

247 CMR 20.00: Reporting

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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 7 business days of discovery of the improper dispensing.

~~(2) A pharmacist, including a pharmacist who practices in a facility, 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 a pharmacy, to the Board within 7 business days.~~

(23) 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 7 business days of the knowledge of the serious adverse drug event by any pharmacy employee.

(34) 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.

(45) 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.

20.03: General Reporting Requirements

(1) Each licensee shall maintain his/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/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 ~~30~~ 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 ~~seven business~~ 14 calendar days of receipt any disciplinary action, as defined in 247 CMR 2.00, or loss of certification.

(5) Each pharmacy ~~and individual~~ licensed by the Board shall report to the Board any adverse change in status of accreditation within 14 calendar days of a change, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning. All such reports shall be made within seven business days of an action taken by the accrediting agency.

(6) Each pharmacy ~~and pharmacist~~ licensed by the Board shall provide the Board with a copy of each inspection report, investigation report, or FDA warning letter, ~~or correspondence~~ 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 pharmacy 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" (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 and every pharmacy located in a health facility registered with the Commissioner of the Department that dispenses controlled substances in Schedule II 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). Effective January 1, 2011, every pharmacy registered by the Board that dispenses controlled substances in Schedules II-V 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). (M.G.L. c. 94C, §§ 24 and 24A)

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

20.05: Change of Manager of Record

(1) A pharmacy shall notify the Board within 14 calendar days of the resignation or termination of its Manager of Record. An application for change of Manager of Record shall satisfy this requirement.

(2) A Manager of Record shall notify the Board of his/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 ~~every six months~~annually, or upon request by

the Board, at a minimum, 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 out of specification result relating to the potency, pyrogenicity, stability, improper composition, contamination, or sterility of a CSP.
- (3) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report above action level environmental monitoring results and/or failure of certification of primary or secondary engineering control, as required by 247 CMR 17.XX.
- (4) 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 retail 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 change of office, corporate office or manager of record, file a report containing the information disclosed under clause (a).

20.07: Non-Resident Pharmacies

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

(a) (1) —the location, name, and title of all principal managers and the name and Massachusetts license number of the designated pharmacist in charge;

(b) (2) —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) (3) —a letter or documentation from the in-state Board of Registration in Pharmacy certifying that the non-resident pharmacy maintains a current, unrestricted license, permit, or registration to operate the pharmacy; and

(d) (4) —a list of all prescriptions dispensed in the commonwealth.

A non-resident pharmacy shall submit this information on an annual basis and within 30 days after any change of office, corporate office or manager of record.

(2) A non-resident pharmacy shall report to the Board any improper dispensing, into the commonwealth of Massachusetts, of a prescription drug that results in serious injury or death within 7 business days of discovery of the improper dispensing.

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

*****The following definitions pertaining to 247 CMR 20.00 should be located in 247 CMR 2.00.*****

(1) Above Action Level Environmental Monitoring Results means results of viable and nonviable testing that exceed levels described in 247 CMR 17.XX.

(2) Accreditation means a process by which a professional association or non-governmental agency grants recognition to a pharmacy for demonstrated ability to meet certain pre-defined criteria.

(3) Disciplinary action means an action including, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice

pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.

(4) Federal agency means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.

(5) Improper dispensing of a prescription drug means the incorrect dispensing of a prescribed medication that is received by a patient, as more particularly described in 247 CMR 15.01: Quality-related Event or QRE.

(6) Serious adverse drug event means any untoward, preventable medical occurrence associated with the use of a drug in humans that results in any of the following outcomes:

- (a) death;
- (b) a life-threatening outcome;
- (c) inpatient hospitalization or prolongation of existing hospitalization;
- (d) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- (e) a congenital anomaly or birth defect; or
- (f) any other kind of harm as determined by the Department of Public Health in regulation.

Adverse medical occurrences directly associated with the use of a drug in humans that may not immediately result in one of the outcomes listed in 247 CMR 20.01(1)(b) may be considered a serious adverse drug event if they develop into or result in any of the outcomes listed in 247 CMR 20.01(1)(b).

(7) Serious injury means an injury that is life threatening, results in serious disability or death, or ~~requires results in a patient to undergo~~ additional treatment, testing, or monitoring in a hospital or emergency room.

(8) Serious disability means injuries requiring major intervention and loss, or substantial limitation of bodily function lasting greater than seven days (e.g. bodily function related to breathing, dressing/undressing; drinking; eating; eliminating

waste products; getting into and out of bed, chair, etc.; hearing; seeing; sitting; sleeping or walking).

(9) State agency means any U.S. State or Territory that licenses, oversees, or otherwise regulates pharmacies or pharmacist practice.

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