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Board of Registration in Pharmacy

Policy 2024-04: Defective Drug Preparations

The Board of Registration in Pharmacy ("Board") would like to inform licensees of the requirement to maintain a defective drug preparation log and specific reporting requirements surrounding defective drug preparations pursuant to M.G.L. c. 112, § 39D(e).

Per M.G.L. c. 112, § 39D(e), a pharmacy that is licensed with the Board has a legal responsibility to recall a compounded drug preparation if it knows or should have reason to know that a compounded drug preparation dispensed **into, within, or from Massachusetts** by the pharmacy is or may be defective in any way.

The requirement to maintain a defective drug preparation log applies to any pharmacy that holds a license with the Board.

A **defective drug preparation** is defined as any out of specification result such as the potency, pyrogenicity, stability, improper composition, contamination, mislabeling, or sterility of a compounded sterile product ("CSP") or the potency, purity, quality, mislabeling, or stability of any compounded non-sterile preparation ("CNSP").

Pharmacies shall report to the Board **within seven days** any defective CSP or complex category CNSP dispensed by the pharmacy into, within, or from Massachusetts utilizing the Board's *Defective Drug Preparation* reporting form.

Defective Drug Preparation Log

A defective drug preparation log documenting the recalled drug preparation shall be kept by the pharmacy including information on:

1. The drug preparation name, potency and dosage form;
2. The reason for the recall;
3. The amount of the drug preparation made;
4. The date that the drug preparation was made;

5. The amount of the drug preparation dispensed;
6. The actual drug preparation potency and dosage form; and
7. Any and all serious adverse drug events ("SADE") related to the drug preparation in question.

The defective drug preparation log shall be kept on record for at least 10 years and shall be made available for Board inspection.

Any of the same compounded drug preparation remaining in the possession of the pharmacy shall be located and segregated and shall not be dispensed.

Upon recall of a defective drug preparation, the pharmacy shall immediately contact the recipient(s) of the defective drug preparation for appropriate follow-up.

The pharmacy shall maintain records of all defective drug preparations that are destroyed or returned to an authorized vendor for at least 10 years and shall provide to the Board any information or records surrounding the destruction or return of defective drug preparations, as requested.

If a pharmacy discovers that a compounded drug preparation is defective **prior to dispensing**, it is recommended that the pharmacy document the event in its continuous quality improvement ("CQI") program. These events do **not** need to be reported to the Board.

If the defective drug preparation has caused, or is suspected to have caused an SADE, the pharmacy shall **immediately** submit a *Serious Adverse Drug Event* form to the Board.

Required Actions

All pharmacies that are licensed with the Board shall:

- **Maintain** a defective drug preparation log for all recalled defective CSPs and CNSPs dispensed into, within, or from Massachusetts.
- **Report** to the Board all recalled defective CSPs or complex category CNSPs dispensed into, within, or from Massachusetts.

Please direct any questions to: **Pharmacy.Admin@mass.gov**