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**9.01: Practice Standards**

- (1) A licensee shall conduct professional activities in conformity with applicable federal, state, and local laws, regulations, and ordinances.
- (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) 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/her education, training, and experience and within the recognized pharmacist scope of practice.
- (5) Unless otherwise permitted by law or regulation, a licensee may not re-dispense any medication which has been previously dispensed.
- (6) Unless otherwise permitted by law or regulation, a licensee may not accept, store, dispense, package, label, or compound any medication that was previously processed or

dispensed by another pharmacy.

(7) A licensee may not accept or purchase medications designated as “drug samples not for resale” for the purpose of compounding, repacking, dispensing, or in any way reselling said medications.

(8) 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 this section 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) While on duty, a pharmacist shall be responsible for the proper preservation, storage, and security of all controlled substances in the pharmacy.

(10) A licensee may not engage in any fraudulent or deceptive act.

(11) A licensee may not in any way aid or abet the unlawful practice of pharmacy.

(12) 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.

(13) 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.

(14) 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.

(15) A licensee may not provide any practitioner with prescription forms which refer to any pharmacist or pharmacy.

(16) Unless otherwise permitted by law or regulation, a licensee may not limit his/her services to a particular segment or segments of the general public.

(17) 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.

(18) A licensee shall maintain patient confidentiality and may not disclose patient confidential information. Confidential information includes any information which can be associated with a particular individual from which he/she is individually identifiable. Confidential information includes the past, present, and future health or condition of an individual, the provision of health care to an individual, and the payment for the provision of the health care to the individual.

(19) A pharmacist, pharmacy intern, or pharmacy technician may not work in a pharmacy for more than twelve hours without completing an eight 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 twelve hours in order to act in the best interest of the patient, provided the time in excess of twelve hours is minimized and the licensee documents the extenuating circumstance.

(20) A licensee who changes his/her mailing address, email address, or name shall notify the Board of such change(s) in writing within 14 days. In the case of a change of name, a licensee shall submit a sworn statement indicating that the licensee has changed his/her name with a photocopy of a valid picture identification card and any other documentation that may be required by the Board.

(21) A licensee may not display or allow to be displayed his/her certificate of personal registration in any pharmacy where said licensee is not employed or associated.

(22) A pharmacist, pharmacy intern, and pharmacy technician shall carry, post on the wall of the pharmacy where he/she works, or have readily available at the pharmacy where he/she works, a certificate of personal registration or an official statement from the Board which indicates that the licensee is currently registered by the Board to practice as a pharmacist, pharmacy intern, or pharmacy technician.

(23) A pharmacist shall wear a name tag with at least his/her first name and the title "Registered Pharmacist" or "R.Ph."

(24) A pharmacy may not allow any individual who is not a Massachusetts registered pharmacist to direct or supervise the practice of pharmacy.

(25) A pharmacist shall maintain an NABP e-profile number.

### **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 pharmacist shall verify that packing, shipping, and transportation processes do not adversely affect the integrity or stability of medications dispensed by mail.

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

### **9.03: Advertising**

(1) A pharmacist or pharmacy may not utilize false, deceptive, or misleading advertising.

(2) An advertisement for a particular prescription drug may not contain any representation, either expressed or implied, concerning that drug's safety, effectiveness, or indications for use.

(3) An advertisement for a particular prescription drug shall include the following information:

- (a) the proprietary name of each drug, if any;
- (b) the established or generic name of each drug, if any;
- (c) the quantity of each active ingredient per dosage unit;
- (d) the dosage form of each drug; and
- (e) the cash price of the prescription drug, including any professional or handling fees and any mailing and delivery fees.

(4) An advertisement for a prescription drug may contain a description of professional or convenience services provided by the pharmacy.

(5) The requirements of 247 CMR 9.04 shall apply to all pharmacy advertisements and promotional materials regardless of the format.

### **9.04: Requirements for Dispensing and Refilling Prescriptions**

(1) A pharmacist shall verify each prescription and is responsible for ensuring each prescription is properly filled and properly dispensed.

(2) A pharmacy shall maintain a workflow that promotes accuracy and patient safety during the processing, verification, and dispensing of prescriptions.

(3) A pharmacy shall utilize a computerized pharmacy system for dispensing and refilling prescriptions and for maintaining patient profiles.

(4) A pharmacy shall utilize computerized prescription scanning, barcode scanning, and product imaging technology or other technology approved by the Board.

(5) A licensee shall ensure the label affixed to a prescription drug container 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 not to exceed 48 hours.

(6) 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.

(7) 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;
- (c) his/her initials; and
- (d) attestation to refilling controlled substance prescriptions in accordance with 21 CFR s. 1306.22.

(8) A prescription that has been filled or refilled shall be deemed to have been dispensed for the full face amount of the prescription, unless otherwise indicated in the computerized pharmacy system or on the written prescription.

(9) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record in the computerized pharmacy system the NDC number, the name of the manufacturer, or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.

(10) Only a pharmacist, 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.

(11) 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/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
- (e) the pharmacist and pharmacy shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf.

(12) In order to determine whether a prescription is within date, the date the prescription was written or the "do not fill before" date shall not be counted. The last day of the period shall be counted.

(13) A pharmacy may not dispense any medication that was processed or verified outside its licensed pharmacy premises unless said process and verification was performed by an on-site Massachusetts registered pharmacist or performed in a pharmacy licensed by the Board.

(14) A pharmacist may not fill or dispense any prescription for a hydrocodone-only extended release medication that is not in an abuse deterrent form unless:

- (a) the medication is stored in a securely locked and substantially constructed cabinet at all times while on pharmacy premises;
- (b) the medication is dispensed in a container with a child proof safety cap or within a locked box;
- (c) the prescriber has supplied a new Letter of Medical Necessity for each prescription that includes the patient's diagnoses and treatment plan, verifies other pain management treatments are inadequate, and indicates a risk assessment was performed and the prescriber and patient entered into a Pain Management Treatment Agreement or indicates that the prescriber has determined that a Pain Management Treatment Agreement is not clinically indicated due to the severity of the patient's medical conditions, and the pharmacist keeps the Letter of Medical Necessity in a readily retrievable manner;
- (d) each prescription is accompanied by a written warning approved by the Board regarding the specific dangers of hydrocodone-only extended release medication that is not in an abuse deterrent form;

- (e) the pharmacist provides counseling that includes a review of the written warning supplied in accordance with 247 CMR 9.04(8)(d) and may include:
  - 1. the name and description of the medication;
  - 2. the dosage form, dosage, route of administration and duration of drug therapy;
  - 3. special instructions and precautions for preparation, administration and use by the patient;
  - 4. common adverse or severe side effects or interactions and therapeutic contraindications;
  - 5. techniques for self-monitoring drug therapy;
  - 6. proper storage;
  - 7. prescription refill information;
  - 8. action to be taken in the event of a missed dose; and
  - 9. signs and symptoms of an acute overdose.
- (f) the pharmacist reviews the patient's history on the online Prescription Monitoring Program and documents the results.

(15) 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 that a prescription expires and the pharmacist is unable to obtain authorization in a timely manner the pharmacist in his/her professional judgment may dispense a quantity not to exceed seven days.

#### **9.05: Daily Dosage Planners**

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

- (1) A pharmacy or pharmacist may not place any medication in a 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 daily dosage planners, and for the prevention of cross-contamination.
- (3) The pharmacy maintains policies and procedures pertaining to daily dosage planners that include cleaning, labeling, dispensing, and proper hand hygiene.
- (4) The pharmacy cleans and stores daily dosage planners in a manner that prevents contamination to the pharmacy environment or specialty patient packaging.
- (5) The pharmacy labels each daily dosage planner with all information required by M.G.L. c. 94C, § 21 for each medication.

(6) A pharmacist shall visually inspect and verify the contents of a daily dosage planner prior to dispensing.

**9.06: Specialty Packaging**

(1) A pharmacy or pharmacist may utilize specialty 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 specialty packaging, and for the prevention of cross contamination.
- (b) The pharmacy maintains policies and procedures pertaining to each type of specialty packaging utilized that include cleaning, labeling, dispensing, proper hand hygiene, quarantine, and reverse distribution.
- (c) The specialty 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 specialty 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 pharmacist shall visually inspect and verify the contents of each specialty package prior to dispensing.
- (g) A licensee may not place a quantity of drugs in specialty packaging that exceeds the capacity of the container or that may cause damage to the individual dosage forms.

(2) Oral-Liquid-Single-Dose

- (a) A licensee may not dispense a medication in an oral-liquid-single-dose package unless the package has a child proof safety cap.
- (b) A licensee may not place more than one commercially available medication into an oral-liquid-single-dose package unless compounded pursuant to a prescription.

(3) Single-Drug-Single-Dose Packaging

- (a) A pharmacy or pharmacist may utilize single-drug-single-dose packaging for

medications in Schedules II – VI.

- (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.

(4) Multi-Drug-Single-Dose Packaging

- (a) A licensee may not dispense more than a 34 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.
- (d) A licensee may not dispense a Schedule IV or V controlled substance in a multi-drug-single-dose package unless the medication is prescribed for maintenance therapy.

(5) 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 to a patient for the purpose of repackaging and re-dispensing to that same patient.
  - (i) 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.
  - (ii) 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.
  - (iii) A pharmacy shall label the multi-drug-single-dose package in accordance with 247 CMR 9.07(6) prior to re-dispensing.
  - (iv) 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 or dispense to any patient.

- (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.
- (6) A pharmacy and pharmacist 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 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 and a beyond-use date, which may not exceed the shortest expiration date on the original manufacturer's container or 90 days, for each drug contained in a multi-drug-single-dose package; and
  - (d) the telephone number of the pharmacy.
- (7) If a cell is removable, a pharmacy shall label a multi-drug-single-dose package with a label of sufficient size to properly and clearly label each cell with each drug name and strength.

#### **9.07: Emergency Medication Kits**

- (1) A pharmacy shall maintain a policy and procedure for the proper dispensing of emergency medication kits that includes labeling, verification by a registered pharmacist, expiration date checking, restocking, and cleaning of the container.
- (2) A pharmacist, pharmacy intern, or pharmacy technician shall prepare, package, and seal emergency medication kits.
- (3) An emergency medication kit shall contain a list of contents on the outside cover and within the box. Each emergency medication kit shall have a label on the outside cover that states the earliest expiration date of the medications in the kit.
- (4) A pharmacy shall reconcile used emergency medication kits with prescriptions or orders.
- (5) A pharmacy and pharmacist shall fill Emergency Medication Kits for Long Term Care Facilities in accordance with 105 CMR 150.008(E).

#### **9.08: Automated Pharmacy Systems**

- (1) A pharmacy may dispense Schedule VI controlled substances for refill prescriptions 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 20 feet of 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 APS is monitored by video surveillance.
  - (d) The pharmacy notifies the Board in writing of its intent to use an APS. The notification shall include:
    - 1. the name and address of the pharmacy;
    - 2. APS hours of operation;
    - 3. type of APS system; and
    - 4. a description of how the APS system is to be used.
  - (e) The APS maintains the following electronic data for each prescription it dispenses:
    - 1. name of the pharmacy;
    - 2. name of the patient;
    - 3. name of the prescriber;
    - 4. prescription number;
    - 5. name, strength, dosage form, and quantity of the drug dispensed;
    - 6. date and time of dispensing;
    - 7. identity of the pharmacist who verified the prescription; and
    - 8. identity of the person to whom the drug was released.
  - (f) The pharmacy provides the patient an opportunity for a pharmacist consultation during all hours that the APS is in operation for dispensing.
  - (g) 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 that include:
- (a) the name and address of the pharmacy where APS is used;
  - (b) the APS manufacturer's name, model, serial number, and other identifying information;
  - (c) a description of how the APS is used by the pharmacy;
  - (d) quality assurance procedures;
  - (e) APS operation, safety, security, accountability, accuracy, patient confidentiality, and access;

- (f) procedures to be followed in the event of a malfunction, including that any malfunction is immediately reported to the pharmacist on duty;
  - (g) procedures to identify, analyze, and report each dispensing error, in accordance with 247 CMR 15.00; and
  - (h) stocking the APS.
- (3) A pharmacy shall ensure the stocking and return of all prescription medications in the APS occurs in the following manner:
- (a) a pharmacist, pharmacy intern, or certified pharmacy technician stocks and returns prescription medications;
  - (b) the APS, pharmacist, pharmacy intern, or certified pharmacy technician records all stocking and return activities, including the identification of each person who accessed the APS;
  - (c) the pharmacy may not stock medications in an APS that require refrigeration or reconstitution;
  - (d) the APS utilizes two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to ensure that the proper medication is dispensed from the system.

**9.09: Pharmacy Processing Automation**

- (1) A pharmacy may utilize Pharmacy Processing Automation (“PPA”) to count, fill vials or specialty packages, and label, provided the following requirements are met:
- (a) a pharmacist, pharmacy intern, or certified pharmacy technician stocks the PPA;
  - (b) a pharmacist verifies the stocking of the PPA;
  - (c) the PPA, pharmacist, pharmacy intern, or certified pharmacy technician records all stocking and return activities, including the identification of each person who accessed the PPA;
  - (d) the PPA utilizes two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to ensure that the proper medication is dispensed from the system;

- (e) Schedule II controlled substances are not stocked in or dispensed from a PPA;
  - (f) the PPA prevents unauthorized access by utilizing passwords, biometric scanning, or other coded identification; and
  - (g) lot numbers are not comingled in a single cell.
- (2) The pharmacist manager of record or his/her designee shall have sole responsibility to assign, discontinue, or change access to the PPA.
- (3) The pharmacy shall implement and maintain policies and procedures pertaining to the PPA that include:
- (a) system access;
  - (b) controlled substance accountability;
  - (c) routine cleaning and maintenance of the PPA and measures to prevent cross-contamination;
  - (d) documentation of lot numbers and expiration dates of each medication added to the PPA in order to respond to recalls in the event lots are comingled; and
  - (e) responding to a recall event.

### **9.10: Automated Dispensing Devices**

- (1) Unless otherwise prohibited by law, a pharmacy may dispense controlled substances from an automated dispensing device (“ADD”) located in a health care facility, provided it satisfies the following:
- (a) The ADD only dispenses controlled substances for immediate administration to inpatients and outpatients of the health care facility pursuant to a valid prescription or medication order.
  - (b) The ADD appropriately stores, secures, and accounts for controlled substances.
  - (c) The ADD limits access to authorized individuals;
- (2) A pharmacy shall establish and maintain policies and procedures pertaining to ADDs that include use, access, quality assurance, accountability, accuracy, security, and patient confidentiality.
- (3) A pharmacy shall maintain in a readily retrievable manner an accurate record of all the controlled substances that are delivered to an ADD prior to and after loading in the machine.

- (4) The Pharmacist manager of record or pharmacist designee shall review user access reports at least quarterly.
- (5) A pharmacist, pharmacy intern, or certified pharmacy technician shall verify the inventory provided for loading or loaded into the ADD is correct.
- (6) A registered pharmacy technician or technician in training may not load controlled substances in schedules II – V into the automated dispensing device.
- (7) Medications returned to the ADD return bin or returned to the pharmacy shall be verified by a pharmacist prior to reloading into the ADD dispensing compartment.
- (8) Unless an emergent or urgent need exists, a pharmacist shall review medication orders and prescriptions prior to removal of any controlled substances from an automated dispensing device. In the case of removal of medications for emergent or urgent need, a pharmacist shall review the order within 24 hours.
- (9) A pharmacy shall maintain a listing of all locations of ADDs that it operates. This listing shall be readily retrievable and retained for at least two years.

#### **9.11: Return to Stock**

- (1) In the event a pharmacy fills and prepares a prescription but the patient does not pick up the medication, the pharmacy may return the medication to stock. A pharmacy shall ensure the following conditions are satisfied if it returns a medication to stock:
  - (a) A pharmacy may not return a medication to the manufacturer's stock bottle or PPA. 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;
  - (b) Only a pharmacist, pharmacy intern, or pharmacy technician may return medications to stock. A pharmacist shall verify any return to stock performed by a pharmacy intern or pharmacy technician. A pharmacy technician in training may not return a medication to stock. A pharmacy technician may not return a Schedule II medication to stock.
- (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.

### **9.12: Transfer of Prescriptions**

(1) A pharmacy shall transfer a prescription to another pharmacy, at the request of a patient or his/her agent, in a timely manner so as not to delay patient therapy, if the following conditions are met:

- (a) the pharmacy has not yet dispensed the initial prescription for Schedule VI medication or refills remain on a prescription for Schedule III, IV, V, or VI medication;
- (b) the prescription has not expired; and
- (c) the transfer is not otherwise prohibited by law.

The transferee pharmacy may act as the patient's agent in order to facilitate a transfer.

(2) A pharmacy that transfers a prescription shall maintain the original prescription for at least two years from the date of the last transfer.

(3) A pharmacy that receives a transferred prescription shall maintain the transferred prescription for at least two years from the date of last refill.

(4) A pharmacy may not charge a fee for transferring a prescription.

(5) In order to transfer a prescription in Schedules III, IV, or V, the transferring pharmacist or pharmacy intern shall:

- (a) Document the transfer and invalidate the original prescription in the computerized pharmacy system or by writing the word "void" on prescription;
- (b) Record in the computerized pharmacy system or on the reverse side of the invalidated prescription the name, address, and DEA registration number of the pharmacy receiving the transfer and the name of the pharmacist receiving the prescription information;
- (c) Record in the computerized pharmacy system or on a transfer log, the prescription number, if applicable, date of the transfer, name of the pharmacist transferring the prescription, and the name of the pharmacy receiving the prescription; and
- (d) Cancel all refills remaining on the transferred prescription at the original

pharmacy.

(6) A licensee may not transfer a Schedule III, IV, or V prescription if that prescription was previously transferred.

(7) In order to transfer a prescription in Schedule VI, the transferring pharmacist, pharmacy intern, or certified pharmacy technician shall:

- (a) Record in the computerized pharmacy system or in a transfer log the following information:
  - 1. the prescription number;
  - 2. date of the transfer;
  - 3. the name or identification of the pharmacist transferring the prescription; and
  - 4. the name of the pharmacy to which the prescription is transferred.
- (b) Cancel all refills remaining on the transferred prescription.

(8) A licensee may not transfer a prescription authorizing refills for Schedule VI controlled substances more than one year from the date the prescription was issued.

(9) A pharmacist or pharmacy intern who receives a transferred prescription in Schedule III, IV, V, or VI shall:

- (a) Document the transfer in the computerized pharmacy system or by writing the word “transfer” on the face of the transferred prescription; and
- (b) Record in the computerized pharmacy system or by writing on the prescription the following information:
  - 1. the date of issuance of the original prescription;
  - 2. the number of refills authorized on the original prescription;
  - 3. the date of original dispensing;
  - 4. the number of valid refills remaining and date of last refill; and
  - 5. the pharmacy’s name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.
- (c) Inform the patient that the prescription’s refills were canceled at the pharmacy from which it was transferred.

### **9.13: Verifying a Practitioner's Prescriptive Authority**

(1) A pharmacist who is eligible to register for the Massachusetts Prescription Monitoring

Program (“PMP”) shall register with and maintain login information for PMP.

(2) A pharmacist may not fill a prescription unless the pharmacist, in the exercise of his/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/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).

(3) A pharmacy shall maintain a policy and procedure pertaining to verifying a practitioner’s prescriptive authority.

**9.14: Maintenance of Prescription Files**

(1) A pharmacist and pharmacy shall maintain prescription files, 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, electronically separable if maintained in electronic format, and available at the time of an inspection.

(3) Prescriptions for Schedule III, IV, and V controlled substances shall be segregated if maintained in paper format, electronically separable if maintained electronic format, and available at the time of an inspection.

(4) Prescriptions for Schedule VI controlled substances shall be segregated if maintained in paper format, electronically separable if maintained in electronic format, and available at the time of an inspection.

(5) A pharmacy shall be able to print copies of electronic prescriptions.

(6) 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, email address, telephone number, 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.

### **9.15: 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 Veterinarian Reference; and
  - (e) other peer-reviewed medical literature.
- (4) The DUR shall include a review of the patient's active prescription medication profile within the preceding twelve (12) months.
- (5) The DUR shall include any over-the-counter medication, herbal medicine, or nutritional supplement that is included in the patient profile or disclosed to the pharmacist or pharmacy by the patient or patient's agent.

#### **9.16: 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.
- (2) A pharmacist shall ensure his/her designee is appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.
- (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 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 pharmacist or pharmacist’s designee shall maintain patient confidentiality when counseling and making the offer to counsel.
- (9) A pharmacy and pharmacist shall ensure counseling is available at all times when a pharmacy is open for business.
- (10) The provisions of 247 CMR 9.17 do not apply to pharmacists while practicing in an inpatient setting, unless otherwise required by law or regulation.

**9.17: 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 (MLID), 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 – 42A, 105 CMR 700.000, 105 CMR 701.00, 105 CMR 720.00, and 105 CMR 721.00, and 247 CMR 2.00 – 20.00;

- (d) a current copy or access to electronic version of Plumb's Veterinarian Reference or other veterinary reference approved by the Board;
  - (e) a balance capable of accurately weighing quantities as small as 10 milligrams, shall be tested and sealed by the state or local sealer of weights and measures at least once every 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 accuracy;
  - (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;
  - (j) a designated compounding area for simple and moderate non-sterile compounding; and
  - (k) dedicated equipment for highly cross-sensitive medications and hazardous drugs.
- (2) A pharmacy that obtained its Drug Store pharmacy license prior to July 1, 2015 shall have a prescription area that is at least 300 square feet. A pharmacy that obtained its Drug Store pharmacy license on or after July 1, 2015 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 are certified at least once every two years by a qualified vendor.
- (4) The prescription area shall provide for the arrangement and storage of drugs, supplies, and equipment that is calculated to prevent their accidental misuse and that:
- (a) stores products intended solely for animal use in a designated area;
  - (b) stores hazardous drugs in a designated area;
  - (c) separates ophthalmic from otic medications;
  - (d) quarantines products subject to recall, return, or disposal with proper storage and

security;

- (e) identifies high alert high risk drugs and look alike sound alike drugs as identified by ISMP; and
- (f) separates internal from external use medications.

(5) A pharmacy shall store medications in the manufacturer's stock bottles or in containers that are clearly labeled with the product name, strength or concentration, NDC number, manufacturer or supplier, lot number, 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 9.18(9) in a readily retrievable manner.

(9) 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 222C 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 and whether the pharmacy is a sterile compounding pharmacy or complex non-sterile compounding pharmacy.

(12) A pharmacy shall effectuate a recall of medication in accordance with all applicable state and federal laws and regulations.

(13) A pharmacy shall obtain and document consent from a patient or patient's agent prior to enrolling that patient in an automatic refill program. A pharmacy may not include any drug with a Narrow Therapeutic Index 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) A registered pharmacist shall be on duty and 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:
  - (i) ensure compliance with supervisory ratios in accordance with 247 CMR 8.XX;
  - (ii) maintain proper storage and security of controlled substances;
  - (iii) report problems with sanitary conditions or good repair to Manager of Record;
  - (iv) limit access to all pharmacy areas to authorized personnel;
  - (v) be familiar with applicable Board approved audit tool(s); and
  - (vi) 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/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/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.

(18) Upon commencement of the employment of a registered pharmacist, pharmacy intern, pharmacy technician, or other licensed health care provider, 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 and in accordance with local, state, and federal laws and regulations.

(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 9.18(2), (12), (15), and (18) do not apply to non-resident pharmacies.

#### **9.18: 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.

#### **9.19: 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 Schedule II controlled substances in a securely locked and substantially constructed cabinet and in such a manner as to obstruct theft and diversion.

(3) A pharmacy shall store Schedules III, IV, and V controlled substance in a securely locked and substantially constructed cabinet or dispersed throughout the stock of Schedule VI controlled substances and in such a manner as to obstruct theft and diversion.

(4) 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.

(5) 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 30 days or, in the case of known or suspected theft or diversion, at least two years.

(6) 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.

(7) The pharmacist Manager of Record and the pharmacist on duty are responsible for pharmacy security and shall control access to the prescription area.

(8) All drug order deliveries containing controlled substances shall be delivered directly to the pharmacy.

(10) 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 in accordance with the law. 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 perpetual inventory adjustment 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) 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 and in the case of Schedule II drugs shall maintain proper DEA forms.

(f) A pharmacy technician or other unlicensed individual may not make any entry into or adjust the perpetual inventory.

(11) Each requirement of 247 CMR 9.19 shall apply to controlled substances that are expired, quarantined, or pending reverse distribution.

(12) The requirements of 247 CMR 9.19 do not apply to non-resident pharmacies.

### **9.20: 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. 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 maintain a refrigerator temperature of 36° to 46° F (2° to 8° C). A pharmacy shall maintain a freezer temperature of 14° to -13° F (-25° to -10° C).

(4) A pharmacy shall utilize a certified calibrated analogue thermometer or certified calibrated digital thermometer equipped with an out of range alarm or notification for monitoring refrigerator and freezer temperatures.

(5) A pharmacy shall maintain daily 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.

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

### **9.21: 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 laws and regulations governing the practice of pharmacy;
- (b) the proper maintenance of records as required by the Massachusetts Controlled Substances Act, M.G.L. c. 94C, Board regulations at 247 CMR 2.00 *et seq.*, and all other applicable state and federal laws and regulations;

- (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, based upon federal biennial inventory requirements, pursuant to the requirements of 247 CMR 6.03(b);
  - (h) maintaining a copy of all standing orders for medications dispensed by the pharmacy;
  - (i) ensuring that all licensees working in the pharmacy have completed continuing education requirements;
  - (j) approving security access to the pharmacy, pharmacy's computer systems, and pharmacy automation; and
  - (k) ensuring technician training program is Board approved and up to date.
- (2) A Manager of Record may not be the Manager of Record of more than one pharmacy at a time.
- (3) A Manager of Record shall work at least 30 hours per week at the pharmacy he/she manages.
- (4) 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/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/her position for 100 days or more, the pharmacy shall submit an application for a change of Manager of Record.

### **9.22: 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.

### **9.23: 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.

\*\*\*DRAFT\*\*\*

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

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