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**

**Serious Adverse Drug Event Report**

Pursuant to M.G.L c. 112, § 39D(b)&(c), retail pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) shall report to the Board **within seven business days** any serious adverse drug event that occurs as a result of:

1. any compounded preparation dispensed from a pharmacy (sterile or non-sterile);
2. any improper dispensing of a prescription drug resulting in serious injury or death.

Use this form to report events related to medications **dispensed into, within, or from Massachusetts.**

A **serious adverse drug event (SADE)** is defined as any untoward, preventable medical occurrence associated with the use of a drug in humans that results in death, a life-threatening outcome, inpatient hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly or birth defect, or any other kind of harm as defined by the department. M.G.L. c. 111, § 51H.

A **serious injury** is defined as an injury that is life threatening, results in serious disability or death, or results in additional treatment, testing, or monitoring in a hospital or emergency department.

**Improper dispensing of a prescription drug** shall mean the incorrect dispensing of a prescribed medication that is received by a patient.

A pharmacy shall retain all records relating to the improper dispensing of a prescription drug that results in serious injury or death and all records relating to serious adverse drug events for a minimum period of five years from the date the report is filed with the Board. The records shall be readily retrievable.

**Print 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 Email: Enter Here

Pharmacy Tel. No.: Enter Here Pharmacy Fax No.: Enter Here

Manager of Record (MOR) / Designated Pharmacist-in-Charge (PIC): Enter Here MA Lic. No.: Enter Here

Patient Name: Enter Here Patient Gender: [ ]  Male[ ]  Female Age (years): Enter Here

Prescription Number(s): Enter Here [ ]  New Prescription or [ ]  Refill Prescription or [ ]  Other: Enter Here

Date and Time Drug Dispensed: Enter Here

Date of Discovery: Enter Here

Medication PRESCRIBED: Enter Here Quantity (units): Enter Here Strength (units): Enter Here

Dosage Form: Enter Here

Medication DISPENSED: Enter Here Quantity (units): Enter Here Strength (units): Enter Here

Dosage Form: Enter Here

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

 If so, please enter which state: Enter Here

Type of Event (check all that apply):

[ ]  Incorrect Patient [ ]  Incorrect Medication [ ]  Incorrect Strength

[ ]  Incorrect Directions [ ]  Incorrect Drug Utilization Review [ ]  Incorrect Counseling

[ ]  Compounded Preparation [ ]  Other: Enter Here

Outcome of Serious Adverse Drug Event:

[ ]  Death [ ]  Life-Threatening Outcome [ ]  Inpatient Hospitalization

[ ]  Prolonged Hospitalization [ ]  Disability/ Incapacitated [ ]  Congenital Anomaly/ Birth Defect

[ ]  Other: Enter Here

Description of Event and Outcome: Enter Here

Action/Intervention by Pharmacy: Enter Here

**NOTE:** If the serious adverse drug event was associated with a defective drug preparation that is a compounded sterile preparation or complex non-sterile preparation dispensed by the pharmacy, [a *Defective Drug Preparation* report](https://www.mass.gov/lists/reporting-forms-for-the-board-of-registration-in-pharmacy) must also be submitted:

This information must be submitted to the [FDA MedWatch Program](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda) and the [Betsy Lehman Center](https://betsylehmancenterma.gov/) for any SADE resulting from a compounded preparation.

**Initial that this has been completed: \_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­\_**

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 have completed this form.

Enter Here Enter Here Enter Here

Print Name of MOR or designee / PIC Title Date

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

Signature Contact Phone #

A signed copy of this form must be scanned and emailed to the Board of Registration in Pharmacy at SeriousReportableEvents@mass.gov