HOUSE DOCKET, NO. 1476 FILED ON: 1/15/2025

HOUSE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Kathleen R. LaNatra

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:	DISTRICT/ADDRESS:	DATE ADDED:
Kathleen R. LaNatra	*12th Plymouth*	*1/15/2025*

HOUSE DOCKET, NO. 1476 FILED ON: 1/15/2025

HOUSE . . . . . No.

[Pin Slip]

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:

Section 1. As used in this section, the following words shall have the following meanings:

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

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

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

Section 2.

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

(a) No retail pharmacy shall resell compounded medications.

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

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

Section 3.

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

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

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

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

(c) with respect to the compounded drug:

(i) the lot or batch number;

(ii) the established name of the drug;

(iii) the dosage form and strength;

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

(v) the date that the drug was compounded;

(vi) the expiration date;

(vii) storage and handling instructions;

(viii) the NDC number, if available;

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

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

(3) The container from which the individual units of the compounded drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include-- (a) a list of active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient; (b) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and (c) directions for use, including, as appropriate, dosage and administration.

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

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

Section 4. Enforcement

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

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

Section 5. Severability

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