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**

**Reporting of Serious Adverse Drug Events**

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.

This form applies to events that occur related to medications **dispensed into or from Massachusetts.**

A **serious adverse drug event** 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.

**Please 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): 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

**The pharmacy is required to submit this information to the FDA MedWatch Program for SADE’s resulting from a compounded preparation. Please initial in attestation that this has been completed: \_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­\_\_\_\_­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_**

\*\*Submission of this form meets the requirement to report to the Betsy Lehman Center for Patient Safety and Medical Error Reduction.

**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 *Pharmacy Report of Defective Drug Preparation* must also be submitted: (**[**http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/defective-drug-prep-log.pdf**](http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/defective-drug-prep-log.pdf)**).**

**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 his/her designee Title Date

/ or designated MA licensed pharmacist in charge

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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@massmail.state.ma.us](mailto:SeriousReportableEvents@massmail.state.ma.us)