

SENATE No. 1497

The Commonwealth of Massachusetts

PRESENTED BY:

John J. Cronin

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 protecting patient safety regarding non-FDA approved drugs.

PETITION OF:

NAME:

John J. Cronin

DISTRICT/ADDRESS:

Worcester and Middlesex

SENATE No. 1497

By Mr. Cronin, a petition (accompanied by bill, Senate, No. 1497) of John J. Cronin for legislation to protect patient safety regarding non-FDA approved drugs. Public Health.

The Commonwealth of Massachusetts

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

An Act protecting patient safety regarding non-FDA approved drugs.

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. As used in this section, the following words shall have the following
2 meanings:

3 "Compounded Medication" means a medication that is prepared, mixed, assembled,
4 altered, or otherwise modified by a licensed pharmacist to meet the unique needs of an individual
5 patient pursuant to a prescription.

6 "Retail Pharmacy" means any establishment, including a community pharmacy, licensed
7 by the state to dispense prescription medications directly to patients.

8 "Resale" means selling, distributing, or otherwise transferring a medication that a retail
9 pharmacy has purchased, in any quantity, to another entity or individual who is not the patient
10 for whom the medication was originally compounded.

11 SECTION 2.

12 In order to ensure the safe and ethical distribution of compounded medications:

13 (a) No retail pharmacy shall resell compounded medications.

14 (b) Compounded medications prepared by a retail pharmacy shall be dispensed only to
15 the patient for whom the medication was originally compounded, pursuant to a valid
16 prescription.

17 (c) Any violation of this section shall subject the retail pharmacy to disciplinary actions
18 as determined by the state's Board of Registration in Pharmacy, including but not limited to
19 fines, suspension, or revocation of the pharmacy's license.

20 SECTION 3.

21 (1) The resale of a compounded drug that is labeled "not for resale" in accordance with
22 section (2)(c)(ix) is prohibited.

23 (2) The label of any drug compounded or repackaged by an outsourcing facility shall
24 include, but not be limited to the following:

25 (a) a statement that the compounded drug is a compounded drug or a reasonable
26 comparable alternative statement that prominently identifies the drug as a compounded drug;

27 (b) the name, address, and phone number of the applicable outsourcing facility; and

28 (c) with respect to the compounded drug:

29 (i) the lot or batch number;

30 (ii) the established name of the drug;

- 31 (iii) the dosage form and strength;
- 32 (iv) the statement of quantity or volume, as appropriate;
- 33 (v) the date that the drug was compounded;
- 34 (vi) the expiration date;
- 35 (vii) storage and handling instructions;
- 36 (viii) the NDC number, if available;
- 37 (ix) the statement that the drug is not for resale, and if the drug product is distributed by
38 an outsourcing facility other than pursuant to a prescription for an individual identified patient,
39 the statement “office use only”;
- 40 (x) a list of the active and inactive ingredients, identified by established name, and the
41 quantity or proportion of each ingredient.

42 (3) The container from which the individual units of the compounded drug are removed
43 for dispensing or for administration (such as a plastic bag containing individual product syringes)
44 shall include--

45 (a) a list of active and inactive ingredients, identified by established name, and the
46 quantity or proportion of each ingredient;

47 (b) the following information to facilitate adverse event
48 reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or
49 phone number); and

50 (c) directions for use, including, as appropriate, dosage and administration.

51 (4) No compounded or repackaged drug will be sold or transferred by any entity other
52 than the outsourcing facility that compounded or repackaged such drug. This does not prohibit
53 the administration of a drug in a health care setting or an outsourcing facility dispensing a drug
54 pursuant to a properly executed prescription.

55 (5) A compounded drug labeled “office use only” in accordance with section (2)(c)(ix)
56 shall be administered in the office and not dispensed to the patient.

57 SECTION 4. Enforcement

58 (a) The state's Board of Registration in Pharmacy shall have the power to enforce the
59 provisions of this Act.

60 (b) The regulatory authority is authorized to promulgate rules and regulations necessary
61 for the implementation and enforcement of this Act.

62 SECTION 5. Severability

63 If any provision of this Act, or the application thereof to any person or circumstance, is
64 held invalid, the remainder of the Act and the application of such provision to other persons or
65 circumstances shall not be affected thereby.