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247 CMR 20.00: REPORTING

Section

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20.01: Format of Reports

All reports required by 247 CMR 20.00 shall be made in the manner and format determined by the Board.

20.02: Duty to Report Certain Improper Drug Dispensing and Serious Adverse Drug Events to the Board

(1) A Manager of Record of a pharmacy shall report to the Board any improper dispensing of a prescription drug that results in serious injury or death within seven business days of discovery of **serious injury or death related to the** improper dispensing.

(2) A Manager of Record of a pharmacy, shall report any serious adverse drug event that occurs as a result of a patient's interaction with any drug or pharmaceutical manufactured, produced, or compounded at the pharmacy, to:

- (a) the Board;
- (b) the Federal Food and Drug Administration MedWatch Program; and
- (c) the Betsy Lehman Center for Patient Safety and Medical Error Reduction.

A Manager of Record shall report a serious adverse drug event within seven business days of the knowledge of the serious adverse drug event by any pharmacy employee.

(3) The duty to report to the Board improper dispensing of a prescription drug that results in serious injury or death or a serious adverse drug event shall be in addition to the Continuous Quality Improvement (CQI) Program requirements of 247 CMR 15.00.

(4) 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.

(5) The reporting requirements in 247 CMR 20.02 do not apply to non-resident

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pharmacies.

20.03: General Reporting Requirements

- (1) Each licensee shall maintain his or her personal demographic information, including mailing address, phone number, and email address, in the licensee's Massachusetts Department of Public Health on-line licensing profile. A licensee shall update the on-line licensing profile within 14 calendar days of a change of mailing address, phone number, or email address.
- (2) In the event of a change in name, a licensee shall submit a sworn statement indicating that the licensee has changed his or her name along with a photocopy of a valid picture identification card and any other documentation that may be required by the Board within 14 calendar days.
- (3) Every individual licensed by the Board shall report to the Board, within 14 calendar days, any arrest, pending criminal charge, or conviction.
- (4) Each pharmacy and individual licensed by the Board shall report to the Board, within 14 calendar days, any disciplinary action, as defined in 247 CMR 2.00, or loss of certification.
- (5) Each pharmacy licensed by the Board shall report to the Board, within 14 calendar days, any adverse change in accreditation status.
- (6) Each pharmacy licensed by the Board shall provide the Board with a copy of each inspection report, investigation report, or FDA warning letter, received from a local, state, or federal agency that pertains to the pharmacy or the practice of pharmacy within 14 calendar days of receipt.
- (7) A Drug Store pharmacy, sterile compounding pharmacy, complex non-sterile compounding pharmacy, and nuclear pharmacy located in Massachusetts shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of "Report of Theft or Loss of Controlled Substance" and ~~(DEA BND Form 106)~~, within seven days of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police.

20.04: Orally and Electronically Transmitted Prescriptions and Reporting Requirements to the Prescription Monitoring Program (PMP)

- (1) Every pharmacy licensed by the Board that dispenses controlled substances in Schedules II through V pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012).

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- (2) Failure to comply with the Prescription Monitoring Program reporting requirements set forth in 105 CMR 700.012 or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the licensed pharmacist or the pharmacy by the Board or other state and federal law enforcement agencies.

20.05: Change of Manager of Record and Pharmacist in Charge

- (1) A pharmacy located in Massachusetts shall notify the Board within 14 calendar days of the resignation, ~~or~~ termination, or change of its Manager of Record. An application for change of Manager of Record shall satisfy this requirement.
- (2) A non-resident pharmacy shall notify the Board within 14 calendar days of the resignation, termination, or change of its Massachusetts licensed designated pharmacist in charge. An application for change of Massachusetts licensed designated pharmacist in charge shall satisfy this requirement.
- (32) A Manager of Record shall notify the Board of his or her resignation or termination as Manager of Record within 14 calendar days.

20.06: Compounding Pharmacies

- (1) Each sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall report to the Board annually, or upon request by the Board, the following information:
 - (a) a list of sterile and complex non-sterile prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions;
 - (b) the states in which the sterile and complex non-sterile prescriptions were dispensed and the status of any non-resident licenses issued by other states;
- (2) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report, within seven business days of identification, any defective compounded sterile preparation dispensed into or from Massachusetts. ~~any out of specification result relating to the potency, pyrogenicity, stability, improper composition, contamination, or sterility of a compounded sterile product.~~
- (3) Each complex non-sterile compounding pharmacy and non-resident complex non-sterile compounding pharmacy shall report, within seven days of identification, any defective complex non-sterile compounded preparation dispensed into or from Massachusetts.

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(43) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report above action level environmental monitoring results ~~or failure of certification of primary or secondary engineering control~~, as required by 247 CMR 17.00.

(5) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report failure of certification of primary or secondary engineering control, as required by 247 CMR 17.00.

(64) A Manager of Record of a sterile compounding pharmacy, complex non-sterile compounding pharmacy, or institutional sterile compounding pharmacy shall:

- (a) disclose to the board the location, name and title of all principal managers and the name and Massachusetts license number of the designated Manager of Record;
- (b) certify the sterile compounding pharmacy's compliance with reasonable informational requests made by the Board;
- (c) certify to the Board that the Manager of Record has fulfilled continuing education requirements for sterile compounding and ensured that all pharmacy staff has received the appropriate training and education required by law and regulation before engaging in compounding;
- (d) submit to the Board the names and titles of all individuals employed by the sterile compounding pharmacy, complex non-sterile compounding pharmacy, or institutional sterile compounding pharmacy; and
- (e) annually, and within 30 days after any transfer of ownership or change in corporate officers, management personnel or Manager of Record, file a report containing the information disclosed under clause (a).

20.07: Non-Resident Pharmacies

(1) A non-resident pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall comply with all provisions of 247 CMR 20.00 unless otherwise provided.

(2) The designated pharmacist in charge of a non-resident pharmacy shall submit the following to the Board:

- (a) the location, name, and title of all principal managers and the name and Massachusetts license number of the designated pharmacist in charge;
- (b) a letter or documentation from the in-state Board of Registration in Pharmacy certifying that the pharmacist in charge is in good standing with the in-state board of registration;
- (c) ~~a letter or~~ documentation ~~from the in-state Board of Registration in Pharmacy certifying that demonstrating~~ the non-resident pharmacy maintains a current, unrestricted license, permit, or registration to operate the pharmacy; and

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(d) a list of all prescriptions dispensed in Massachusetts.

A non-resident pharmacy shall submit this information on an annual basis and within 30 days after any transfer of ownership or change in corporate officers, management personnel or Manager of Record.

(3) A non-resident pharmacy shall report to the Board any improper dispensing, into Massachusetts, of a prescription drug that results in serious injury or death within even business days of discovery of the improper dispensing.

REGULATORY AUTHORITY:

M.G.L. c. 94C, § 6; M.G.L. c. 112, §§ 39G, 39H, 39I, 39J, and 42A.