The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

Board of Registration in Pharmacy

Advisory: Information for Managers of Record

The "Manager of Record" is a licensed pharmacist who assumes full responsibility for the operation of a Board-licensed pharmacy in a manner complying with the laws and regulations governing the practice of pharmacy in Massachusetts. The Manager of Record ("MOR") has additional responsibilities compared to other pharmacists and the Board wishes to remind MORs of some of these responsibilities.

Utilize pharmacy.admin@mass.gov for any questions and / or to request to be added to the Board's distribution list to receive important updates.

The following links contain important information:

State and Federal Laws and Regulations:
https://www.mass.gov/doc/multistate-pharmacy-jurisprudence-examination-mpje-review-information/download

Inspection Templates / Advisories / Policies / Standing Orders:
https://www.mass.gov/lists/pharmacy-practice-resources

Draft Regulations:
These regulations are not yet in effect but are a good resource for coming changes.
https://www.mass.gov/lists/draft-regulations-for-the-board-of-registration-in-pharmacy

Please note carefully that this list is not meant to be exhaustive. Rather, the Board intends for this guidance document to simply highlight common compliance issues. The MOR is responsible for ensuring the pharmacy complies with ALL laws and regulations governing the practice of pharmacy, including laws and regulations not cited in this document. Be advised that the citations referenced in this document may also change with regulatory updates.

1. Develop, monitor, and enforce policies and procedures including the proper supervision of technicians and interns. [247 CMR 9.23(2)]

2. Review the most recent Board of Pharmacy inspection report for any cited deficiencies and the plan of correction ("POC"). Perform a self-inspection at least once per year.

3. Procedures for appointing an interim manager within 5 calendar days when an MOR will be away from their position. [247 CMR 9.23(5)]
Policy: Extended Absence or Departure of a Manager of Record

4. Applications for a change in MOR must be submitted to the Board within 14 calendar days. [247 CMR 20.05]

5. A pharmacist leaving the MOR position of a Massachusetts-located pharmacy must also <u>personally</u> notify the Board (by email) within 14 calendar days of leaving the position. [247 CMR 20.05(3)]

6. Upon leaving the MOR position, conduct an inventory with the incoming MOR.
[247 CMR 6.10(2)(a)]

- Complete an exact count of federally controlled substances and Schedule VI drugs that are reported to the PMP.
- If the outgoing MOR is unavailable, a staff pharmacist may perform the inventory with the incoming MOR.
- File this document with the pharmacy's controlled substance records.

7. Ensure that all employee and pharmacy licenses are valid, current, and properly displayed. [247 CMR 9.01(18); 247 CMR 9.19(7)]

- All employees performing pharmacy technician duties must have a license.
- Pharmacy technician trainee ("PTT") licenses are only valid for 1 year or 1500 hours whichever comes first.
- Technician ("PT") licenses expire on their birthdays.
- Certified pharmacy technicians MUST ALSO have a Massachusetts pharmacy technician license.
- All licenses must be renewed prior to expiration in order to continue practice. There are no grace periods.

8. Develop a tracking system to ensure pharmacy technician trainees take a pharmacy technician licensing exam after 500 hours of training and that they do not exceed 1500 hours or 1 year without an extension. [247 CMR 8.03(5)]

9. Staffing levels must be adequate and compliant with ratios. [247 CMR 9.23(2)(c); 247 CMR 8.06(3); Policy 2024-03: Ratios, Intern Supervision, and Dedicated Training Personnel]

10. Maintain daily reports or logs signed by the pharmacist for refills of Schedule III - VI controlled substances. [21 CFR 1306.22]

11. Maintain a Continuous Quality Improvement ("CQI") program to detect, identify, and prevent prescription errors in pharmacies. [247 CMR 15.00]

12. Any theft or significant loss of controlled substances must be reported to the Board within 7 calendar days.
[247 CMR 20.03(7); Policy 2022-01: Loss or Theft of Controlled Substances]

13. Permitted practices for each licensee type.
[Policy 2020-15: Licensee Scope of Practice]

14. Medication refrigerators and freezers must be properly maintained, not used for food storage, and temperatures must be monitored in accordance with Board policy.
[247 CMR 9.22; Policy 2020-05: Refrigerated and Frozen Medication Storage]

15. Security and storage of controlled substances.
[247 CMR 9.21]

- All prescription medications (including vaccines and epinephrine) must be stored within the prescription-filling area.
- Damaged and expired Schedule II drugs must be maintained on a perpetual inventory and counted until returned / reverse distributed / sent for destruction.
- Damaged and expired controlled substances scheduled for return / reverse distribution / destruction must be secured.

16. Inventory of federally controlled substances.

- Perpetual inventory of each Schedule II controlled substance must be reconciled at least once every 10 days, including expired and damaged medications. [247 CMR 9.21(8)(c)]
- Biennial inventory of Schedule II through V controlled substances. [247 CMR 9.23(2)(g); 21 CFR 1304.11(a)]

17. Ordering of Schedule II controlled substances, including power of attorney.
[21 CFR 1305.12(d); 21 CFR 1305.05(a); 21 CFR 1305.13(e)]

18. Invoice records for federally controlled substances.
[21 CFR 1305.22(g); 21 CFR 1304.21]

19. Pharmacy records must be maintained for at least 2 years but other agencies or organizations (i.e., 3rd party payers) may require longer retention periods.
[247 CMR 9.16(1); 105 CMR 700.006; 21 CFR 1304.21]

20. Facility, equipment, and reference material requirements.
[247 CMR 9.19(1)(3)(4)(5)(6)]

- The pharmacy must be kept clean and sanitary.
- Balances / scales must be sealed each calendar year.
- New balances must be designated as "legal for trade".

21. Signage requirements.
Patient consultation area, right to counseling ("Dear patients"), hours of operation, MOR name, lock boxes, etc. [247 CMR 9.18(6)(7); 247 CMR 9.19(9)(10)(13); MGL c. 94C § 21B]

22. Name tag requirements.
[247 CMR 8.01(14); 247 CMR 8.02(6)(a); 247 CMR 8.03(4)(a); 247 CMR 8.04(4)(a)]

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