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**THE BOARD OF REGISTRATION IN PHARMACY**  
**ADVISORY ON NEW MANAGERS OF RECORD**

The “Manager of Record” or “Pharmacist in Charge” is a licensed pharmacist who signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances. The Manager of Record (MOR) has additional responsibilities compared to the other pharmacists working in the pharmacy and their individual pharmacist license can be disciplined if the pharmacy is found to be in violation.

The Board wishes to remind new Managers of Record of some of the responsibilities that are required of them when assuming the MOR position. Regulations, policies and a link to the Retail Inspection Tool can be found at the following links:

**Retail Inspection Tool:**

<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/compliance-inspection-tool.pdf>

**Regulations:**

<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/pharmacy-regs/>

*Please note carefully that the list of regulations cited is not meant to be exhaustive. Rather, the board intends for this guidance document to simply highlight common compliance issues. A manager of record 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. Review the most recent Board of Pharmacy inspection report for any deficiencies.**
- 2. Please be aware that an application for a change in pharmacist MOR must be submitted to the Board of Pharmacy. [247 CMR 6.03 (1)]**
- 3. A pharmacist who ceases management of the pharmacy shall also notify the Board of that fact. [247 CMR 6.03 (1)]**

- 4. Upon change of MOR, a complete exact count of the inventory of controlled substances in Schedules II, III, IV and V must be taken and filed with the pharmacy's controlled substance records.**
  - Inventory must be completed with at least 2 pharmacists. [247 CMR 6.03 (1) (a)]
- 5. The MOR is responsible for the monitoring and enforcement of policies and procedures.**
  - The responsibilities of the MOR shall include the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including the proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty. [247 CMR 6.07 (1) (e)]
- 6. As MOR, you will be responsible for renewing the pharmacy license.** [247 CMR 6.06]
- 7. Review the regulations concerning the display of licenses.**  
[247 CMR 6.02 (3) (a) (b) (c) (d)]
- 8. Please be aware of the regulations regarding signs that are required in the pharmacy.**  
[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)] Session Laws: Ch. 244 Section 6 (b) of the Acts of 2012
- 9. The MOR is responsible for ensuring that all pharmacists, interns, technicians and technicians-in-training have current and active licenses readily available in your store.**  
[247 CMR 4; 247 CMR 8.01; 247 CMR 8.07; 247 CMR 6.05 (3)]
- 10. Please be aware that you are responsible for the training of pharmacy technicians and the record keeping of such training.**
  - Pharmacy technician trainees are required to complete a minimum of 500 hours and maximum of 1000 hours of employment. Pharmacy technician trainees under 18 are not subject to the 1000 hour limitation. [247 CMR 8.02 (5)]
  - Applicants for registration as a pharmacy technician must pass training programs and examination requirements. The pharmacy must have training program information available upon request. [247 CMR 8.06 (2); 247 CMR 8.02 (6)]
  - Pharmacy technicians currently registered by the Board and certified by a Board-approved certifying body, may perform the duties as authorized to be performed by a certified pharmacy technician in 247 CMR 8.04 (2). Evidence of current National Certification required. [247 CMR 8.04 (1)]
- 11. Written descriptions of the duties and scopes of responsibilities of pharmacy employees should be readily accessible.** [247 CMR 8.06 (1) (b) (c)]
- 12. Please be aware of the regulations requiring name tags.**  
[247 CMR 8.01 (11); 247 CMR 8.02 (3) (a); 247 CMR 8.03 (2) (a); 247 CMR 8.04(2) (a)]

**13. The MOR is responsible for proper staffing of the pharmacy.**

- The responsibilities of the MOR shall include the maintenance of adequate staff in the pharmacy or pharmacy department in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 et seq. and all other applicable federal and state laws and regulations.  
[247 CMR 6.07 (1) (f)]

**14. Please be aware of the pharmacy technician/intern-to-pharmacist ratio.**

- Pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions may utilize such support personnel in accordance with the following ratio requirements:
  - One pharmacist for a maximum of four support personnel (**1:4**); provided:
    - at least one of the four support personnel is a certified pharmacy technician and one is a pharmacy intern; or
    - at least two of the support personnel are certified pharmacy technicians; or
    - two of the support personnel are pharmacy interns.
  - One pharmacist for a maximum of three support personnel (**1:3**); provided at least one of the three support personnel is a pharmacy intern or a certified pharmacy technician. [247 CMR 8.06 (3)(a)]
  - A registered pharmacist shall not directly supervise more than two pharmacy interns at one time. [247 CMR 8.01 (13)]
  - Persons denoted on the schedule as performing duties not related to assisting the pharmacist with filling prescriptions in any way does not need to be counted in the ratios. [247 CMR 8.06 (3)(b)]
- The Board of Pharmacy Advisory on Staff Ratios may be found here:  
<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-ratio.pdf>

**15. Be familiar with the regulations concerning the security of the pharmacy and/or prescription department.** [247 CMR 9.01 (5); 247 CMR 6.02] Board Policy No. 2000-03

**16. Please be aware that the MOR is responsible for security and storage of controlled substances.**

- All controlled substances in Schedules II through VI shall be stored within the prescription area. [247 CMR 6.02 (6)]
- Damaged and expired controlled substances scheduled for return must be secured.

**17. Be familiar with the regulations concerning computer refill signature logs.**

- Subject to the provisions of federal regulations at 21 CFR 1306, an automated data-processing system may be used as an alternative to the provisions of 247 CMR 9.04 (4) and (5). This data-processing system may be used for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI. [247 CMR 9.04 (4) (5) (6)]

**18. The MOR is responsible for developing procedures for validating questionable prescriptions. [247 CMR 6.07 (1) (j)]**

- Review the NABP “Red Flags” video: <https://www.nabp.net/news/new-educational-video-for-pharmacists-addresses-prescription-drug-abuse>
- Utilization of the PMP is highly recommended.
- Ensure correct information has been entered into PMP. Commonly overlooked is the DEA number of the medical resident. Initial prescriptions, written by medical residents, often use the hospital’s DEA number. Once they have their own DEA number, this information shall be accurately updated in the pharmacy data entry system when dispensing new prescriptions.

**19. Be familiar with the regulations concerning inventory of controlled substances.**

- A pharmacist shall keep perpetual inventory of each Schedule II controlled substance, reconciled at least once every ten days, including expired and damaged medications. [247 CMR 9.01 (14)]
- The MOR is responsible for the biennial inventory of Schedule II, III, IV, and V. [247 CMR 6.07 (1) (i); 247 CMR 9.01 (1); 21 CFR 1304.11(a)]

**20. Familiarize yourself with the regulations concerning the ordering of Schedule II controlled substances.**

- Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under §1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space. [247 CMR 9.01 (1); 21 CFR 1305.12 (d); 21 CFR 1305.05 (a); 21 CFR 1305.13 (e)]

**21. Review the regulations concerning invoice records for CII thru CV controlled substances.**

- Controlled Substance Ordering System (CSOS): When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived. [247 CMR 9.01 (1); 21 CFR 1305.22 (4) (g)]
- The date on which the controlled substances are actually received shall be used as the date of receipt (e.g., invoices or packing slips). [247 CMR 9.01 (1); 21 CFR 1304.21 (d)]

**22. Please be aware of the regulations concerning the retention of pharmacy records.**

- [247 CMR 6.07 (1) (b); 247 CMR 9.00; 105 CMR 700; 247 CMR 2.00 et seq.; 21 CFR 1304.21 (a); MGL c.94C]

**23. Familiarize yourself with procedures for emergency dispensing of Schedule II medications.**

- On the emergency prescription, document the details of the request for the hard copy. Practitioners should provide hard copies for schedule II emergency supplies within 7 days. [247 CMR 5.03(3) (4)]

**24. Review the procedures for transferring prescriptions. [247 CMR 9.02 (2) (3)]**

**25. Be familiar with facility and equipment requirements.**

- A pharmacy shall be kept clean and sanitary. [247 CMR 6.02 (1)]
- A pharmacy shall have the necessary equipment including: a balance, suitable sink, prescription area no less than 300 square feet, and designated consultation area. [247 CMR 6.01 (5) (a) (b) (d)]
- New balances must be labeled “legal for trade”.

**26. Please review the procedures for the temporary absence of a MOR.**

[247 CMR 9.21(4)]

- A pharmacy shall appoint an Interim Manager who is registered by the Board prior to any planned absence of the MOR that is expected to last 30 days or longer.
- A pharmacy shall appoint an Interim Manager who is registered by the Board within five days of any unplanned absence of the Manager of Record that is likely to last 30 days or longer.
- Prior to his/her absence, a Manager of Record shall perform a controlled substances inventory that is signed by the Manager of Record and the Interim Manager. If the Manager of Record is unexpectedly not available, another registered pharmacist shall perform the controlled substances inventory.
- In the event a Manager of Record is away from his/her position for 100 days or more, the pharmacy shall submit an application for a change of Manager of Record.

**27. Familiarize yourself with the refrigeration policy.**

- A pharmacy shall utilize a clean, organized, defrosted refrigerator/freezer (combo or stand alone) that is maintained within proper range (Refrigeration at 36° to 46°F/2° to 8°C; Freezer at -13° to 14°F/-25° to -10°C USP recommended range).
- A pharmacy shall utilize a certified thermometer with out of range alarm or utilize a daily temperature log and have a policy for out of range temperatures to ensure integrity of stored medications.
- Refrigerator should be organized to allow proper airflow. Refrigerators and freezers shall not be overstocked.
- No food or beverages shall be allowed in the refrigerators or freezers.  
[247 CMR 9.01 (1) and (5)] (Board Policy No. 2011-01)

**28. Please review regulations for labeling.**

- The controlled substance labeling affixed to the container shall contain all required elements listed in 105 CMR 722.070.
- The words “interchange”, generic name or brand name, and manufacturer shall be on the label accordingly. [247 CMR 9.01 (1); 105 CMR 722.070]
- Specialty packaging requirements. [247 CMR 9.06; Policy 98-011]

**29. Be familiar with regulations regarding prescriptions.**

- Prescriptions shall be written in the format described in 105 CMR 721.020.

- Review tamper-resistant prescription methods:  
<http://www.massmed.org/Physicians/Practice-Management/Practice-Ownership-and-Operations/Tamper-Resistant-Prescriptions--CMS-and-MassHealth-Guidelines/>

**30. Review the pharmacist's DUR and consultation requirements.** [247 CMR 9.07]

**31. Please be aware of the regulations concerning substandard drugs.**

- A pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity that is not licensed or legally authorized to receive such drugs or devices. [247 CMR 9.01]

**32. Each pharmacy shall maintain a Continuous Quality Improvement (CQI) program designed to detect, identify and prevent prescription errors in pharmacies.** [247 CMR 15.00]

**33. Be aware of the procedures if closing a pharmacy business.**

- Any person who intends to close a pharmacy registered by the Board shall officially notify the Board in writing, by certified mail, at least 14 days, before the intended closing in accordance with 247 CMR 6.09.
- For continuity of care, patients should be notified at least 30 days prior to closing.

**34. Any theft or loss of a significant amount of controlled substances must be reported to the Board within seven days.**

- Review Policy 16-02 regarding losses:  
<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/policy-16-02.pdf>
- A pharmacy shall report theft or loss of significant amount of controlled substances to the Board by submitting a "Report of Theft or Loss of Controlled Substance" (DEA BND Form 106), within seven days. [247 CMR 6.02 (10)]

**35. Review the regulations and policy regarding immunizations.**

- Only vaccines included in the most recent Recommended Adult Immunization Schedule – United States approved by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) may be administered under this policy. [247 CMR 9.01 (1); 105 CMR 700.004 (6)] (Board Policy No. 2015-01)

**36. Review procedures for dispensing Naloxone by standing order.**

<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>

**37. Be aware of the regulations regarding required references.** [247 CMR 6.01 (5)]

**38. Be familiar with regulations regarding non-sterile compounding (simple to moderate compounding only).**

- Hazardous drugs shall be properly stored and handled.
- Significant procedures shall be written in the SOP with Material Safety Data Sheets (MSDS) readily accessible.

- Compounding facilities shall have adequate clean compounding space, washing facilities, clean equipment, and purified water for compounding.
- The drug and preparation shall have the appropriate BUD, labeling, and expiration.
- A Master Formulation Record and Compounding Record shall be kept and completed.
- Further guidance can be found in [247 CMR 9.01 (3) and USP Chapter <795>]

**For any questions, contact the Board of Registration in Pharmacy at [Pharmacy.Admin@MassMail.State.Ma.US](mailto:Pharmacy.Admin@MassMail.State.Ma.US) or 1-800-414-0168.**

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