for that designated information, the department must notify the submitter of the request. The submitter must respond within 15 days of the receipt of such notice to demonstrate to the department’s satisfaction that the information is proprietary information and thus should not be disclosed; and
- The department subsequently will determine whether the information is proprietary information and whether the information should be disclosed. The statute includes additional provisions regarding an appeal of the department’s decision on disclosure.

This confidentiality language and the definition of “proprietary information” in the majority report amendment to LD 8 are extremely similar or identical to other confidentiality provisions in Title 38, all of which reference the section 1310-B process for the handling of confidential records by the department (see, e.g., 38 MRSA §§1609(15), 1610(6-A)(F), 1661-A(4), 1776(10), 2144(5)(F) and 2324(3)).

Reviewing the statutory criteria for the proposed exception to public records in the majority report amendment to LD 8, we would comment as follows:

A. Need to collect the information. Under the proposal, a manufacturer of covered drugs, directly or through a drug take-back stewardship organization, would be required to submit to the department certain information in a drug

take-back stewardship plan, an amendment to an approved plan or in an annual report that could potentially include confidential proprietary information.

B. Value in maintaining the information. Maintenance of the information received by the department from manufacturers of covered drugs is important in the determination of whether a proposed program plan or a proposed change to a program plan meets the requirements of the law for such program and the information received in annual program reports is important in the department's assessment of whether the program is operating consistent with its approved program plan and meeting any established performance goals.

C. Federal law. We are unaware of any federal law requiring this information to be confidential.

D. Balancing the individual's privacy rights and the public interest. Review of the balancing of interests under this proposed exception is perhaps better considered under criteria E.

E. Balancing the effect of disclosure on business competition against the public interest. Public disclosure of this proprietary information may place the submitter at a competitive disadvantage and does not appear to serve a significant public interest.

F. Interfering in public negotiations. We are unaware of any connection between this information and negotiations involving a public body.

G. Balancing the public interest and potential jeopardy to public safety or a member of the public. We are unaware of any connection between the public interest in disclosure of this information and the safety of a member of the public or the public in general.

H. Narrowness of the exception. This exception only applies to certain information submitted to the department by a manufacturer of covered drugs that is designated as confidential, that is not otherwise publicly available and that the disclosure of which would impair the competitive position of the submitter.

I. Any other criteria.

Thank you for reviewing this proposed public records exception. Please let us know if you require any additional information.

cc: Members, Environment and Natural Resources Committee

Original bill



130th MAINE LEGISLATURE

FIRST REGULAR SESSION-2021

Legislative Document

No. 8

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'.

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,

- 1 antiperspirant or other personal care products that are regulated as both cosmetics
2 and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;
- 3 (4) Pet pesticide products contained in pet collars, powders, shampoos, topical
4 applications or other forms;
- 5 (5) Drugs that are biological products, as defined in 21 Code of Federal
6 Regulations, Section 600.3(h), if the manufacturer provides a program to take back
7 that drug;
- 8 (6) Drugs for which a manufacturer provides a program to take back those drugs
9 as part of a United States Department of Health and Human Services, Food and
10 Drug Administration managed risk evaluation and mitigation strategy;
- 11 (7) Emptied syringes or emptied medical devices or the component parts or
12 accessories of those products or devices;
- 13 (8) Drugs that are used solely in a clinical setting; and
- 14 (9) Dialysate drugs required to perform home kidney dialysis.
- 15 E. "Drug take-back stewardship organization" or "stewardship organization" means a
16 corporation, nonprofit organization or other legal entity created by one or more
17 manufacturers to implement a stewardship program under this section.
- 18 F. "Drug take-back stewardship plan" or "plan" means a plan designed by a
19 manufacturer or stewardship organization for the establishment of a stewardship
20 program.
- 21 G. "Drug take-back stewardship program" or "stewardship program" means a system
22 implemented under this section for the collection, transportation and disposal of
23 covered drugs that are household pharmaceutical waste.
- 24 H. "Household pharmaceutical waste" means useless, unwanted or discarded drugs
25 generated by a household.
- 26 For the purposes of this paragraph, "household" includes, but is not limited to, a single
27 residential unit, a multifamily residential unit, an apartment and an independent living
28 community. "Household" does not include a hospital, health clinic, hospice facility,
29 skilled nursing facility or other long-term care facility, physician's office, pharmacy or
30 veterinary office or clinic.
- 31 I. "Mail-back envelope" means a prepaid, preaddressed mailing envelope, as
32 authorized by federal law and regulation, that is provided by or through a company or
33 organization licensed or otherwise authorized to dispose of covered drugs that are
34 household pharmaceutical waste received in such mailing envelopes and that is made
35 available through a stewardship program to persons seeking to dispose of covered
36 drugs that are household pharmaceutical waste.
- 37 J. "Mandatory pharmacy collector" means a pharmacy licensed by the Maine Board of
38 Pharmacy pursuant to Title 32, section 13751.
- 39 For the purposes of this paragraph, "pharmacy" has the same meaning as in Title 32,
40 section 13702-A, subsection 24, except that "pharmacy" does not include a pharmacy
41 that purchases drugs for and dispenses drugs to a limited, institutional patient
42 population.

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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.

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

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

2. Manufacturer responsibility. A manufacturer shall:

- A. Individually or jointly with one or more manufacturers, implement, administer and operate a stewardship program pursuant to a plan that has been approved by the department; or
- B. Enter into an agreement with a stewardship organization to implement, administer and operate a stewardship program pursuant to a plan that has been approved by the department.

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

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

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

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

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

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

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

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

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

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

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

41 A. Costs of installing, managing and servicing collection receptacles at and collecting
42 covered drugs that are household pharmaceutical waste from participating authorized
43 collectors, transporting such covered drugs for disposal, disposing of such covered
44 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.

8.07.15

Majority OTP-AM
amendment

L.D. 8

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Date:

(Filing No. S-)

ENVIRONMENT AND NATURAL RESOURCES

Reproduced and distributed under the direction of the Secretary of the Senate.

STATE OF MAINE

SENATE

130TH LEGISLATURE

FIRST REGULAR SESSION

COMMITTEE AMENDMENT " " to S.P. 15, L.D. 8, "An Act To Support Collection and Proper Disposal of Unwanted Drugs"

Amend the bill in section 2 in §1612 in subsection 1 in paragraph D in subparagraph (4) in the last line (page 2, line 4 in L.D.) by inserting after the following: "forms" the following: 'and prescription pet food'

Amend the bill in section 2 in §1612 in subsection 1 in paragraph H in the first line (page 2, line 24 in L.D.) by inserting after the following: "unwanted" the following: ', expired'

Amend the bill in section 2 in §1612 in subsection 3 by striking out all of paragraph E (page 4, lines 10 to 18 in L.D.) and inserting the following:

'E. A certification that, upon implementation of the plan, the operator, jointly with the operators of other approved plans if any, will develop and administer a publicly accessible website that includes:

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

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

(3) A statement that the stewardship program or programs are designed for the collection of covered drugs that are household pharmaceutical waste only;'

Amend the bill in section 2 in §1612 in subsection 3 in paragraph J in subparagraph (1) in the 3rd line (page 4, line 43 in L.D.) by striking out the following: "90%" and inserting the following: '80%'

COMMITTEE AMENDMENT

RECEIVED

1 Amend the bill in section 2 in §1612 in subsection 5 in the first blocked paragraph in
2 the first line (page 6, line 10 in L.D.) by inserting after the following: "program," the
3 following: 'or if multiple stewardship programs exist.'

4 Amend the bill in section 2 in §1612 in subsection 5 in the first blocked paragraph in
5 the 2nd line (page 6, line 11 in L.D.) by inserting after the following: "program" the
6 following: 'or programs'

7 Amend the bill in section 2 in §1612 in subsection 10 in paragraph J in the last line
8 (page 8, line 41 in L.D.) by striking out the following: "and"

9 Amend the bill in section 2 in §1612 in subsection 10 in paragraph K in the last line
10 (page 8, line 44 in L.D.) by striking out the following: ";" and inserting the following: ";
11 and'

12 Amend the bill in section 2 in §1612 in subsection 10 by inserting after paragraph K
13 the following:

14 'L. An analysis of the market share of covered drugs sold by participating
15 manufacturers in the State and any other information required by the department for
16 determining appropriate cost allocation in accordance with subsection 5.'

17 Amend the bill in section 4 in the first 2 lines (page 10, lines 15 and 16 in L.D.) by
18 striking out the following: "Within 180 days after the effective date of this Act" and
19 inserting the following: 'On or before July 1, 2022'

20 Amend the bill by inserting after section 4 the following:

21 '**Sec. 5. Appropriations and allocations.** The following appropriations and
22 allocations are made.

23 **ENVIRONMENTAL PROTECTION, DEPARTMENT OF**
24 **Maine Environmental Protection Fund 0421**

25 Initiative: Provides an allocation for one Environmental Specialist III position and
26 associated costs.

27	OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
28	POSITIONS - LEGISLATIVE COUNT	1.000	1.000
29	Personal Services	\$59,642	\$89,688
30	All Other	\$6,071	\$8,662
31			
32	OTHER SPECIAL REVENUE FUNDS TOTAL	<u>\$65,713</u>	<u>\$98,350</u>

33
34 Amend the bill by relettering or renumbering any nonconsecutive Part letter or section
35 number to read consecutively.

36 **SUMMARY**

37 This amendment, which is the majority report of the committee, amends the bill to
38 exclude prescription pet food from the definition of "covered drug"; to amend the drug
39 take-back program consumer awareness goals; to clarify the allocation of program costs
40 among participating manufacturers if more than one drug take-back program is in

COMMITTEE AMENDMENT

ROPS

COMMITTEE AMENDMENT “ ” to S.P. 15, L.D. 8

1 operation; to require that a drug take-back stewardship plan must be submitted by a drug
2 manufacturer or drug take-back stewardship organization to the Department of
3 Environmental Protection for review on or before July 1, 2022; and to incorporate other
4 technical changes. It also adds an appropriations and allocations section.

5
6

FISCAL NOTE REQUIRED

(See attached)



130th MAINE LEGISLATURE

LD 8

LR 245(02)

An Act To Support Collection and Proper Disposal of Unwanted Drugs

Fiscal Note for Bill as Amended by Committee Amendment " "

Committee: Environment and Natural Resources

Fiscal Note Required: Yes

Fiscal Note

	FY 2021-22	FY 2022-23	Projections FY 2023-24	Projections FY 2024-25
Appropriations/Allocations				
Other Special Revenue Funds	\$65,713	\$98,350	\$102,821	\$107,067
Revenue				
Other Special Revenue Funds	\$65,713	\$98,350	\$102,821	\$107,067

Fiscal Detail and Notes

This bill would establish a drug take-back stewardship program requirement for household pharmaceutical waste overseen by the Department of Environmental Protection (DEP). Manufacturers of household pharmaceuticals would be able to choose to create individual programs, coordinate with other manufacturers or utilize a third-party administrator when developing drug take-back programs to meet the stewardship requirements. Costs related to the drug take-back stewardship programs would be paid by participating manufacturers. The bill authorizes the DEP to establish fees, to be paid by participants in the programs, to offset department costs related to overseeing the program requirements. DEP has indicated that additional staffing would be required and the bill includes allocations of \$65,713 in fiscal year 2021-22 and \$ 98,350 in fiscal year 2022-23 to DEP for one Environmental Specialist III position and associated costs. It is anticipated that the DEP will be able to fund the increased allocation with the new fees.

EOFS

Minority OTP-AM
amendment

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L.D. 8

Date: (Filing No. S-)

ENVIRONMENT AND NATURAL RESOURCES

Reproduced and distributed under the direction of the Secretary of the Senate.

**STATE OF MAINE
SENATE
130TH LEGISLATURE
FIRST REGULAR SESSION**

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(3) A statement that the stewardship program or programs are designed for the collection of covered drugs that are household pharmaceutical waste only.'

Amend the bill in section 2 in §1612 in subsection 3 in paragraph J by striking out all of subparagraph (1) (page 4, lines 41 to 44 in L.D.) and inserting the following:

'(1) Ensure awareness of the program by 50% of residents of the State after 3 years of stewardship program implementation and by 70% of residents of the State after 6 years of implementation; and'

COMMITTEE AMENDMENT

ROPS

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2 the first line (page 6, line 10 in L.D.) by inserting after the following: "program," the
3 following: 'or if multiple stewardship programs exist.'

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COMMITTEE AMENDMENT “ ” to S.P. 15, L.D. 8

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2 manufacturer or drug take-back stewardship organization to the Department of
3 Environmental Protection for review on or before July 1, 2022; and to incorporate other
4 technical changes. It also adds an appropriations and allocations section.

5 **FISCAL NOTE REQUIRED**

6 (See attached)

COMMITTEE AMENDMENT



130th MAINE LEGISLATURE

LD 8

LR 245(03)

An Act To Support Collection and Proper Disposal of Unwanted Drugs

Fiscal Note for Bill as Amended by Committee Amendment " "

Committee: Environment and Natural Resources

Fiscal Note Required: Yes

Fiscal Note

	FY 2021-22	FY 2022-23	Projections FY 2023-24	Projections FY 2024-25
Appropriations/Allocations				
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§1310-B. Confidential information

1. Public records. Except as provided in subsections 2 and 3, information obtained by the department under this chapter is a public record as provided by Title 1, chapter 13, subchapter I.

In addition to remedies provided under Title 1, chapter 13, subchapter I, the Superior Court may assess against the department reasonable attorney fees and other litigation costs reasonably incurred by an aggrieved person who prevails in the appeal of the department's denial for a request for information under subchapter V.

[PL 1989, c. 794, §3 (AMD).]

2. Hazardous waste information and information on mercury-added products and electronic devices; chemicals; recyclables. Information relating to hazardous waste submitted to the department under this subchapter, information relating to mercury-added products submitted to the department under chapter 16-B, information relating to electronic devices submitted to the department under section 1610, subsection 6-A, information related to priority toxic chemicals submitted to the department under chapter 27, information related to products that contain the "deca" mixture of polybrominated diphenyl ethers submitted to the department under section 1609 or information related to reporting on reportable recyclable materials submitted to the department under section 2145 may be designated by the person submitting it as being only for the confidential use of the department, its agents and employees, the Department of Agriculture, Conservation and Forestry and the Department of Health and Human Services and their agents and employees, other agencies of State Government, as authorized by the Governor, employees of the United States Environmental Protection Agency and the Attorney General and, for waste information, employees of the municipality in which the waste is located. The designation must be clearly indicated on each page or other portion of information. The commissioner shall establish procedures to ensure that information so designated is segregated from public records of the department. The department's public records must include the indication that information so designated has been submitted to the department, giving the name of the person submitting the information and the general nature of the information. Upon a request for information, the scope of which includes information so designated, the commissioner shall notify the submitter. Within 15 days after receipt of the notice, the submitter shall demonstrate to the satisfaction of the department that the designated information should not be disclosed because the information is a trade secret or production, commercial or financial information, the disclosure of which would impair the competitive position of the submitter and would make available information not otherwise publicly available. Unless such a demonstration is made, the information must be disclosed and becomes a public record. The department may grant or deny disclosure for the whole or any part of the designated information requested and within 15 days shall give written notice of the decision to the submitter and the person requesting the designated information. A person aggrieved by a decision of the department may appeal only to the Superior Court in accordance with the provisions of section 346. All information provided by the department to the municipality under this subsection is confidential and not a public record under Title 1, chapter 13. In the event a request for such information is submitted to the municipality, the municipality shall submit that request to the commissioner to be processed by the department as provided in this subsection.

[PL 2019, c. 291, Pt. B, §1 (AMD).]

3. Release of information. The commissioner shall not release the designated information prior to the expiration of the time allowed for the filing of an appeal or to the rendering of the decision on any appeal.

[PL 1979, c. 699, §17 (NEW).]

4. License and enforcement information. Information required by the department for the purpose of obtaining a permit, license, certification or other approval may not be designated or treated as designated information under subsection 2.

[PL 1979, c. 699, §17 (NEW).]

5. Rules. The board may adopt rules to carry out the purposes of this section. The rules shall be consistent with the provisions of Title 1, chapter 13, subchapter I.

[PL 1981, c. 470, Pt. A, §173 (AMD).]

6. Prohibition; penalties.

A. It is unlawful to disclose designated information to any person not authorized by this section. [PL 1979, c. 699, §17 (NEW).]

B. Any person who solicits, accepts or agrees to accept, or who promises, offers or gives any pecuniary benefit in return for the disclosure of designated information is guilty of a Class D crime and to the civil penalty of paragraph C. [PL 1979, c. 699, §17 (NEW).]

C. Any person who knowingly discloses designated information, knowing that he is not authorized to do so, is subject to a civil penalty of not more than \$5,000. [PL 1979, c. 699, §17 (NEW).]

D. In any action under this subsection, the court shall first declare that the information is a trade secret or production, commercial or financial information, the disclosure of which would impair the competitive position of the submitter and would make available information not otherwise publicly available. [PL 1979, c. 699, §17 (NEW).]

[PL 1979, c. 699, §17 (NEW).]

SECTION HISTORY

PL 1979, c. 699, §17 (NEW). PL 1981, c. 470, §§A172,A173 (AMD). PL 1985, c. 267, §2 (AMD). PL 1987, c. 517, §24 (AMD). PL 1989, c. 794, §3 (AMD). PL 1989, c. 890, §§A40,B233 (AMD). PL 2001, c. 373, §1 (AMD). PL 2003, c. 661, §1 (AMD). PL 2003, c. 689, §B6 (REV). PL 2005, c. 561, §7 (AMD). PL 2005, c. 590, §3 (AMD). PL 2007, c. 466, Pt. A, §72 (AMD). PL 2009, c. 397, §1 (AMD). PL 2009, c. 579, Pt. A, §1 (AMD). PL 2009, c. 610, §1 (AMD). PL 2011, c. 420, Pt. A, §35 (AMD). PL 2011, c. 657, Pt. W, §5 (REV). PL 2015, c. 250, Pt. C, §10 (AMD). PL 2019, c. 291, Pt. B, §1 (AMD).

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Memo re: JUD review
of LD 1460 (2020)

SENATE

MICHAEL E. CARPENTER, DISTRICT 2, CHAIR
SHENNA BELLOWS, DISTRICT 14
LISA M. KEIM, DISTRICT 18



MARGARET J. REINSCH, SENIOR LEGISLATIVE ANALYST
LYNNE CASWELL, LEGISLATIVE ANALYST
SUSAN M. PINETTE, COMMITTEE CLERK

HOUSE

DONNA BAILEY SACO, CHAIR
CHRISTOPHER W. BABIDGE, KENNEBUNK
BARBARA A. CARDONE, BANGOR
LOIS GALGAY RECKITT, SOUTH PORTLAND
RACHEL TALBOT ROSS, PORTLAND
THOM HARNETT, GARDINER
DAVID G. HAGGAN, HAMPDEN
PHILIP CURTIS, MADISON
JOHN DEVEAU, CARIBOU
JEFFREY EVANGELOS, FRIENDSHIP

STATE OF MAINE
ONE HUNDRED AND TWENTY-NINTH LEGISLATURE
COMMITTEE ON JUDICIARY

July 29, 2020

TO: Senator Brownie Carson, Senate Chair
Representative Ralph Tucker, House Chair
Joint Standing Committee on Environment and Natural Resources

FROM: Senator Michael Carpenter, Senate Chair
Representative Donna Bailey, House Chair
Joint Standing Committee on Judiciary

Re: LD 1460, An act to Support Collection and Proper Disposal of
Unwanted Drugs

This memo memorializes the recommendations of the Joint Standing Committee on Judiciary pursuant to Title 1, section 434 on the proposed committee amendment to LD 1460, An act to Support Collection and Proper Disposal of Unwanted Drugs. Please let us know if you would like a more detailed report of our evaluation and review.

The Committee reviewed the draft attached to the July 6, 2020 memo, and recommends no changes concerning freedom of access issues in the proposed language.

We would appreciate the work that went into the memo transmitting the amended bill to our committee for review and evaluation.

Thank you for your serious consideration of the Freedom of Access issues, and for your cooperation in this process.

Please contact us if you have any questions.