HOUSE DOCKET, NO. 1973 FILED ON: 1/19/2023

HOUSE . . . . . No. 1208

The Commonwealth of Massachusetts

PRESENTED BY:

Bradley H. Jones, Jr.

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act establishing a state-wide drug repository program.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Bradley H. Jones, Jr.	*20th Middlesex*	*1/18/2023*
Nicholas A. Boldyga	*3rd Hampden*	*1/26/2023*
F. Jay Barrows	*1st Bristol*	*1/26/2023*
Paul K. Frost	*7th Worcester*	*1/31/2023*
Kimberly N. Ferguson	*1st Worcester*	*1/31/2023*
Hannah Kane	*11th Worcester*	*3/1/2023*
Mary S. Keefe	*15th Worcester*	*6/2/2023*

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HOUSE . . . . . No. 1208

By Representative Jones of North Reading, a petition (accompanied by bill, House, No. 1208) of Bradley H. Jones, Jr., and others for legislation to establish a state-wide drug repository program. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

An Act establishing a state-wide drug repository program.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. For the purposes of this section the below terms shall be defined as follows:

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of 21 CFR Part 1308.

"Donor" shall mean any person, including an individual member of the public, or any entity legally authorized to possess medicine, including but not limited to a wholesaler or distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation centers, jails, prisons, laboratory, medical or pharmacy school, prescriber or other health care professional, long-term care facility or healthcare facility. Donor shall also mean government agencies and entities that are federally authorized to possess medicine including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, FDA authorized importers such as those under Federal FD&C Section 801, 804, or similar provisions, and prisons.

“Recipient” means any entity legally authorized to possess medicine with a license or permit in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, clinic, or prescriber office.

“Eligible patient” means an individual who is indigent, uninsured, underinsured, or enrolled in a public health benefits program. Other patients shall be considered eligible if a need for the donated medicine is not identified among indigent, uninsured, underinsured, or public health benefits program enrolled individuals.

"Orally administered cancer medicine" means either of the following:

a) An orally administered medicine that is used to treat cancer or its side effects; or

b) An orally administered medicine that is used to treat the side effects of a medicine used to treat cancer.

"Unopened tamper-evident packaging” shall have the same meaning as United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

“Medicine” means both prescription and non-prescription (“over-the-counter”) drugs including FDA-approved drugs labeled for investigational use. It also includes prescription and non-prescription supplies and medical devices.

“Health care professional” means a person who is licensed to practice as a physician, registered nurse, licensed practical nurse, optometrist, pharmacist, or any other practitioner authorized to dispense or administer.

"Returns processor" shall have the same meaning as 21 U.S.C. Section 360eee(18) and shall include but is not limited to a reverse distributor.

SECTION 2. Notwithstanding any general or special law to the contrary, donors may donate medicine to a recipient. A recipient may receive donated medicine from donors. Prior to the first donation from a new donor, a recipient must verify and record the following:

a) The donor meets the definition provided in paragraph (1)(b);

b) The donor's name, address, phone number, and license number if applicable;

c) The donor will only make donations of medicine in accordance with paragraph (5);

d) If applicable, the donor will remove or redact any patient names and prescription numbers on donated medicine or otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient.

e) No other record prior to the first donation other than described in subsection (a) of this section shall be required.

SECTION 3. Under this section, a recipient may: (1) transfer donated medicine to another recipient or to an entity participating in a drug donation program operated by another state; (2) repackage donated medicine as necessary for storage, dispensing, administration, or transfers in accordance with section 9 of this act; and (3) replenish medicine of the same drug name and strength previously dispensed or administered to eligible patients in accordance with federal 340b statute.

SECTION 4. A drug manufacturer, repackager, dispenser, or wholesaler other than a returns processor participating in this program shall comply with the requirements of 21 U.S.C. Sections 360eee-1 through 360eee-4 relating to drug supply chain security.

SECTION 5. A recipient may only accept into inventory donated medicine that:

a) is in unopened, tamper-evident packaging; has been repackaged under this program; or is orally administeSred cancer medicine in opened packaging;

b) is not adulterated or misbranded;

c) is not a controlled substance;

d) has been maintained in accordance with the federal Food and Drug Administration risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 if applicable; and

e) has a USP-recognized method to detect improper temperature variations if the medicine requires temperature control other than “room temperature storage”

No other medicine shall be eligible for donation.

SECTION 6. Donated medicine that does not meet the requirements of section 5 must be disposed by returning it to the medicine donor, destroying it by an incinerator, medical waste hauler, or other lawful method, or transferring it to a returns processor. A record of disposed medicine shall consist of the disposal method as described above, the date of disposal, and the name, strength, and quantity of each drug disposed. No other record of disposal shall be required.

SECTION 7. All medicine received but not yet accepted into inventory shall be kept in a separate designated area. Prior to or upon accepting a donation or transfer into inventory, a

recipient shall maintain a written or electronic inventory of the donation, consisting of the name, strength, and quantity of each accepted drug, and the name, address and phone number of the donor. This record shall not be required if the two parties are under common ownership or common control. No other record of donation shall be required.

SECTION 8. A recipient must store and maintain donated medicine physically or electronically separated from other inventory and in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) standards.

SECTION 9. Repackaged medicine shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a health care professional. If multiple packaged donated medicines with varied expiration dates are repackaged together, the shortest expiration date shall be used.

SECTION 10. A recipient may only administer or dispense medicine that:

a) meet the requirements of section 5 based on inspection by a healthcare professional;

b) are, if dispensed to a patient, repackaged into a new container or have all previous patient information on the donated container redacted or removed;

c) are properly labeled in accordance with the regulations of the Board of Pharmacy; and

d) have an expiration or beyond use date brought forward from the donated medicine that will not expire before the use by the patient based on the prescribing practitioner's directions for use or, for over-the-counter medicine, on the package's label.

SECTION 11. A recipient may dispense or administer prescription drugs to an eligible patient only if otherwise permitted by law. Prescription drugs may only be dispensed or administered to eligible patients pursuant to a valid prescription drug order and shall have patient-specific written or electronic records maintained in accordance with the regulations of the Board of Pharmacy.

SECTION 12. When the prescribed drug does not use a unique delivery system technology, a recipient may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same dose schedule and is therapeutically equivalent to the drug prescribed.

SECTION 13. The donation, transfer, receipt or facilitation of donations, transfers, and receipt of medicine pursuant to this article shall not be considered wholesale distribution and shall not require licensing as a wholesale distributor.

SECTION 14. Medicine donated to the program shall not be resold and shall be considered nonsaleable; provided, however, that handling, dispensing, or usual and customary charges to an eligible patient, health plan, pharmacy benefit manager, pharmacy services administrative organization, government agency, or other entity shall not be considered reselling. If the authorized recipient is for-profit, these charges shall not exceed the authorized recipient's cost of providing that medicine including but not limited to the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies and equipment. The amount of these charges shall not have any additional limitations except as described above.

SECTION 15. When performing any action associated with this program or otherwise processing donated medicine for tax, manufacturer, or other credit, a recipient is considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns under federal law.

SECTION 16. All records required by this Chapter shall be retained in physical or electronic format, on or off the recipient's premise for a period of six years. A donor or authorized recipient may contract with one another or a third-party to create and/or maintain records on each other's behalf. An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to this Chapter if it allows for such information to be readily retrievable. Upon request by a state or federal regulator the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

SECTION 17. A donation, or other transfer of possession or control, shall not be construed as a change of ownership unless it is specified as such by the authorized recipient. If a record of the donation's transaction information or history is required, the history shall begin with the donor of the medicine, shall include all prior donations, and, if the medicine was previously dispensed, shall only include drug information required to be on the patient label in accordance with the Board of Pharmacy rules and regulations.

SECTION 18. An entity participating in a drug donation or repository program operated by another state may participate in this program, and in the case of a pharmacy, may dispense donated drugs to residents of this state. This entity is required to comply with all laws and rules

in this state unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is located.

SECTION 19. A health care professional may substitute a prescribed drug for:

a) A drug that is in stock and which is a therapeutically equivalent drug; or

b) A biological product with an interchangeable biological product.

Substitutions under this section may include but are not limited to:

a) splitting a combination drug into two or more drugs;

b) combining two or more drugs into a combination drug; and

c) a different form of the prescribed drug, including but not limited to oral tablet, capsule,

If an eligible recipient dispenses or administers a substitute for a donated drug, communication of such substitution to the patient and the provider shall be required unless the repository program substitution policy is readily available on the program's website.

SECTION 20. When acting in good faith, the following shall not be subject to civil or criminal liability or professional disciplinary action:

a) a person or entity involved in the supply chain of donated medicine including the donor, recipient, a manufacturer, repackager, wholesaler, and pharmacy; and

b) a person or entity, including all employees, officers, volunteers, owners, partners, members, directors, contractors, and other persons or entities associated with the person or

entity, that in compliance with this section prescribes, donates, receives, dispenses, administers, transfers, replenishes, or repackages medicine, or facilitates any of the above.

c) The Board of Registration in Pharmacy.