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) 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](mailto: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*](https://www.mass.gov/doc/defective-drug-preparations-pdf/download).

**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***](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 or their designee / or PIC Title Date

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

Signature Contact Phone #