



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 or from Massachusetts** utilizing this form. Please submit this information to the Board of Registration in Pharmacy at abnormalresults@massmail.state.ma.us.

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*, [link](#).

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): [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 there was a serious adverse drug event related to the drug preparation in question, please immediately submit the Board's *Serious Adverse Drug Events and Improper Dispensing* reporting form, located on the Board's website ([Link](#)), and submit.

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 or his/her designee / or
designated MA licensed pharmacist in charge

[Enter Here](#)

Title

[Enter Here](#)

Date

Signature

[Enter Here](#)

Contact Phone #