The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
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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) shall report to the Board **within seven days** any defective drug preparation that is a compounded sterile product or **complex** non-sterile product dispensed or distributed by the pharmacy **into, within, or from Massachusetts** utilizing this form. Please submit this information to the Board of Registration in Pharmacy 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 distributed or dispensed. A defective drug preparation log documenting the recalled drug preparation shall be kept by the pharmacy and submitted with this report.

For more information, please reference the Board's *Pharmacy Requirement to Maintain Defective Drug Preparation Log*.

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: Enter Here Date and Time Drug Dispensed: Enter Here

Prescription Number: Enter Here Batch/Lot Number (if applicable): Enter Here

☐ New Prescription or ☐ Refill Prescription or ☐ Other: Explain

Patient Name: Enter Here

How was original prescription/order received? ☐ Written or ☐ Telephone/Verbal or ☐ Fax or ☐ Electronic

☐ Check if this medication was shipped 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 the 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	Enter Here	Enter Here
Print Name of MOR or their designee / or PIC	Title	Date

_____ Enter Here
Signature Contact Phone #