

247 CMR 9.00: PROFESSIONAL PRACTICE STANDARDS

Section

- 9.01: General Practice Standards
- 9.02: Prescriptions by Mail
- 9.03: Advertising
- 9.04: Requirements for Dispensing and Refilling Prescriptions
- 9.05: Interchangeable Drugs
- 9.06: Opioid Antagonists
- 9.07: Reusable Daily Dosage Planners
- 9.08: Compliance Packaging
- 9.09: Emergency Medication Kits
- 9.10: Automated Pharmacy Systems
- 9.11: Pharmacy Processing Automation
- 9.12: Automated Dispensing Devices
- 9.13: Return to Stock
- 9.14: Transfer of Prescriptions
- 9.15: Verifying a Practitioner's Prescriptive Authority
- 9.16: Maintenance of Pharmacy Records
- 9.17: Prospective Drug Utilization Review
- 9.18: Patient Counseling
- 9.19: Pharmacy Operation
- 9.20: Non-resident Pharmacies
- 9.21: Security of Controlled Substances
- 9.22: Proper Storage of Refrigerated and Frozen Medications
- 9.23: Pharmacist Manager of Record
- 9.24: Inspection and Investigation of Pharmacies
- 9.25: Plans of Correction

9.01: General Practice Standards

- (1) A licensee shall conduct professional activities in conformity with M.G.L. c. 112, §§ 24 through 42D, M.G.L. c. 94C, and 247 CMR 2.00: *Definitions*.
- (2) A licensee may not process a prescription; dispense a drug, device, or other substance; or administer a controlled substance or vaccine in a manner which is intended, either directly or indirectly, to circumvent any law or regulation governing the practice of pharmacy.
- (3) Unless otherwise regulated by the Board, a licensee shall adhere to the most current standards established by each chapter of the United States Pharmacopeia ("USP").
- (4) A pharmacist shall practice pharmacy within the scope of his or her education, training, and experience and within the recognized pharmacist scope of practice.
- (5) Unless otherwise permitted by law, regulation, or Board policy, a licensee may not re-dispense any medication which has been previously dispensed.
- (6) A licensee may not accept or purchase medications designated as "drug samples not for resale" for the purpose of compounding, repackaging, or in any way reselling said medications.
- (7) A pharmacy shall accept a medication that it previously dispensed to a patient if the medication:
 - (a) was dispensed to the patient in error; or
 - (b) is suspected to be defective or contaminated.A medication accepted by a pharmacy pursuant to 247 CMR 9.01 may not be returned to the pharmacy's inventory and must be quarantined and properly disposed. A pharmacy is not required to accept a medication from a patient that was properly dispensed and not defective at the time it was dispensed.

9.01: continued

- (8) While on duty, a pharmacist shall be responsible for the proper preservation, storage, and security of all controlled substances in the pharmacy.
- (9) A licensee may not engage in any fraudulent or deceptive act.
- (10) A licensee may not in any way aid or abet the unlawful practice of pharmacy.
- (11) A licensee may not offer, solicit, or receive remuneration or anything of value to or from any person who owns, operates, manages, or is an employee of a hospital, nursing home, or other health care facility in return for a referral to a pharmacy, pharmacist, pharmacy technician, or pharmacy intern or the generation of business from sale or furnishing of any drugs, devices, or services to any such persons or institutions.
- (12) A licensee may not dispense or distribute any expired, outdated, defective, contaminated, counterfeit, contraband, or otherwise substandard drug or device to any person or entity who is not licensed or legally authorized to receive such drug or device.
- (13) Unless otherwise permitted by law, a pharmacist connected with, or employed by, a hospital or clinic pharmacy that does not hold a Drug Store pharmacy license may not dispense drugs to any person other than inpatients or outpatients of the hospital or clinic, or to employees of said hospital or clinic, or to said employees' spouses and children who live in the same household with said employees.
- (14) A licensee may not provide any practitioner with blank prescription forms which refer to any pharmacist or pharmacy.
- (15) A licensee may not refuse to compound simple or moderate non-sterile compounded preparations customary to the community needs except upon extenuating circumstances or by a waiver of Board regulation.
- (16) A licensee shall maintain patient confidentiality and protect a patient's confidential information.
- (17) A pharmacist, pharmacy intern, or pharmacy technician may not practice in a pharmacy for more than 12 hours in a 24 hour period without completing an eight consecutive hour rest period prior to resuming work in a pharmacy. In the event of an extenuating circumstance, a pharmacist, pharmacy intern, or pharmacy technician may exceed 12 hours in order to act in the best interest of the patient, provided the time in excess of 12 hours is minimized and the licensee documents the extenuating circumstance.
- (18) A pharmacist, pharmacy intern, and pharmacy technician shall carry, post on the wall of the pharmacy where he or she works, or have readily available at the pharmacy where he or she works, a license issued by the Board.
- (19) A pharmacist shall wear a name tag with at least his or her first name and the title "Pharmacist", "Registered Pharmacist", or "R.Ph."
- (20) A pharmacist shall maintain an NABP e-profile number.
- (21) A pharmacist shall comply with all elements of a drug's FDA required risk evaluation and mitigation strategy ("REMS"), including any distribution or dispensing restriction included in its REMS.

9.02: Prescriptions by Mail

- (1) A pharmacy and pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations.
- (2) A pharmacy shall ensure that packing, shipping, and transportation processes do not adversely affect the integrity or stability of medications dispensed by mail.

9.02: continued

- (3) A pharmacy shall maintain policies and procedures regarding packing, shipping, transporting, and delivering controlled substances.

9.03: Advertising

A licensee may not engage in any advertising that is false, deceptive, or misleading.

9.04: Requirements for Dispensing and Refilling Prescriptions

- (1) A licensed pharmacist is responsible for the final dispensing process validation of a prescription.
- (2) A pharmacy shall utilize a computerized pharmacy system for processing prescriptions and for maintaining patient profiles.
- (3) A licensee shall ensure the label affixed to a prescription drug container or package is clearly printed by a computerized pharmacy system. In the event of printing or equipment failure, a prescription label may be legibly handwritten or typed during an emergency period.
- (4) A pharmacy that provides bed-side delivery service of discharge prescriptions to patients in an inpatient healthcare facility must obtain patient consent to provide such services and may not restrict a patient's freedom of choice of pharmacy services. A pharmacy that provides bed-side delivery service shall deliver any medications directly to the patient or patient's agent.
- (5) A licensee shall adhere to 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts* when dispensing a controlled substance in Schedule II in an emergency situation.
- (6) A pharmacist who refills a prescription for a controlled substance in Schedules III through VI shall record the following information in the computerized pharmacy system or on the written prescription:
 - (a) the date of dispensing;
 - (b) the amount of drug dispensed; and
 - (c) his or her initials.
- (7) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record the NDC number in the computerized pharmacy system. In the event an NDC number does not exist, the pharmacist shall record the name of the manufacturer, or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.
- (8) A pharmacy intern, or certified pharmacy technician who has the approval of the pharmacist on duty may receive new prescriptions over the telephone from a prescriber or authorized agent.
- (9) A pharmacist or individual acting on behalf of a pharmacy may not collect prescriptions at industrial plants, places of business, or other sites where specific groups of people are regularly employed or affiliated, unless the following requirements are met:
 - (a) the prescriptions are written for persons regularly employed at, or affiliated with, such plant, place of business, or other such site or the immediate family members living at the same address of persons regularly employed at, or affiliated with, such plant, place of business, or other such site;
 - (b) a pharmacist, pharmacy employee, or authorized agent of the pharmacy collects the prescriptions in person;
 - (c) a pharmacist, pharmacy employee, or authorized agent of the pharmacy dispenses the prescription medications directly to the patient or patient's agent;
 - (d) a pharmacist, pharmacy employee, or authorized agent of the pharmacy returns all prescription medications that he or she does not dispense directly to a patient or patient's agent to the pharmacy. Prescription medications may not be left or stored at the delivery location; and

9.04: continued

- (e) the pharmacist and pharmacy shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf.
- (10) In order to determine whether a prescription is within date, a pharmacist shall count the day after the prescription was written as day one.
- (11) A pharmacy may not dispense any medication that was processed outside its licensed pharmacy premises unless said process was verified by a Massachusetts licensed pharmacist or performed in a pharmacy licensed by the Board.
- (12) A prescription for a Schedule VI medication is valid for one year from the date of issue. A licensee may not refill a Schedule VI prescription after one year. In the event a Schedule VI prescription expires or has no remaining refills and the pharmacist is unable to obtain prescriber authorization in a timely manner, the pharmacist in his or her professional judgment may dispense a quantity not to exceed 14 days or the smallest available unit of use packaging.
- (13) A licensee may not fill or refill a prescription for a Schedule V controlled substance more than six months after the date on which said prescription was issued. A prescription for a Schedule V controlled substance may not be refilled more than five times.
- (14) Requirements for Positive Identification for Dispensing of a Controlled Substance in Schedule II through V:
 - (a) For the purposes of 247 CMR 9.04, Customer Identifier means the identification number on a valid government issued identification, as specified by the Department, which a licensee obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed.
 - (b) A licensee shall require that a Customer Identifier be presented by the ultimate user or agent of the ultimate user to whom a prescription for a controlled substance in Schedules II through V, or a controlled substance classified as an additional drug in accordance with 105CMR 700.012(A)(1) is dispensed.
 - (c) A licensee may dispense a controlled substance in Schedule II through V or an additional drug without requiring a customer identifier provided that:
 - 1. the licensee has reason to believe that the failure to dispense the controlled substance or additional drug would result in a serious hardship for the ultimate user or agent of the ultimate user, and documents the reason; and
 - 2. the ultimate user or agent of the ultimate user prints his or her name and address on the reverse side of the prescription or in an electronic or paper prescription log and signs his or her name thereto.
 - (d) The Commissioner may waive or modify the requirement for a customer identifier for prescription refills, prescription deliveries or other activities specified in the PMP Data Entry and Data Submitters Guide.
- (15) The requirements of 247 CMR 9.04(4), (5), (6), (9), (10), (12), (13), and (14) do not apply to institutional sterile compounding pharmacies.

9.05: Interchangeable Drugs

- (1) Medical Emergencies
 - (a) In a medical emergency a pharmacist may fill a prescription marked "no substitution" by dispensing a less expensive interchangeable drug product as allowed by the *Massachusetts List of Interchangeable Drugs* if the particular brand is not in stock; similarly, a pharmacist may fill a prescription not marked "no substitution" in a medical emergency by dispensing the brand name product as written if he or she has no less expensive interchangeable drug product in stock to be dispensed.
 - (b) In such instances, the pharmacist must record the date, hour, and nature of the medical emergency on the back of the prescription or in the computerized pharmacy system and the person purchasing the drug product must indicate acceptance of this deviation from the law in writing. All such prescriptions shall be clearly identifiable and available for review by the Board.

9.05: continued

(2) Generic Prescriptions. Upon receiving a prescription for a generic name drug product with no manufacturer specified by the prescriber, a pharmacist may select, regardless of whether or not the prescriber has marked "no substitution" on the prescription, any legally marketed drug product whether or not it appears in the *Massachusetts List of Interchangeable Drugs*, in accordance with the prescriber's intent and the normal exercise of professional judgment.

(3) Labeling

(a) When a less expensive generic drug product has been dispensed, the words "interchange" plus the generic name and manufacturer of the product shall appear on the label in the following manner: "Interchange": (Generic name of less expensive drug product dispensed plus manufacturer);

(b) When a less expensive brand name drug product has been dispensed, the words "interchange" plus either the generic name and manufacturer of the product or the less expensive brand name dispensed shall appear on the label in the following manner: "Interchange": (generic name of less expensive brand drug plus manufacturer of brand name of less expensive drug product);

(c) In addition to the above, the brand name of the prescribed drug product may also appear on the label in the following manner: "Interchange": (name of less expensive generic drug product plus manufacturer or brand name drug product actually dispensed) for (brand name drug product dispensed);

(d) Abbreviations are permissible as long as they are commonly understood. For example, "IC" may be used for "interchange" and manufacturers' names may be abbreviated as shown in the *Massachusetts List of Interchangeable Drugs*;

(e) 247 CMR 9.05 shall only apply to prescriptions dispensed by a pharmacy with a Drug Store Pharmacy License.

9.06: Opioid Antagonists

(1) For purposes of 247 CMR 9.06:

(a) High overdose area shall mean a geographical area that appears on a list published by the Board, in consultation with the Department of Public Health, of areas with high incidence of opiate overdose.

(b) "Opioid antagonist information pamphlet" shall mean a Board approved pamphlet that provides information about an opioid antagonist and responding to an overdose.

(c) Opioid antagonist shall mean naloxone or any other drug approved by the United States Food and Drug Administration as a competitive narcotic antagonist used in the reversal of overdoses caused by opioids;

(d) Statewide standing order shall mean an order issued by the Commissioner or a physician designated by the Commissioner of the Department of Public Health and registered to distribute or dispense controlled substances pursuant to M.G.L. c. 94C, § 19B;

(2) High overdose area:

(a) A pharmacy located in a high overdose area shall maintain a continuous supply of naloxone rescue kits or other approved opioid antagonists readily available for dispensing.

(b) A pharmacy that is not located a high overdose area may dispense naloxone rescue kits or other approved opioid antagonists pursuant to the statewide standing order or a prescription, provided that the pharmacy complies with all other provisions in 247 CMR 9.06.

(3) A pharmacy that dispenses a naloxone rescue kit or other approved opioid antagonist shall provide counseling and the "opioid antagonist information pamphlet" at the time of dispensing.

(4) A pharmacy that does not have a naloxone rescue kit or other approved opioid antagonist readily available for dispensing at the time requested shall refer the requestor to the nearest location that has a naloxone rescue kit or other approved opioid antagonist readily available.

(5) A pharmacy that assembles opioid antagonist rescue kits shall affix a label to the outer package noting "Opioid Antagonist Rescue Kit" or "[NAME OF THE OPIOID ANTAGONIST] Rescue Kit" and the expiration date, which shall be based on the expiration date of the included unit.

9.07: Reusable Daily Dosage Planners

At the patient's or patient's agent's request a pharmacy may dispense medications in a reusable daily dosage planner provided the following requirements are met:

- (1) A pharmacy may not place any medication in a reusable daily dosage planner that was previously dispensed by a different pharmacy.
- (2) The pharmacy designates a space that allows for the orderly placement of equipment, materials, and medications, for the proper preparation of reusable daily dosage planners, and for the prevention of cross-contamination.
- (3) The pharmacy maintains policies and procedures pertaining to reusable daily dosage planners that include cleaning, labeling, dispensing, and proper hand hygiene.
- (4) The pharmacy cleans and stores reusable daily dosage planners in a manner that prevents contamination to the pharmacy environment or reusable daily dosage planner.
- (5) The pharmacy labels each reusable daily dosage planner with all information required by M.G.L. c. 94C, § 21 for each medication.

9.08: Compliance Packaging

(1) A pharmacy or pharmacist may utilize compliance packaging, including oral-liquid-single-dose packaging, single-drug-single-dose packaging, and multi-drug-single-dose packaging provided the following requirements are met:

- (a) The pharmacy designates a space that allows for the orderly placement of equipment, materials, and medications, for the proper preparation of the compliance packaging, and for the prevention of cross contamination.
- (b) The pharmacy maintains policies and procedures pertaining to each type of compliance packaging utilized that include cleaning, labeling, dispensing, proper hand hygiene, quarantine, and reverse distribution.
- (c) The compliance packaging does not conflict with the USP-DI monograph or FDA-approved labeling.
- (d) The medications are compatible with packaging components and with each other.
- (e) The compliance packaging is designed to prevent the container from being re-closed, to show evidence of having been opened, and in such a manner that the label cannot be altered or removed.
- (f) A licensee may not place a quantity of drugs in compliance packaging that exceeds the capacity of the container or that may cause damage to the individual dosage forms.
- (g) The compliance packaging must adhere to USP requirements for containers and packaging.
- (h) A licensee may not place more than one commercially available medication into an oral-liquid-single-dose package unless compounded pursuant to a prescription.

(2) Single-drug-single-dose Packaging.

- (a) A pharmacy or pharmacist may utilize single-drug-single-dose packaging for solid oral dosage forms.
- (b) If a pharmacy or pharmacist places a medication in a single-drug-single-dose package prior to the receipt of a patient specific prescription, the pharmacy and pharmacist shall properly label the package and utilize a bar-code scanning or similar technology to ensure proper identification of the pre-packaged medication at the time of dispensing.

(3) Multi-drug-single-dose Packaging. A pharmacy or pharmacist may utilize multi-drug-single-dose packaging for solid oral dosage forms provided the following requirements are met:

- (a) A licensee may not dispense more than a 60-day supply of medication in a multi-drug-single-dose package.
- (b) A licensee may not dispense Schedules II or III controlled substances in a multi-drug-single-dose package.
- (c) A licensee may not dispense medications to be taken on an as needed basis in a multi-drug-single-dose package.

9.08: continued

(4) Return and Repackaging of Multi-drug-single-dose Packaging.

(a) A pharmacy or pharmacist may accept a return of a multi-drug-single-dose package that the pharmacy previously dispensed for the purpose of repackaging and re-dispensing to that same patient.

1. If a patient's medication was discontinued, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package and re-dispense the remaining medications in the multi-drug-single-dose package to the same patient.

2. If a patient's drug therapy changed, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package(s) and may add a new medication(s) to the multi-drug-single-dose package and re-dispense the multi-drug-single-dose package to the same patient.

3. A pharmacy shall label the multi-drug-single-dose package in accordance with 247 CMR 9.08(5) prior to re-dispensing.

4. A pharmacy shall implement policies and procedures pertaining to security and accountability of controlled substances during return and repackaging.

(b) A licensee may not return any medication removed from a multi-drug-single-dose package to inventory. A licensee may not dispense any medication removed from a multi-drug-single-dose package to any patient other than the patient who returned the multi-drug-single-dose package.

(c) A pharmacy shall maintain a record that accounts for and documents any repackaging, removal, or re-dispensing of any medication it previously dispensed in a multi-drug-single-dose package. The record shall identify the pharmacist making the change.

(5) A licensee shall label each oral-liquid-single dose, single-drug-single-dose, and multi-drug-single-dose package with the following information:

(a) information required by M.G.L. c. 94C, § 21 and USP for each medication in the package;

(b) the name, strength, physical description, and total quantity of each drug dispensed;

(c) the dispensing or preparation date;

(d) a beyond-use date, which may not exceed the shortest expiration date on the original manufacturer's container or 60 days, for each drug contained in a multi-drug-single-dose package; and

(e) the telephone number of the pharmacy.

(6) If the compliance package has removable cells, a pharmacy shall label each cell with a label of sufficient size to properly and clearly label each cell with each drug name and strength.

9.09: Emergency Medication Kits

(1) A pharmacy shall maintain a policy and procedure for the proper dispensing of medication through emergency medication kits pertaining to security, maintenance, and use.

(2) A pharmacy shall reconcile medication dispensed through emergency medication kits with prescriptions or orders.

(3) A pharmacy may only provide emergency medication kits to types of facilities approved by the Board.

9.10: Automated Pharmacy Systems

(1) A pharmacy may dispense Schedule IV - VI controlled substances from an Automated Pharmacy System ("APS") to a patient or a patient's agent during or after pharmacy hours of operation provided the following requirements are met:

(a) The APS is located within the same building as the pharmacy.

(b) The APS is secured against or within a wall or floor in a manner that prevents unauthorized access and removal.

(c) The location and APS are monitored by continuous, recordable video surveillance.

(d) A pharmacy may not stock medications in an APS that require refrigeration or reconstitution.

9.10: continued

- (e) The APS utilizes industry standard technological verification, such as barcode verification, electronic verification, weight verification, radio frequency identification, or another similar process, to ensure the correct medication is dispensed to the correct patient.
- (f) The APS or the pharmacy that operates the APS maintains electronic data that creates an audit trail of activity and includes the identity of each person to whom a drug was released.
- (g) The pharmacy provides the patient an opportunity for a pharmacist consultation during all hours that the APS is in operation for dispensing.
- (h) The pharmacy allows the patient to choose whether or not to use an APS.

(2) A pharmacy with an APS shall maintain policies and procedures pertaining to the APS that include:

- (a) APS location(s);
- (b) operation and maintenance;
- (c) security;
- (d) controlled substances accountability;
- (e) quality assurance;
- (f) stocking and return activities; and
- (g) patient confidentiality.

9.11: Pharmacy Processing Automation

(1) A pharmacy may utilize Pharmacy Processing Automation ("PPA") to count, fill vials or compliance packaging, and label, provided the following requirements are met:

- (a) the PPA utilizes technological verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to ensure that the correct medication is dispensed; and
- (b) if lot numbers are comingled in a single cell, the pharmacy maintains a policy and procedure to quarantine all comingled lot numbers in the event a single lot number is recalled.

(2) The pharmacy shall implement and maintain policies and procedures pertaining to the PPA that include:

- (a) operation and maintenance;
- (b) security;
- (c) controlled substance accountability;
- (d) quality assurance; and
- (e) stocking and return activities.

9.12: Automated Dispensing Devices

A pharmacy may utilize an automated dispensing device ("ADD") for controlled substances provided that:

- (1) The ADD is located in a licensed health care facility;
- (2) Dispensing is pursuant to a valid patient specific prescription or order;
- (3) Utilization is in accordance with all laws, regulations, and policies; and
- (4) The pharmacy maintains ADD policies and procedures including the following:
 - (a) location;
 - (b) operation and maintenance;
 - (c) security;
 - (d) controlled substances accountability;
 - (e) quality assurance;
 - (f) stocking and return activities; and
 - (g) patient confidentiality.

9.13: Return to Stock

(1) In the event a pharmacy prepares a prescription for dispensing but the medication is not dispensed, the pharmacy may return the medication to stock. A pharmacy shall ensure the following conditions are satisfied if it returns a medication to stock:

9.13: continued

- (a) A pharmacy may not return a medication to the manufacturer's stock bottle.
- (b) A pharmacy shall keep a medication to be returned to stock in the original patient container or place medication in an appropriate container and shall affix a label to the container containing the following information:
 - 1. product name;
 - 2. strength or concentration;
 - 3. name of the manufacturer, supplier, or NDC number; and
 - 4. the expiration date assigned at the time of filling.
- (2) A pharmacy shall maintain a policy and procedure regarding returning medications to stock.
- (3) In the event of a recall, a pharmacy may not dispense any medication that has been returned to stock and is potentially subject to the recall unless it can confirm the specific lot number is not included in the recall.

9.14: Transfer of Prescriptions

- (1) A pharmacy shall transfer a prescription to another pharmacy, at the request of a patient or his or her agent, in a timely manner so as not to delay patient therapy.
- (2) The pharmacy may act as the patient's agent in order to facilitate a transfer.
- (3) A pharmacy may not charge a fee for transferring a prescription.
- (4) Schedule VI.
 - (a) A pharmacy shall transfer prescriptions for Schedule VI controlled substances in the same manner as prescriptions for Schedules III - V controlled substances.
 - (b) Prescriptions for Schedule VI controlled substances may be transferred up to the maximum number of remaining refills authorized by the prescriber.
 - (c) A pharmacy may not transfer a prescription authorizing refills for Schedule VI controlled substances more than one year from the date the prescription was issued.

9.15: Verifying a Practitioner's Prescriptive Authority

- (1) A pharmacist who dispenses medications reported to the Massachusetts Prescription Monitoring Program ("PMP") shall register with and maintain login information for the electronic system to monitor the prescribing and dispensing of controlled substances authorized by M.G.L. c. 94C, § 24A, known as PMP or MassPAT.
- (2) A pharmacist may not fill a prescription unless the pharmacist, in the exercise of his or her professional judgment, determines that:
 - (a) the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice;
 - (b) there is a valid patient-practitioner relationship;
 - (c) the prescription is authentic; and
 - (d) the dispensing is in accordance with M.G.L. c. 94C, § 19(a).

9.16: Maintenance of Pharmacy Records

- (1) A pharmacist and pharmacy shall maintain prescription records, purchasing and return records, and disposal and destruction records in a readily retrievable manner for at least two years.
- (2) Prescriptions for Schedule II controlled substances shall be segregated if maintained in paper format, and electronically separable if maintained in electronic format.
- (3) Prescriptions for Schedule III, IV, and V controlled substances shall be segregated if maintained in paper format, and electronically separable if maintained in electronic format.

9.16: continued

- (4) Prescriptions for Schedule VI controlled substances shall be segregated if maintained in paper format and electronically separable if maintained in electronic format.
- (5) A pharmacy shall be able to print readable copies of electronic prescriptions.
- (6) A pharmacy shall be able to print electronically stored images of prescriptions.
- (7) A pharmacist and pharmacy shall maintain a confidential patient profile for each patient to whom a prescription is dispensed. The computerized pharmacy system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the following information:
 - (a) name, address, contact information, date of birth or age, and gender of the patient for whom the prescription is intended;
 - (b) patient history, including known drug allergies and drug reactions;
 - (c) a comprehensive list of medications and relevant devices dispensed by the pharmacy; and
 - (d) the pharmacist's comments relevant to the patient's drug therapy.
- (8) The requirements in 247 CMR 9.16 do not apply to institutional sterile compounding pharmacies.

9.17: Prospective Drug Utilization Review

- (1) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription or medication order is dispensed or delivered to a patient or a patient's agent. The DUR may include a review of computerized alerts, the patient record, and each new and renewed prescription or medication order for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the following:
 - (a) over-utilization or under-utilization;
 - (b) therapeutic duplication;
 - (c) drug-disease contraindication;
 - (d) drug-drug interaction;
 - (e) drug-food interaction;
 - (f) incorrect drug dosage or duration of drug treatment;
 - (g) drug-allergy interactions;
 - (h) abuse or misuse;
 - (i) any significant change in drug, dose, or directions; and
 - (j) any age related contraindications.
- (2) Upon identifying any of the above, a pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner or direct consultation with the patient or patient's agent. A pharmacist shall document any measures taken in response to a drug utilization review.
- (3) The DUR shall be based upon current standards which may include the following:
 - (a) the American Hospital Formulary Service Drug Information;
 - (b) the United States Pharmacopoeia Drug Information;
 - (c) the American Medical Association Drug Evaluations;
 - (d) *Plumb's Veterinary Drug Handbook*; and
 - (e) other peer-reviewed medical literature.

9.18: Patient Counseling

- (1) A pharmacist or pharmacist's designee shall offer the counseling services of the pharmacist to each person who receives a prescription medication.

9.18: continued

- (2) A pharmacist shall ensure his or her designee is appropriately trained to make the offer to counsel.
- (3) Counseling shall be made by a pharmacist or a pharmacy intern. A pharmacy technician or other individual may not counsel any patient.
- (4) A pharmacist or pharmacy intern shall provide counseling on each new drug therapy and each drug therapy that in the pharmacist's professional judgment is deemed to be significant for the health and safety of the patient.
- (5) When counseling a patient, a pharmacist or pharmacy intern shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:
 - (a) name, description, and indication of the medication;
 - (b) dosage form, dosage, route of administration and duration of therapy;
 - (c) special directions and instructions for preparation, administration, and use by the patient;
 - (d) common side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications and other substances which the pharmacist deems relevant;
 - (e) techniques for self-monitoring drug therapy;
 - (f) proper storage and disposal;
 - (g) prescription refill information; and
 - (h) action to be taken in the event of a missed dose or adverse reaction.
- (6) A pharmacy shall have a designated patient consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area shall be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.
- (7) A pharmacy shall post a sign of not less than 11 inches in height by 14 inches in width in a conspicuous place, adjacent to each area where prescriptions are dispensed, for the purpose of informing customers of their right to counseling by a pharmacist. Said sign shall read, in letters not less than ½ inch in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."
- (8) A pharmacy and pharmacist shall ensure counseling is available at all times when a pharmacy is open for business.
- (9) A pharmacy and pharmacist shall dispense or recommend a proper measuring device with all liquid medications.
- (10) The provisions of 247 CMR 9.18 do not apply to pharmacists while practicing in an inpatient setting, unless otherwise required by law or regulation.

9.19: Pharmacy Operation

- (1) A pharmacy shall maintain the following on the pharmacy premises:
 - (a) a current copy or electronic version of the *Massachusetts List of Interchangeable Drugs*, including the *Orange Book*, Additional List, Exception List;
 - (b) a current copy or access to electronic version with quarterly updates of a compendia appropriate to the practice setting approved by the pharmacist manager of record;
 - (c) a current copy or access to electronic version of laws and regulations governing the practice of pharmacy, including, M.G.L. c. 94C, M.G.L. c. 112, §§ 24 through 42A, 105 CMR 700.000: *Implementation of M.G.L. c. 94C*, 105 CMR 720.00: *List of Interchangeable Drug Products*, and 105 CMR 721.00: *Standards for Prescription Format and Security in Massachusetts*, and 247 CMR 2.00 through 21.00;
 - (d) a current copy or access to electronic version of *Plumb's Veterinary Drug Handbook* or other veterinary reference approved by the Board;

9.19: continued

- (e) a balance capable of accurately weighing quantities as small as ten milligrams, which shall be tested and sealed by the state or local sealer of weights and measures at least once each calendar year. All new balances shall have "legal for trade" designation;
- (f) the equipment, supplies, and medications necessary to conduct the practice of pharmacy in accordance with the usual needs of the community and scope of practice of the pharmacy;
- (g) the equipment necessary to perform simple and moderate non-sterile compounding;
- (h) policies and procedures to ensure supplies, tools, utensils, and equipment are used and maintained in a manner that avoids cross contamination and ensures proper functioning;
- (i) a potable water supply in or near the prescription area in order to wash hands and equipment. The sink shall have hot and cold water, soap or detergent, and single use towels; and
- (j) a designated compounding area for simple and moderate non-sterile compounding.

(2) A pharmacy that obtained its Drug Store pharmacy license on or after July 1, 2020 shall have a prescription area that is at least 325 square feet.

(3) A pharmacy shall ensure the accuracy and performance of electronic counting machines for solid dosage forms and other electronic measuring devices.

(4) The prescription area shall provide for the arrangement and storage of drugs, supplies, and equipment in a manner that is calculated to prevent accidental misuse, cross contamination, and error.

(5) A pharmacy shall store medications in the manufacturer's stock bottles or in other stock containers that are clearly labeled with the product name, strength or concentration, NDC number, manufacturer or supplier, lot number, assigned expiration date, and date that the medication was transferred out of its original stock bottle.

(6) A pharmacy shall be clean and sanitary and in good repair at all times.

(7) Pharmacy equipment shall be clean and sanitary and in good repair at all times.

(8) A pharmacy in Massachusetts shall conspicuously display within the pharmacy:

- (a) the pharmacy's Massachusetts Drug Store pharmacy license;
- (b) other pharmacy license issued by the Board, as applicable;
- (c) the pharmacy's Massachusetts controlled substance registration; and
- (d) the pharmacy's U.S. Drug Enforcement Administration registration.

A non-resident pharmacy shall maintain the documents identified in 247 CMR 9.19(8) in a readily retrievable manner.

(9) As applicable, a pharmacy shall post on the wall or maintain the following in readily retrievable location:

- (a) immunization certifications and current CPR card for each pharmacist and pharmacy intern that perform immunizations;
- (b) current power of attorney ("POA") forms required for DEA 222 forms, as applicable;
- (c) Collaborative Drug Therapy Management Agreements;
- (d) written finding from the Board waiving any Board regulations; and
- (e) standing orders, if any.

(10) A pharmacy shall have a sign affixed to each customer entrance that is easily observable from the outside and clearly identifies the presence of a pharmacy.

(11) A pharmacy shall conspicuously display, in legible letters not less than one inch high, over, on, or adjacent to the main entrance of the pharmacy, the name of the pharmacist Manager of Record.

(12) A pharmacy shall effectuate a recall of medication that is or may be defective in any way.

9.19: continued

(13) A pharmacy shall obtain and record consent from a patient or patient's agent prior to enrolling that patient in an automatic refill program. A pharmacy shall provide a method for patients to discontinue participation in an automatic refill program.

(14) A pharmacy shall meet the following requirements concerning the posting of hours of operation:

- (a) The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy located within a retail establishment, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy; and
- (b) if the hours of operation of a pharmacy located within another retail establishment are different from those of the retail establishment, all advertising referring to the pharmacy shall clearly specify the pharmacy's hours of operation.

(15) A pharmacy shall maintain a written continuity of care plan that describes the manner in which patient needs will be met in the event the pharmacy is unexpectedly unable to provide pharmacy services. The pharmacy shall notify the Board if pharmacy operations are unexpectedly suspended for more than 24 hours.

(16) Registered Pharmacists on Duty.

- (a) Unless otherwise permitted by law or regulation, a licensed pharmacist shall be on the pharmacy premises at all times the pharmacy is open for business and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy.
- (b) While on duty, a pharmacist shall:
 1. ensure compliance with supervisory ratios in accordance with 247 CMR 8.06: *Duties of Pharmacist Utilizing Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees*;
 2. maintain proper storage and security of controlled substances;
 3. report problems with sanitary conditions or repair to Manager of Record;
 4. limit access to all pharmacy areas to authorized personnel;
 5. be familiar with applicable Board approved audit tool(s); and
 6. have access to all pharmacy records and be able to provide requested records to Board investigators.

(17) Temporary Absence of a Pharmacist.

- (a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy prescription area temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy or removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the controlled substances and devices will be maintained in his or her absence. A pharmacist must remain on the pharmacy premises, but is not required to remain in the prescription area. A temporary absence shall not exceed 30 minutes per six hours.
- (b) During a pharmacist's temporary absence, a pharmacy may not provide any prescription medication to a patient or a patient's agent unless the prescription is a refill medication that the pharmacist has checked and determined not to require the consultation of a pharmacist prior to being released to the patient. A new prescription which has been previously prepared, visibly checked by a pharmacist, and had a drug utilization performed by a pharmacist, may be picked up by a patient provided that a log, including the patient's phone number, of all such transactions is kept. The pharmacist upon return from break and within a reasonable time shall call the patient to review any pertinent counseling deemed appropriate.
- (c) During a pharmacist's temporary absence, the pharmacy technical support staff may continue to perform the non-discretionary duties. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.
- (d) In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.
- (e) A pharmacy shall maintain written policies and procedures regarding the operation of the pharmacy during the temporary absence of a pharmacist.

9.19: continued

- (18) Upon commencement of the employment of a registered pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician in training, the pharmacy shall verify that the individual's license to practice is current.
- (19) A pharmacy shall store and dispose of waste in a sanitary and timely manner.
- (20) A pharmacy shall maintain an e-Profile Number from the National Association of Boards of Pharmacy ("NABP") or other national database, as required by the Board.
- (21) A pharmacy shall perform a self-inspection within seven days of any renovation, expansion, relocation, or change of Manager of Record, and at least one time per year, utilizing a Board-approved inspection tool for routine compliance, sterile compounding, and non-sterile compounding, as applicable. The pharmacy shall retain the completed self-inspection tool for at least two years.
- (22) A pharmacy shall maintain a readily accessible policy and procedure for computer downtime which shall include:
 - (a) a process for filling prescriptions during downtime;
 - (b) a process for ensuring prescriptions dispensed during computer downtime are duly recorded in the patient's medication profile of the computerized pharmacy system when it becomes operational;
 - (c) continuity of care, if necessary; and
 - (d) process for performing an appropriate drug utilization review.
- (23) The requirements of 247 CMR 9.19(1)(e), (1)(j), (2), (9), (10), (11), (14), (16), and (17) do not apply to non-resident pharmacies.
- (24) The requirements of 247 CMR 9.19(1)(a), (1)(d), (1)(e), (1)(g), (1)(j), (8), (11), and (20) do not apply to institutional sterile compounding pharmacies.

9.20: Non-resident Pharmacies

A non-resident pharmacy shall comply with all Massachusetts laws and regulations governing the practice of pharmacy when filling, dispensing, or shipping medications into Massachusetts, unless otherwise specified.

9.21: Security of Controlled Substances

- (1) A pharmacy shall store all controlled substances within the secured prescription area and in a safe and secure manner.
- (2) A pharmacy shall store Schedules II through V controlled substances in a securely locked and substantially constructed cabinet, or similarly secured storage area, or dispersed throughout the stock of Schedule VI controlled substances and in such a manner as to obstruct theft and diversion.
- (3) A pharmacy shall maintain a centrally monitored security system that is able to detect a breach in security and is designed to prevent theft. A pharmacy shall activate the security system when the pharmacy is closed.
- (4) A pharmacy shall maintain surveillance cameras in a manner designed to record theft and diversion of controlled substances. A pharmacy shall retain video records for at least 14 days or, in the case of known or suspected theft or diversion, at least two years.
- (5) A pharmacy that is located within another retail establishment shall be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy is closed.

9.21: continued

- (6) The pharmacist Manager of Record and the pharmacist on duty are responsible for pharmacy security and shall control access to the prescription area.
- (7) All drug order deliveries containing controlled substances shall be delivered directly to the pharmacy.
- (8) Schedule II Perpetual inventory
 - (a) A pharmacy and pharmacist shall maintain a perpetual inventory of each controlled substance in Schedule II which the pharmacy has received, dispensed, or disposed of. The perpetual inventory may be in a hard copy, written format or in an electronic format. The perpetual inventory shall reflect the amount of each Schedule II controlled substance that is located on the pharmacy premises.
 - (b) The perpetual inventory record shall include the names and strengths of each Schedule II control substance, quantity of each drug purchased or added to inventory, starting inventory, prescription numbers, dispensed quantity, remaining balance, and pharmacist identification for each transaction.
 - (c) A pharmacy shall reconcile the perpetual inventory for each Schedule II controlled substance at least once every ten days by performing an accurate physical count of inventory on hand and comparing that number with the perpetual inventory. The Manager of Record shall investigate any discrepancy and report any significant loss or suspected theft in accordance with federal and state requirements.
 - (d) A pharmacy shall require any inventory adjustment resulting from a discrepancy be performed only by the pharmacist Manager of Record. In the absence of the Manager of Record, a pharmacist designee may make the changes and report to Manager of Record.
 - (e) An unlicensed individual may not make any entry into or adjust the perpetual inventory.
 - (f) A certified pharmacy technician may make entries into the perpetual inventory.
- (9) A pharmacy shall maintain an accurate record of all controlled substances returned to a reverse distributor or disposed of in accordance with state and federal laws and regulations, including proper DEA forms in the case of Schedule II controlled substances.
- (10) Each requirement of 247 CMR 9.21 shall apply to controlled substances that are expired, quarantined, or pending reverse distribution.
- (11) The requirements of 247 CMR 9.21 do not apply to non-resident pharmacies.
- (12) An institutional sterile compounding pharmacy shall store and secure controlled substances in accordance with 105 CMR 700.000: *Implementation of M.G.L. c. 94C*.

9.22: Proper Storage of Refrigerated and Frozen Medications

- (1) A pharmacy shall maintain policies and procedures to ensure proper refrigeration equipment is available, of adequate size, and utilized to maintain proper refrigeration and freezer temperatures. The policies and procedures shall include a protocol to respond to any out of range temperature, including an assessment of the integrity of the medication.
- (2) A pharmacy shall utilize a combination refrigerator/freezer or a standalone refrigerator or standalone freezer. Freezer units shall be frost-free with an automatic defrost cycle, unless otherwise approved by the Board. A pharmacy may not utilize an appliance that contains a freezer compartment within the refrigerator space, such as a dorm-style refrigerator.
- (3) A pharmacy shall measure and maintain refrigerator and freezer temperatures in accordance with Board guidance.
- (4) A pharmacy shall maintain temperature logs to clearly identify out of range temperatures and shall document actions taken in response to an out of range temperature. A pharmacy shall maintain records for at least one year.

9.22: continued

- (5) A pharmacy may not store any food or beverage in a refrigerator or freezer used to store medications.

9.23: Pharmacist Manager of Record

- (1) A pharmacy shall designate a Manager of Record who is registered as a pharmacist in Massachusetts.
- (2) A Manager of Record is responsible for the following:
 - (a) operation of the pharmacy in compliance with M.G.L. c. 112, §§ 24 through 42D, M.G.L. c. 94C, and 247 CMR 2.00: *Definitions*;
 - (b) the proper maintenance of records as required by M.G.L. c. 112, §§ 24 through 42D, M.G.L. c. 94C, and 247 CMR 2.00: *Definitions*;
 - (c) planning and maintaining adequate staffing that promotes patient safety;
 - (d) the establishment, monitoring, and enforcement of policies and procedures which maintain the standards of professional practice, compliance with state and federal laws and regulations governing the practice of pharmacy, and adequate staffing.
 - (e) the maintenance of records relating to the responsibilities of pharmacy technicians as outlined in 247 CMR 8.02(6);
 - (f) notification to the Board in writing of his/her termination or resignation as pharmacist Manager of Record within ten days;
 - (g) taking an inventory of controlled substances in Schedules II, III, IV and V, in accordance with 21 CFR § 1304.11;
 - (h) maintaining a copy of all standing orders used by the pharmacy; and
 - (i) ensuring technician training program is Board approved and up to date, if applicable.
- (3) A Manager of Record of a retail drug store pharmacy may not be the Manager of Record of more than one pharmacy at a time.
- (4) A Manager of Record shall work an average of at least 30 hours per week at the pharmacy he or she manages.
- (5) Temporary Absence of a Manager of Record
 - (a) A pharmacy shall appoint an Interim Manager who is registered by the Board prior to any planned absence of the Manager of Record that is expected to last 30 days or longer.
 - (b) 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.
 - (c) Prior to his or 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.
 - (d) In the event a Manager of Record is away from his or her position for 100 days or more, the pharmacy shall submit an application for a change of Manager of Record.

9.24: Inspections and Investigations of Pharmacies

- (1) The Board or its designee(s) may visit any pharmacy licensed by the Board at any time without prior notice and inspect the pharmacy staff, activities, and records to determine compliance with laws and regulations governing the practice of pharmacy.
- (2) All costs associated with inspections of non-resident pharmacies shall be paid by the non-resident pharmacy or applicant.
- (3) A pharmacy shall provide all documents requested by the Board or its designee(s) in connection with an inspection or investigation.

9.25: Plans of Correction

- (1) A pharmacy shall submit to the Board a written plan of correction for each violation cited in a statement of deficiency or inspection report within 21 days or in the timeframe directed by the Board. A pharmacy shall prepare and submit a plan of correction in the manner and format specified by the Board.
- (2) A plan of correction shall describe the corrective action in response to each violation cited in a statement of deficiency or inspection report, expected completion or implementation date for the plan of correction, and individual(s) responsible for each action.
- (3) The Manager of Record and the licensee who supervises the Manager of Record's practice of pharmacy, if applicable, shall sign the plan of correction.
- (4) A pharmacy shall achieve compliance with the laws and regulations governing the practice of pharmacy in the most expeditious manner possible.
- (5) A plan of correction which does not meet the requirements of the relevant 247 CMR section shall be considered unacceptable by the Board and returned to the pharmacy. The pharmacy shall submit a revised plan of correction within seven days.

REGULATORY AUTHORITY

247 CMR 9.00: M.G.L. c. 94C, §§ 6, 19B and 19C, and c. 112, §§ 12D, 30, and 42A.