

HOUSE No. 1374

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>1/15/2025</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>	<i>1/21/2025</i>
<i>Paul K. Frost</i>	<i>7th Worcester</i>	<i>1/31/2025</i>
<i>Todd M. Smola</i>	<i>1st Hampden</i>	<i>3/10/2025</i>
<i>Hannah Kane</i>	<i>11th Worcester</i>	<i>1/31/2025</i>

HOUSE No. 1374

By Representative Jones of North Reading, a petition (accompanied by bill, House, No. 1374) of Bradley H. Jones, Jr., and others for legislation to establish a state-wide drug repository program. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 1208 OF 2023-2024.]

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Fourth General Court
(2025-2026)**

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 Chapter 111 of the General Laws, as appearing in the 2022 Official Edition Is here by
2 amended by adding the following new sections:-

3 Section 244. (a) For the purposes of this section the below terms shall be defined as
4 follows:

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

7 “Donor” shall mean any person, including an individual member of the public, or any
8 entity legally authorized to possess medicine, including but not limited to a wholesaler or
9 distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center,

10 detention and rehabilitation centers, jails, prisons, laboratory, medical or pharmacy school,
11 prescriber or other health care professional, long-term care facility or healthcare facility. Donor
12 shall also mean government agencies and entities that are federally authorized to possess
13 medicine including but not limited to drug manufacturers, repackagers, relabelers, outsourcing
14 facilities, Veteran Affairs hospitals, FDA authorized importers such as those under Federal
15 FD&C Section 801, 804, or similar provisions, and prisons.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

55 (d) A drug manufacturer, repackager, dispenser, or wholesaler other than a returns
56 processor participating in this program shall comply with the requirements of 21 U.S.C. Sections
57 360eee-1 through 360eee-4 relating to drug supply chain security.

58 (e) A recipient may only accept into inventory donated medicine that:

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

61 b) is not adulterated or misbranded;

62 c) is not a controlled substance;

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

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

67 No other medicine shall be eligible for donation.

68 (f) Donated medicine that does not meet the requirements of section 5 must be disposed
69 by returning it to the medicine donor, destroying it by an incinerator, medical waste hauler, or

70 other lawful method, or transferring it to a returns processor. A record of disposed medicine shall
71 consist of the disposal method as described above, the date of disposal, and the name, strength,
72 and quantity of each drug disposed. No other record of disposal shall be required.

73 (g) All medicine received but not yet accepted into inventory shall be kept in a separate
74 designated area. Prior to or upon accepting a donation or transfer into inventory, a recipient shall
75 maintain a written or electronic inventory of the donation, consisting of the name, strength, and
76 quantity of each accepted drug, and the name, address and phone number of the donor. This
77 record shall not be required if the two parties are under common ownership or common control.
78 No other record of donation shall be required.

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

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

87 (j) A recipient may only administer or dispense medicine that:

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

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

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

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

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

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

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

106 (n) Medicine donated to the program shall not be resold and shall be considered
107 nonsaleable; provided, however, that handling, dispensing, or usual and customary charges to an
108 eligible patient, health plan, pharmacy benefit manager, pharmacy services administrative
109 organization, government agency, or other entity shall not be considered reselling. If the
110 authorized recipient is for-profit, these charges shall not exceed the authorized recipient's cost of
111 providing that medicine including but not limited to the current and anticipated costs of
112 educating eligible donors, providing technical support to participating donors, shipping and

113 handling, labor, storage, licensing, utilities, advertising, technology, supplies and equipment. The
114 amount of these charges shall not have any additional limitations except as described above.

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

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

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

133 (r) An entity participating in a drug donation or repository program operated by another
134 state may participate in this program, and in the case of a pharmacy, may dispense donated drugs

135 to residents of this state. This entity is required to comply with all laws and rules in this state
136 unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is
137 located.

138 (s) A health care professional may substitute a prescribed drug for:

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

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

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

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

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

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

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

148 (t) When acting in good faith, the following shall not be subject to civil or criminal
149 liability or professional disciplinary action:

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

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

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

156 c) The Board of Registration in Pharmacy.