



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

The Board of Registration in Pharmacy

Serious Adverse Drug Event Report

Except for institutional sterile compounding pharmacies that are licensed pursuant to a “Hospital MCSR”, all other pharmacies (including institutional sterile compounding pharmacies with a “Clinic MCSR”) 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](#)

Prescription Number(s): [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):

- | | | |
|---|--|---|
| <input type="checkbox"/> Incorrect Patient | <input type="checkbox"/> Incorrect Medication | <input type="checkbox"/> Incorrect Strength |
| <input type="checkbox"/> Incorrect Directions | <input type="checkbox"/> Incorrect Drug Utilization Review | <input type="checkbox"/> Incorrect Counseling |
| <input type="checkbox"/> Compounded Preparation | <input type="checkbox"/> Other: <u>Enter Here</u> | |

Outcome of Serious Adverse Drug Event:

- | | | |
|--|--|---|
| <input type="checkbox"/> Death | <input type="checkbox"/> Life-Threatening Outcome | <input type="checkbox"/> Inpatient Hospitalization |
| <input type="checkbox"/> Prolonged Hospitalization | <input type="checkbox"/> Disability/ Incapacitated | <input type="checkbox"/> Congenital Anomaly/ Birth Defect |
| <input type="checkbox"/> Other: <u>Enter Here</u> | | |

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](#) must also be submitted:

This information must be submitted to the [FDA MedWatch Program](#) and the [Betsy Lehman Center](#) 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
Print Name of MOR / PIC / or designee

Enter Here
Title

Enter Here
Date

Signature

Enter Here
Contact Phone #

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