

# SENATE . . . . . No. 3068

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## The Commonwealth of Massachusetts

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

SENATE, May 26, 2026.

The committee on Health Care Financing to whom was referred the Senate Bill protecting patient safety regarding non-FDA approved drugs (Senate, No. 1497), - reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 3068).

For the committee,  
Cindy F. Friedman

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**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. Chapter 112 of the General Laws is hereby amended by inserting after  
2 section 297 the following section:-

3           Section 298. (a) For the purposes of this section, the following words shall have the  
4 following meanings:

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

8           "Retail pharmacy", any establishment, including a community pharmacy, licensed by the  
9 state to dispense prescription medications directly to patients.

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

13 (b) No retail pharmacy shall resell compounded medications, and compounded  
14 medications prepared by a retail pharmacy shall be dispensed only to the patient for whom the  
15 medication was originally compounded, pursuant to a valid prescription.

16 (c) Any violation of subsection (b) of this section shall subject the retail pharmacy to  
17 disciplinary actions as determined by the board of registration in pharmacy, including, but not  
18 limited to fines, suspension, or revocation of the pharmacy's license.

19 (d) The resale of a compounded drug that is labeled “not for resale” in accordance with  
20 subsection (b) of this section is prohibited.

21 (e) In addition to the provisions described in section 21 of chapter 94C of the General  
22 Laws, the label of any drug compounded or repackaged by an outsourcing facility shall include,  
23 but not be limited to, the following:

24 (1) the name, address, and phone number of the applicable outsourcing facility; and

25 (2) with respect to the compounded drug:

26 (i) the lot or batch number;

27 (ii) the dosage form and strength;

28 (iii) the statement of quantity or volume, as appropriate;

29 (iv) the expiration date;

30 (v) storage and handling instructions;

31 (vi) the National Drug Code number, if available;

32 (vii) the statement that the drug is not for resale, and if the drug product is distributed  
33 by an outsourcing facility other than pursuant to a prescription for an individual identified  
34 patient, the statement “office use only”; and

35 (viii) a list of the active and inactive ingredients, identified by established name, and  
36 the quantity or proportion of each ingredient.

37 (f) The container from which the individual units of the compounded drug are removed  
38 for dispensing or for administration, such as a plastic bag containing individual product syringes,  
39 shall include a list of active and inactive ingredients, identified by established name, and the  
40 quantity or proportion of each ingredient.

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

45 (h) A compounded drug labeled “office use only” in accordance with subsection  
46 (e)(3)(vii) shall be administered in the office and not dispensed to the patient.

47 (i) Notwithstanding the provisions of any general or special law to the contrary, the use of  
48 compounded medications in veterinary practice as defined in this section shall be exempt.

49 (j) The board of registration in pharmacy shall have the power to enforce the provisions  
50 of this act.

51 (k) The bureau of health professions licensure may promulgate rules and regulations  
52 necessary for the implementation and enforcement of this section.

53           SECTION 2. If any provision of this act, or the application thereof to any person or  
54   circumstance, is held invalid, the remainder of the act and the application of such provision to  
55   other persons or circumstances shall not be affected thereby.