L.D. 1460

Date: (Filing No. S-)

ENVIRONMENT AND NATURAL RESOURCES

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

STATE OF MAINE

SENATE

129TH LEGISLATURE

SECOND SPECIAL SESSION

COMMITTEE AMENDMENT " " to S.P. 445, L.D. 1460, Bill, "An Act To Support Collection and Proper Disposal of Unwanted Drugs"

Amend the bill by striking out everything after the enacting clause and inserting the following:

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

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

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

§1612. Drug take-back stewardship program

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

A. "Authorized collector" means:

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

(2) A law enforcement agency; or

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

"Authorized collector" includes a mandatory pharmacy collector.

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

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

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

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

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

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

"Covered drug" does not include:

(1) Vitamins or supplements;

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

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

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

(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.

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;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

(2) Collection receptacles; or

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

A mandatory pharmacy collector that is a pharmacy not located in the State that provides covered drugs to residents in the State by mail shall provide for the safe collection of covered drugs that are household pharmaceutical waste through the use of mail-back envelopes and shall ensure that consumers in the State purchasing covered drugs from the pharmacy are provided with information regarding the availability of such envelopes upon request and instructions regarding how the customer can request an envelope.

B. An operator shall notify all authorized collectors that are not mandatory pharmacy collectors of the opportunity to serve on a voluntary basis as a collection location

under the stewardship program and shall ensure that any such authorized collector that requests to participate in the program is added to the program within 90 days of the operator's receipt of the request. A participating authorized collector that is not a mandatory pharmacy collector may use any of the collection methods described under paragraph A.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As used in this subsection, "damages" means the actual, direct costs a plaintiff manufacturer or stewardship organization incurs in collecting, handling and disposing of covered drugs that are household pharmaceutical waste reasonably identified as having originated from a defendant manufacturer or manufacturers that are not in compliance

with all applicable requirements of this section; punitive or exemplary damages not exceeding 3 times those incurred costs; and the plaintiff manufacturer's or stewardship organization's attorney's fees and costs of bringing the action under this subsection.

13. Annual report to Legislature. The department shall annually report to the joint standing committee of the Legislature having jurisdiction over environment and natural resources matters on the status of stewardship programs established pursuant to this section and shall recommend amendments to the provisions of this section as necessary. After reviewing the report under this subsection, the committee may report out legislation related to the report. The report under this subsection may be included in the report required pursuant to section 1772, subsection 1.

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

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

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

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

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

ENVIRONMENTAL PROTECTION, DEPARTMENT OF

Maine Environmental Protection Fund 0421

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

OTHER SPECIAL REVENUE FUNDS	**2019-20**	**2020-21**
POSITIONS - LEGISLATIVE COUNT	0.000	1.000
Personal Services	$0	$36,552
All Other	$0	$5,055
OTHER SPECIAL REVENUE FUNDS TOTAL	$0	$41,607

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

SUMMARY

This amendment replaces the bill. It makes technical changes to the bill for clarity and consistency and makes substantive changes, including the following.

1. It deletes the definition of "closed-shop pharmacy," adds definitions of "collection receptacle," "household pharmaceutical waste" and "mail-back envelope" and amends other definitions in the bill, including the definition of "mandatory pharmacy collector," which is revised to include all pharmacies licensed by the Maine Board of Pharmacy except for those pharmacies that purchase drugs for and dispense drugs to a limited, institutional patient population.

2. It clarifies that the drug take-back stewardship program is to be designed for the collection of covered drugs that are household pharmaceutical waste only.

3. It changes provisions in the bill regarding the submission of a drug take-back stewardship plan, the Department of Environmental Protection's review and approval criteria for submitted plans, reporting requirements for the operator of a drug take-back stewardship program and the department's oversight, enforcement and rule-making authority.

4. It clarifies costs related to a drug take-back stewardship program that must be paid by the manufacturer or manufacturers participating in that program, including the costs of installing, managing and servicing collection receptacles under the program.

5. It clarifies requirements for authorized collectors and collection locations under a drug take-back stewardship program, including provisions authorizing mandatory pharmacy collectors under a program to provide for collection of drugs using either a collection receptacle or mail-back envelopes.

6. It adds an appropriations and allocations section.

FISCAL NOTE REQUIRED

(See attached)