The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

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[www.mass.gov/dph/boards](http://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 information 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 and submitted with this report.

For more information, please reference the Board’s [*Policy 2024-04: Defective Drug Preparations*](https://www.mass.gov/lists/pharmacy-practice-resources#compounding-).

**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 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 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 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***](https://www.mass.gov/lists/reporting-forms-for-the-board-of-registration-in-pharmacy)**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 / PIC / or their designee Title Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Enter Here

Signature Contact Phone #