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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, Regulations, and Policies:
https://www.mass.gov/doc/multistate-pharmacy-jurisprudence-examination-mpje-review-information/download

Inspection Templates / Advisories / Policies:
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 6.07(1)(e)]

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.
Policy: Extended Absence of a Manager of Record

4. Applications for a change in MOR must be submitted to the Board within 10 business days. [247 CMR 6.03(1)]

5. A pharmacist leaving the MOR position of a Massachusetts-located pharmacy must also <u>personally</u> notify the Board (by email) within 10 business days of leaving the position. [247 CMR 6.03(3)]

6. Upon leaving the MOR position, conduct an inventory with the incoming MOR.
[247 CMR 6.03(1)(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 6.02(3)]

- 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 <u>do not exceed 1500 hours</u>. [247 CMR 8.03(5)]

9. Staffing levels must be adequate and compliant with ratios. [247 CMR 6.07(1)(f); 247 CMR 8.06(3); Policy: Pharmacy Intern Supervision and Dedicated Training Personnel; Coronavirus Disease (COVID-19) Pharmacy Practice Updates]

10. Prescription requirements, including electronic prescribing and supervising practitioner's names.
[Circular Letter: DCP 19-12-108 Electronic Prescribing and Dispensing Manual; Circular Letter: DCP 21-10-111 Out-of-State Schedule II Prescriptions and Supervised Prescribing; 105 CMR 721.020]

- Otherwise valid oral, paper, and faxed prescriptions for any medications may be filled even though they are not electronically prescribed.
- Prescriptions issued by mid-level prescribers may be filled without a supervising practitioner's name.

11. Veterinary prescriptions. [105 CMR 721.020]

- Veterinarians do not have NPI numbers.
- DEA numbers are not required for Schedule VI prescriptions.
- Only the Massachusetts Controlled Substances Registration ("MCSR") number is required for Schedule VI prescriptions.
- Contact your IT Department / Help Desk / software vendor for the data entry process without an NPI or DEA number and be sure to educate all staff members.

12. Procedures for validating prescriptions. [247 CMR 6.07(1)(j)]

- NABP "Red Flags" video: https://www.youtube.com/watch?v=lnnfVdRLkts
- Advisory: Controlled Substance Prescriptions

13. Identification ("ID") requirements for dispensing and delivering PMP drugs.

- Review procedures in the PMP Data Submission Dispenser Guide for dispensing PMP drugs when the patient does not have an ID.

14. Procedures for emergency dispensing of Schedule II medications.
[105 CMR 721.060]

15. Transferring prescriptions. [247 CMR 9.02; Policy: Unfilled Prescriptions]

- Transfers of certain unfilled Schedule III – VI prescriptions may be performed in accordance with Board policy.

16. Labeling requirements.

- Labels affixed to containers must have all required elements listed in M.G.L. c. 94C § 21.
- Interchange verbiage. [Draft 247 CMR 9.05(3)]
- Compliance packaging. [Policy 2022-08: Compliance Packaging; Draft 247 CMR 9.08]
- Expiration dates must be included and must not exceed 1 year or the manufacturer's expiration date, whichever is earlier. [USP <7> *Labeling*; 247 CMR 9.01(3)]
- Any compounded products must be labeled with a Beyond Use Date ("BUD"), storage information, and a statement that the drug is either a sterile or non-sterile compounded drug preparation. [M.G.L. c. 94C § 21]

17. Maintain daily reports or logs signed by the pharmacist for refills of Schedule III - VI controlled substances. [247 CMR 9.04(6); 21 CFR 1306.22]

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

19. Any theft or significant loss of controlled substances must be reported to the Board within 7 calendar days.
Policy: Loss or Theft of Controlled Substances

20. Permitted practices for each licensee type.
Policy: Licensee Scope of Practice

21. Dispensing naloxone by standing order.
Policy: Naloxone Dispensing

22. Non-sterile compounding guidance including hazardous drugs.
Advisory: Non-Sterile Compounding

23. Community pharmacy implementation of USP <800> *Hazardous Drugs-Handling in Healthcare Settings*.
Advisory: USP <800> in Community Pharmacies

24. Medication refrigerators and freezers must be properly maintained, not used for food storage, and temperatures must be monitored in accordance with Board policy.
Policy: Proper Storage of Refrigerated and Frozen Medications

25. Security and storage of controlled substances.
[247 CMR 6.02(6); 247 CMR 9.01(5); 247 CMR 9.01(14)]

- 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.

26. 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 9.01(14); Coronavirus Disease (COVID-19) Pharmacy Practice Updates]
- Biennial inventory of Schedule II through V controlled substances. [247 CMR 6.07(1)(i); 21 CFR 1304.11(a)]

27. 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)]

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

29. 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 9.05; 105 CMR 700.006; 21 CFR 1304.21]

30. Facility, equipment, and reference material requirements.
[247 CMR 6.01(5); 247 CMR 6.02(1); Draft 247 CMR 9.19(1)(e)]

- 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”.

31. Signage requirements.
Patient consultation area, right to counseling (“Dear patients”), hours of operation, MOR name, lock boxes, etc. [247 CMR 6.01(5)(d)(1); 247 CMR 6.02(5)(7)(8)(a); 247 CMR 9.07(3)(c); 247 CMR 9.01(1); MGL c. 94C § 21B]

32. 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)]