The Commonwealth of Massachusetts
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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

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 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 SeriousReportableEvents@mass.gov