

MAINE STATE LEGISLATURE

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130th MAINE LEGISLATURE

FIRST SPECIAL SESSION-2021

Legislative Document

No. 1584

S.P. 508

In Senate, April 27, 2021

**An Act To Make Donated Medicines Available to Maine Patients at
an Affordable Cost**

Reference to the Committee on Health and Human Services suggested 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 CLAXTON of Androscoggin.

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

2 **Sec. 1. 22 MRSA §2700, sub-§3**, as amended by PL 2013, c. 121, §1, is further
3 amended to read:

4 **3. Return of pharmaceuticals.** The agency may create systems for the safe, effective
5 and proper disposal of unused pharmaceuticals. The systems may include the use of
6 prepaid mailing envelopes into which the unused pharmaceuticals are placed and returned
7 to a single collection location. The prepaid mailing envelopes must be made available to
8 the public at various locations, including, but not limited to, pharmacies, physicians' offices
9 and post offices. The agency may randomly assess the toxicity of materials received under
10 the program as long as the assessment results do not identify the patient, person who mailed
11 the material, prescriber or pharmacy. The agency shall consult with the department to
12 determine the suitability of unused pharmaceuticals for donation to the medicine donation
13 and redispensing program under section 2700-B and transfer suitable pharmaceuticals to
14 the medicine donation and redispensing program.

15 **Sec. 2. 22 MRSA §2700, sub-§4**, as amended by PL 2013, c. 121, §1, is further
16 amended to read:

17 **4. Disposal of pharmaceuticals.** All Except for pharmaceuticals donated to the
18 medicine donation and redispensing program under subsection 3, all unused
19 pharmaceuticals received under the program must be disposed of in a manner that is
20 designed to be effective, secure and in compliance with local, state and federal
21 environmental requirements, including the federal Resource Conservation and Recovery
22 Act of 1976, as amended.

23 **Sec. 3. 22 MRSA c. 606** is enacted to read:

24 **CHAPTER 606**

25 **MEDICINE DONATION AND REDISPENSING PROGRAM**

26 **§2700-B. Medicine Donation and Redispensing Program**

27 **1. Definitions.** As used in this chapter, unless the context otherwise indicates, the
28 following terms have the following meanings.

29 A. "Deliver" or "delivery" has the same meaning as in Title 32, section 13702-A,
30 subsection 6.

31 B. "Dispense" or "dispensing" has the same meaning as in Title 32, section 13702-A,
32 subsection 9.

33 C. "Donor" means a person who meets the requirements of subsection 5 to donate
34 medicines to a recipient.

35 D. "Eligible patient" means an individual who may receive redispensed medicines
36 from a recipient and meets the requirements of subsection 4.

37 E. "Interchangeable biological product" has the same meaning as in Title 32, section
38 13702-A, subsection 14.

- 1 F. "Licensed health care professional" means any individual licensed to authorize,
2 prescribe, dispense or administer medicines under Title 32, chapter 31, 34-A, 36, 48,
3 51, 117 or 143.
- 4 G. "Manufacturer" has the same meaning as in Title 32, section 13702-A, subsection
5 19.
- 6 H. "Medicine" means a nonprescription drug as defined in Title 32, section 13702-A,
7 subsection 20, a prescription drug or legend drug as defined in Title 32, section
8 13702-A, subsection 30, a device as defined in Title 32, section 13702-A, subsection 8
9 or a drug approved by the United States Food and Drug Administration in accordance
10 with 21 Code of Federal Regulations, Part 312.
- 11 I. "Orally administered cancer medicine" means an orally administered medicine that
12 is used to treat cancer or its side effects or the side effects of a medicine used to treat
13 cancer.
- 14 J. "Pharmacy" has the same meaning as in Title 32, section 13702-A, subsection 24.
- 15 K. "Prescription drug order" has the same meaning as in Title 32, section 13702-A,
16 subsection 31.
- 17 L. "Program" means the Medicine Donation and Redispensing Program established in
18 subsection 2.
- 19 M. "Public assistance program" means aid, assistance or benefits available through:
- 20 (1) A program of temporary assistance for needy families administered in this
21 State pursuant to chapter 1053-B or the Parents as Scholars program pursuant to
22 chapter 1054-B;
- 23 (2) A program of medical assistance administered in this State pursuant to chapter
24 855; or
- 25 (3) Any other program that is based on need and is conducted or administered by
26 this State.
- 27 N. "Recipient" means a nonprofit entity that has contracted with the department to
28 operate the program in accordance with subsection 3.
- 29 O. "Returns processor" has the same meaning as in 21 United States Code, Section
30 360eee(18).
- 31 P. "Wholesaler" has the same meaning as in Title 32, section 13702-A, subsection 34.
- 32 **2. Establishment.** The Medicine Donation and Redispensing Program is established
33 to accept donated, unused medicines and redispense those medicines to eligible patients
34 who cannot afford to purchase them.
- 35 **3. Contract for operation.** The department shall contract with nonprofit entities that
36 are in good standing and legally authorized to possess medicine in the State to operate the
37 program. The entities may accept and redispense medicine in accordance with this chapter
38 to the extent authorized by federal law.
- 39 **4. Eligible patients.** A patient is eligible to receive medicine donated and redispensed
40 in accordance with this chapter as long as the patient does not have health insurance, is

1 enrolled in a public assistance program or otherwise meets the criteria established by the
2 department in accordance with subsection 15.

3 **5. Donors.** Any person, including, but not limited to, any individual, manufacturer,
4 licensed health care professional, pharmacy, health care facility licensed under this Title or
5 the Unused Pharmaceutical Disposal Program under section 2700, may donate a medicine
6 to a recipient. A donor must remove or redact any patient names and prescription numbers
7 on donated medicines or otherwise maintain patient confidentiality by executing a
8 confidentiality agreement with the recipient.

9 **6. Medicines and disposal.** Medicine donated to a recipient and redispensed by the
10 recipient must meet the following requirements. The medicine:

11 A. Must be in the medicine's original, unopened, sealed packaging or, if the outside
12 packaging is opened or disturbed, the contents are one or more single-unit doses that
13 are individually contained in unopened, tamper-evident packaging, except that orally
14 administered cancer medicine may be in opened packaging;

15 B. May not be adulterated or misbranded;

16 C. May not be a controlled substance as defined in 21 Code of Federal Regulations,
17 Sections 1308.11 to 1308.15 (2020);

18 D. Must be maintained in accordance with 21 United States Code, Section 355-1
19 (2020) relating to risk and evaluation strategies, if applicable;

20 E. Must have a method to detect improper temperature variations of the medicine, if
21 applicable; and

22 F. Must be maintained in accordance with 21 United States Code, Sections 360eee-1
23 to 360eee-4 (2020) relating to supply chain security, if applicable.

24 A recipient shall ensure that a licensed health care professional verifies that the donated
25 medicine meets the requirements of this subsection before it is redispensed to an eligible
26 patient. Medicine that does not meet the requirements of this subsection must be disposed
27 of by returning it to the donor, destroying it by an incinerator, medical waste hauler or other
28 lawful method or transferring it to a returns processor. The recipient shall maintain a record
29 of any medicine that is disposed of that includes the disposal method, the date of disposal
30 and the name, strength and quantity of each medicine disposed of.

31 **7. Record-keeping requirements.** A recipient shall maintain records in accordance
32 with this subsection. A recipient:

33 A. Shall verify and record donor information, including the following:

34 (1) That the donor is qualified in accordance with subsection 5; and

35 (2) The donor's name, address, phone number and license number, if applicable;

36 B. Shall maintain a written or electronic record of the donated medicine, including the
37 name, strength and quantity of each accepted medicine and the name, address and
38 phone number of the donor of that medicine, except that this requirement does not
39 apply if the donor and recipient are under common ownership or common control;

40 C. Shall maintain separate written or electronic records of the donated medicines from
41 the recipient's other inventory;

1 D. Shall maintain records consistent with requirements for returns of an unsalable
2 product by a returns processor in accordance with federal law;

3 E. Shall retain all records in a physical or electronic format, on or off the recipient's
4 premises for 6 years;

5 F. May contract with a 3rd party to create or maintain records on the recipient's behalf;

6 G. Shall maintain records showing the history of the medicine, beginning with the
7 donor of the medicine, prior donations by the donor, whether the medicine was
8 previously dispensed and the information required to be on the patient label in
9 accordance with applicable rules adopted by the Maine Board of Pharmacy pursuant to
10 Title 32, section 13720;

11 H. Shall use an identifier, such as a serial number or barcode, in place of information
12 in a record or on a label as long as the information is readily retrievable and as long as,
13 upon request of the department in accordance with paragraph I, the identifier used for
14 the requested records is replaced with the original information, except that an identifier
15 may not be used on eligible patient labels when dispensing or administering a medicine;
16 and

17 I. Shall make all records available for audit by the department within 5 business days
18 of the department's request.

19 **8. Medicine storage requirements.** A recipient shall maintain donated medicine in
20 accordance with this subsection. A recipient shall:

21 A. Store and maintain donated medicine separate from the recipient's other inventory;
22 and

23 B. Store and maintain donated medicine in a temperature-controlled environment
24 appropriate for the medicine, as applicable.

25 **9. Delivery of donated medicine.** A recipient may deliver donated medicine to
26 another recipient or to an entity participating in a medicine donation program operated by
27 another state.

28 **10. Repackaging of donated medicine.** A recipient may repackage donated medicine
29 in accordance with this subsection as necessary for storing, dispensing, administering or
30 delivering the medicine. Repackaged medicine must be:

31 A. Labeled with the medicine name, strength and expiration date;

32 B. Kept in a separate, designated area until it is inspected and verified by a licensed
33 health care professional; and

34 C. Labeled with the nearest expiration date, if donated medicines with different
35 expiration dates are repackaged together.

36 **11. Redispensing of donated medicines to eligible patients.** A medicine may only
37 be redispensed to an eligible patient by a recipient if, in addition to all other requirements
38 of this chapter, the provisions of this subsection are met.

39 A. A recipient may dispense or administer a medicine to an eligible patient only if
40 otherwise permitted by law.

1 B. A medicine that is a prescription drug, as defined in Title 32, section 13702-A,
2 subsection 30, may be dispensed or administered only to an eligible patient pursuant to
3 a valid prescription drug order.

4 C. A recipient must maintain eligible patient-specific written or electronic records
5 maintained in accordance with rules adopted by the Maine Board of Pharmacy pursuant
6 to Title 32, section 13720.

7 D. A medicine must be repackaged into a new container or have all previous patient
8 information on the donated container redacted or removed.

9 E. A medicine must be properly labeled in accordance with applicable rules adopted
10 by the Maine Board of Pharmacy pursuant to Title 32, section 13720.

11 F. The expiration date of a medicine may not occur before the eligible patient will use
12 the medicine based on the directions for use of the licensed health care professional
13 who prescribed the prescription for the eligible patient or on the package's label.

14 G. A recipient may substitute an oral tablet, capsule or liquid form of the medicine as
15 long as that form has the same dose schedule and is an interchangeable biological
16 product.

17 H. A recipient may replenish medicine of the same medicine name and strength
18 previously dispensed or administered to an eligible patient in accordance with federal
19 law.

20 I. A recipient may charge a person, including but not limited to an eligible patient,
21 health plan, pharmacy benefits manager or government agency, its usual and customary
22 charges for handling or dispensing the medicine as long as those charges do not exceed
23 the authorized recipient's actual costs of providing the medicine, including, but not
24 limited to, the current and anticipated costs of educating donors, providing technical
25 support to donors, shipping and handling, labor, storage, licensing, utilities,
26 advertising, technology, supplies or equipment.

27 **12. Medicine donation programs in other states.** A recipient may deliver donated
28 medicine to an entity participating in a medicine donation program operated by another
29 state. An entity participating in a medicine donation program operated by another state
30 may dispense donated medicine to residents of this State. An entity participating in a
31 medicine donation program operated by another state must comply with all laws and rules
32 in this State unless the laws and rules conflict with the laws or rules of the state in which
33 the entity is located.

34 **13. Construction.** This chapter may not be construed to:

35 A. Require a donor or recipient to be licensed as a wholesaler solely on the basis of
36 the donor's or recipient's participation in the program;

37 B. Permit the resale of medicine donated as part of the program; or

38 C. Change ownership of the donated medicine from the donor to the recipient, unless
39 the ownership change is specified by the recipient.

40 **14. Immunity from liability.** A person may not be subject to any civil or criminal
41 liability, or to any discipline by a professional licensing board, for any action taken in good
42 faith in accordance with this chapter.

1 **15. Department duties.** The department shall:

2 A. Establish by rule eligibility criteria for eligible patients, including, but not limited
3 to, eligibility for indigent or underinsured patients or patients who do not meet the
4 criteria established in subsection 4, but may be eligible for the program if there is an
5 excess of donated medicines in a recipient's inventory;

6 B. Establish by rule a process by which a donor, recipient or patient in the program
7 may request a waiver from the department from the requirements of this chapter or any
8 rules adopted in accordance with this chapter, except that the department may not adopt
9 a rule that establishes a waiver from the immunity from liability under subsection 14.
10 The department shall grant or deny a waiver submitted in accordance with this
11 paragraph and rules adopted in accordance with this paragraph within 30 days of its
12 submission to the department based on its potential effects on medicine access and
13 safety of eligible patients; and

14 C. Establish by rule a method by which the department may revoke the authority of a
15 recipient to participate in the program by issuing a written notice to the recipient. The
16 rule must require the department to identify the specific requirements the recipient
17 violated and the required corrective actions for the recipient to resume its participation
18 in the program.

19 **16. Rules.** The department may adopt rules to carry out the purposes of the program.
20 Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5,
21 chapter 375, subchapter 2-A.

22 **Sec. 4. 36 MRSA §5218-B** is enacted to read:

23 **§5218-B. Credit for donated medicine**

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

26 A. "Donor" has the same meaning as in Title 22, section 2700-B, subsection 1,
27 paragraph C.

28 B. "Medicine" has the same meaning as in Title 22, section 2700-B, subsection 1,
29 paragraph H.

30 C. "Program" means the Medicine Donation and Redispensing Program established
31 under Title 22, section 2700-B, subsection 2.

32 D. "Recipient" has the same meaning as in Title 22, section 2700-B, subsection 1,
33 paragraph N.

34 **2. Credit allowed.** For tax years beginning January 1, 2022, a donor participating in
35 the program is allowed a credit against the tax imposed by this Part in an amount equal to
36 the sum of:

37 A. The cost to the donor of the medicine donated pursuant to the program during the
38 taxable year as determined pursuant to the Code, Section 170(e)(3)(A); and

39 B. The verifiable cost to the donor to make the donation of the medicine to a recipient
40 during the taxable year.

41 **3. Limitation.** The amount of the credit that may be used by a donor under this section
42 for a taxable year may not exceed the amount of tax otherwise due under this Part. Any

1 unused credit may be carried over to the following year or years for a period not to exceed
2 15 years.

3 **Sec. 5. Department of Health and Human Services to adopt rules regarding**
4 **medicine donation program.** The Department of Health and Human Services shall,
5 within 6 months of the effective date of this Act, adopt rules to create a waiver process and
6 a revocation process in accordance with the Maine Revised Statutes, Title 22, section
7 2700-B, subsection 15, paragraphs B and C.

8 **SUMMARY**

9 This bill establishes the Medicine Donation and Redispensing Program operated by
10 nonprofit entities contracted by the Department of Health and Human Services. The
11 program collects donations of unused medicines from health care providers, health care
12 facilities and other sources and redispenses the medicines to qualified low-income persons.