



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street Boston, MA 02108-4619

Tel: 617-973-0960
www.mass.gov/dph/boards

The Board of Registration in Pharmacy

Defective Drug Preparation

Pursuant to M.G.L. c. 112, § 39D(e), pharmacies that are licensed with the Massachusetts Board of Registration in Pharmacy (Board) must report to the Board **within seven days** any defective drug preparation that is a **compounded sterile** product or **complex non-sterile** product dispensed into, within, or from Massachusetts. Please submit this form to the Board at abnormalresults@mass.gov.

Any of the same drug preparation remaining in the possession of the pharmacy shall be segregated from active inventory and shall not be dispensed. A [defective drug preparation log](#) documenting the recalled drug preparation shall be kept by the pharmacy.

In addition to the definition outlined in [M.G.L. c. 94C, § 1](#), "dispense" also includes any medication or compound that has left the pharmacy, is ready for administration, and will not be subjected to further pharmacy or pharmacist verification before its use upon receipt of a patient-specific prescription or order, generally in a hospital setting.

For more information, please reference the Board's [Policy 2024-04: Defective Drug Preparations](#).

Section A: Pharmacy Demographic Information

Please Enter All Information Clearly and Use One Form for Each Event

Name of Pharmacy: [Enter Here](#)

MA License Number: [Enter Here](#)

Address: [Enter Here](#)

City: [Enter Here](#)

State: [Enter Here](#)

Zip: [Enter Here](#)

Pharmacy Tel. No.: [Enter Here](#)

Pharmacy Fax No.: [Enter Here](#)

Pharmacy Email: [Enter Here](#)

Manager of Record (MOR) / Designated Pharmacist-in-Charge (PIC): [Enter Here](#)

MA Lic. No.: [Enter Here](#)

Section B: Drug Preparation Information

Drug Preparation Information	Prescribed	Dispensed
Compound name	Enter Here	Enter Here
Generic Drug Name(s)/ Ingredients	Enter Here	Enter Here
Potency/Strength/Concentration (units)	Enter Here	Enter Here
Quantity (units)	Enter Here	Enter Here
Dosage Form	Enter Here	Enter Here
Instructions	Enter Here	Enter Here

Date and Time Drug Compounded:

Date and Time Drug Dispensed: [Enter Here](#)

Prescription Number: [Enter Here](#)

Batch/Lot Number (if applicable): [Enter Here](#)

☐ Check if this medication was dispensed out of state from a pharmacy located in Massachusetts.

If so, please enter which state: [Enter Here](#)

Reason for Recall: [Click here to enter text.](#)

Were recipients of the defective drug preparation(s) contacted? ☐ Yes ☐ No [Explain](#)

Was the defective drug preparation retrieved from the patient(s)? ☐ Yes ☐ No [Explain](#)

Was the compounded drug utilized by the patient(s)? ☐ Yes ☐ No

If yes, did the patient(s) experience any adverse event(s)? ☐ Yes ☐ No

Section C: Root Cause and Corrective Actions

Description of Root Cause(s) Identified: [Click here to enter text.](#)

Description of Corrective Action(s): [Click here to enter text.](#)

If there was a serious adverse drug event related to the drug preparation in question, please **immediately** submit the Board's [Serious Adverse Drug Event](#) reporting form.

I certify that the foregoing information is correct to the best of my knowledge and belief. I further certify that I am the individual listed below and that I completed this form.

[Enter Here](#)

Print Name of MOR / PIC / or their designee

[Enter Here](#)

Title

[Enter Here](#)

Date

Signature

[Enter Here](#)

Contact Phone #