

**SENATE . . . . . No.**

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**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.**

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[Pin Slip]

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**The Commonwealth of Massachusetts**

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**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](http://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.