

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:
<i>Bradley H. Jones, Jr.</i>	<i>20th Middlesex</i>	<i>1/18/2023</i>
<i>Nicholas A. Boldyga</i>	<i>3rd Hampden</i>	<i>1/26/2023</i>
<i>F. Jay Barrows</i>	<i>1st Bristol</i>	<i>1/26/2023</i>
<i>Paul K. Frost</i>	<i>7th Worcester</i>	<i>1/31/2023</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>	<i>1/31/2023</i>
<i>Hannah Kane</i>	<i>11th Worcester</i>	<i>3/1/2023</i>

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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

59 b) is not adulterated or misbranded;

60 c) is not a controlled substance;

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

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

65 No other medicine shall be eligible for donation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

139 b) A biological product with an interchangeable biological product.

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

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

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

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

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

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

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

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

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

155 c) The Board of Registration in Pharmacy.