

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 9.00: CODE OF PROFESSIONAL CONDUCT; PROFESSIONAL STANDARDS FOR REGISTERED PHARMACISTS, PHARMACIES AND PHARMACY DEPARTMENTS

Section

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For the purposes of 247 CMR 9.00 "pharmacy" shall include retail, restricted and nuclear pharmacies, and pharmacy departments.

9.01: Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments

- (1) A registered pharmacist shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.
- (2) A pharmacist shall not dispense drugs, devices, or other substances in a manner which is intended, either directly or indirectly, to circumvent the law.
- (3) A pharmacist shall observe the standards of the current United States Pharmacopoeia.
- (4) Unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed.
- (5) While on duty, a pharmacist shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.
- (6) A pharmacist shall not engage in any fraudulent or deceptive act.
- (7) A pharmacist shall not enter into an agreement or arrangement with any person for the purpose of dispensing drugs which have been ordered by coded prescriptions.
- (8) A pharmacist, pharmacy or pharmacy department shall not promise to any person who owns, operates, manages or is an employee of a hospital, nursing home or other health care facility, or to any authorized practitioner, any rebate, refund, discount, commission or other valuable consideration for, or on account of, or based upon income received or resulting from, the sale, or furnishing of any such pharmacist, pharmacy, or pharmacy department, of drugs devices or services to patients of such persons, organizations or facilities.
- (9) A pharmacist shall not in any way aid or abet the unlawful practice of pharmacy.
- (10) A pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity who is not licensed or legally authorized to receive such drugs or devices.
- (11) A pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations, including the regulations of the Board. All pharmacists shall have available sufficient information to contact the patient and the prescribing practitioner.
- (12) Unless otherwise permitted by law, a pharmacist connected with, or employed by, a hospital or clinic shall not dispense drugs to any person other than inpatients or outpatients, or to employees of said hospital or clinic, or to said employees' spouses and children who live in the same household with said employees.

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- (13) A pharmacist, pharmacy, pharmacy department, pharmaceutical organization or pharmacy corporation shall not provide any practitioner with prescription blanks which refer to any pharmacist, pharmacy or pharmacy department.
- (14) A pharmacist shall keep a perpetual inventory of each controlled substance in Schedules II which the pharmacist has received, dispensed or disposed of in accordance with the law. This inventory must be reconciled at least once every ten days.
- (15) Unless otherwise provided for by law, a pharmacist shall not limit his or her services to a particular segment or segments of the general public.
- (16) A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.
- (17) A pharmacist shall not purchase drug samples for the purpose of compounding, dispensing, or in any way reselling these samples.
- (18) A pharmacist shall comply with the mandatory counseling provisions contained in M.G.L. c. 94C, § 21A.
- (19) A pharmacist shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

9.02: Transfer of Prescriptions

- (1) A prescription may be transferred between pharmacies or pharmacy departments, at the patient's request, for the purpose of dispensing authorized refills on the prescription provided that:
- (a) refills remain on the prescription; and
 - (b) the prescription authorizing the refill has not expired.
- (2) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedules III, IV and V shall be as follows:
- (a) The transferring pharmacist must record the following information:
 - 1. Write the word "VOID" on the face of the invalidated prescription;
 - 2. record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and
 - 3. record, on a written transfer log or by entry into a computerized system, the prescription number, date of the transfer, the name or identification of the pharmacist transferring the information and the name of the pharmacy or pharmacy department to which the prescription is transferred.
 - (b) The transferring pharmacist shall cancel all refills remaining on the transferred prescription.
 - (c) The pharmacist receiving the transferred prescription information shall complete the following:
 - 1. Write the word "transfer" on the face of the transferred prescription; and
 - 2. write all information required by state and federal law to be on the prescription and include:
 - a. the date of issuance of the original prescription;
 - b. the original number of refills authorized on the original prescription;
 - c. the date of original dispensing;
 - d. the number of valid refills remaining and date of last refill; and
 - e. the pharmacist's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.

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- (d) The pharmacist receiving the transferred information shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.
- (3) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedule VI shall be as follows:
- (a) The transferring pharmacist or certified pharmacy technician must record, on a written transfer log or by entry into a computerized system the following: the prescription number; date of the transfer; the name or identification of the pharmacist transferring the information; and the name of the pharmacy or pharmacy department to which the prescription is being transferred.
 - (b) The transferring pharmacist or certified pharmacy technician shall cancel all refills remaining on the transferred prescription.
 - (c) The pharmacist or certified pharmacy technician receiving the transferred prescription information shall:
 1. write the word "transfer" on the face of the transferred prescription;
 2. write all information required by state and federal law to be on the prescription including:
 - a. the date of issuance of the original prescription;
 - b. the original number of refills authorized on the original prescription;
 - c. the date of original dispensing;
 - d. the number of valid refills remaining and date of last refill; and
 - e. 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.
 - (d) The pharmacist or certified pharmacy technician receiving the transferred prescription shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.
- (4) Prescriptions authorizing refills for Schedule III through V controlled substances may be transferred between pharmacies or pharmacy departments on a one-time only basis except as otherwise permitted by law.
- (5) Prescriptions authorizing refills for Schedule VI controlled substances may be transferred between pharmacies or pharmacy departments within one year of the date of issuance.
- (6) Both the original and transferred prescriptions must be maintained for a period of two years from the date of last refill.

9.03: Advertising

- (1) A pharmacist shall not utilize false, deceptive or misleading advertising.
- (2) Whenever a pharmacist advertises the consumer price for a particular prescription drug, said advertisement shall not contain any representation, either expressed or implied, concerning that drug's safety, effectiveness, or indications for use.
- (3) Any pharmacist who advertises a prescription drug in a manner which provides price information to consumers shall include the following information regarding each advertised prescription drug:
 - (a) The proprietary name, if any;
 - (b) the established or generic name, if any;
 - (c) the quantity of active ingredient per dosage unit of the prescription drug product whenever the prescription contains a single active ingredient;
 - (d) the strength of the prescription whenever said product contains more than one active ingredient by a relevant strength that can be associated with the product without indicating each active ingredient; the established name and quantity of each active ingredient shall not be required whenever said product contains more than one active ingredient;
 - (e) the dosage form; and
 - (f) the price charged for filling a prescription.

9.03: continued

(4) A pharmacist who advertises prescription drugs in a manner which provides price information to consumers may identify professional or convenience services provided by the pharmacy or pharmacy department, or may include other written, printed or graphic matter, provided that no information included in such advertising shall be false, deceptive or misleading.

(5) Whenever a pharmacist advertises prescription drugs in a manner that provides price information to consumers, any stated price with respect to a particular prescription drug shall include all charges to the consumer. These charges shall include, but not be limited to, any professional or handling fees and any mailing and delivery fees. This advertising may indicate each separate fee which is to be added to the price of the prescription drug.

(6) The requirements of 247 CMR 9.03 apply to all prescription drug advertisements, including price lists, catalogs, and other promotional material, whether mailed, posted in a pharmacy, placed in a newspaper, or aired on radio or television, which serve to provide consumers with information regarding the price charged for prescriptions.

9.04: Requirements for Dispensing and Refilling Prescriptions

(1) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record on the prescription the name of the manufacturer or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.

(2) The information on the label which the pharmacist, pharmacy intern, pharmacy technician or pharmacy technician trainee affixes to a prescription drug container shall be clearly printed or typed.

(3) Only a pharmacist, pharmacy intern, and 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.

(4) A pharmacist who refills a prescription for a controlled substance in Schedules III through VI shall record on the prescription:

- (a) the date of dispensing;
- (b) the amount of the drug dispensed; and
- (c) his or her initials.

(5) A dispensing pharmacist who does not indicate the quantity of a drug dispensed on the back of a prescription which the pharmacist has refilled shall be deemed to have dispensed a refill for the full face amount of the prescription.

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

(7) A pharmacist or anyone acting on behalf of a pharmacy or pharmacy department shall not collect prescriptions at industrial plants, places of business, or other sites where specific groups of people are regularly employed or affiliated, unless the prescriptions meet the following requirements:

- (a) the prescriptions are for persons regularly employed at, or affiliated with, such plant, place of business or other such site;
- (b) the prescriptions are collected in person by a pharmacist, pharmacy employee, or authorized agent of the pharmacy;
- (c) the prescriptions are distributed in person to the patients or an authorized agent of the patient by a pharmacist, pharmacy employee, or authorized agent of the pharmacy; and
- (d) the pharmacist shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf, and for verifying the authority of any person purporting to act on a patient's behalf; nothing in 247 CMR 9.04(7) shall be deemed to permit conduct of a prescription business in violation of any other regulation of the Board.

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- (8) 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, but is not limited to:
 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 checks the patient's history on the online Prescription Monitoring Program.

9.05: Maintenance of Prescription Files

A pharmacist shall maintain prescription files as follows:

- (1) Prescriptions for controlled substances in Schedule II shall be segregated from all other records and shall be maintained in a separate file identified as such.
- (2) Prescriptions for controlled substances in Schedules III, IV, and V shall be maintained in a separate file identified as such.
- (3) Prescriptions for controlled substances in Schedule VI, prescriptions for non-controlled substances, and prescriptions for syringes and instruments adaptable to hypodermic administration, shall be segregated from all other records and shall be maintained together in a separate file identified as such.

9.06: Procedures for Verifying a Practitioner's Prescriptive Authority

A prescription written by a practitioner may be filled only if the pharmacist called upon to fill such prescription, in the exercise of that pharmacist's professional judgment, determines that:

- (1) The prescription is issued pursuant to a valid patient/practitioner relationship and for a legitimate medical purpose by an authorized practitioner acting in the course of his or her professional practice;
- (2) the prescription is authentic; and
- (3) the dispensing is in accordance with M.G.L. c. 94C, § 19(a).

9.07: Maintaining Patient Records, Conducting a Prospective Drug Utilization Review and Patient Counseling

The purpose of 247 CMR 9.07 is to enhance the public health and welfare by requiring that pharmacists offer consultation to patients regarding their prescriptions in order to promote optimum therapeutic outcomes, avoid patient injury and reduce medication errors.

(1) Patient Records.

(a) A pharmacist or pharmacist's designee shall maintain a confidential record for all patients for whom prescriptions are dispensed. The patient record 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:

1. name, address, telephone number, date of birth or age, and gender of the patient for whom the prescription is intended;
2. individual history, including known drug allergies and drug reactions;
3. a comprehensive list of medications and relevant devices dispensed by the pharmacy; and
4. the pharmacist's comments relevant to the patient's drug therapy.

(b) A pharmacist shall maintain the patient's record for a period of not less than 12 months from the date of the last entry in the profile record, except as otherwise required by state and federal law. This record may be computerized.

(2) Prospective Drug Utilization Review.

(a) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. This DUR may include a review of the patient record and each new prescription presented for dispensing, for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the following:

1. over-utilization or under-utilization;
2. therapeutic duplication;
3. drug-disease contraindication;
4. drug-drug interaction;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions;
7. clinical abuse or misuse; and
8. any significant change in drug, dose or directions.

(b) Upon identifying any of the above, the pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner and/or direct consultation with the patient.

(c) The review shall be based upon current standards which may include the following:

1. The American Hospital Formulary Service Drug Information;
2. the United States Pharmacopoeia Drug Information;
3. the American Medication Association Drug Evaluations; and
4. other peer-reviewed medical literature.

(3) Patient Counseling.

(a) The pharmacist or pharmacist's designee shall offer the services of the pharmacist to discuss, with all persons presenting new prescriptions, issues that in the pharmacist's professional judgment are deemed to be significant for the health and safety of the patient.

(b) The pharmacist's designee shall be an individual appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.

(c) A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.07 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. 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."

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- (d) When the offer to counsel is accepted, the pharmacist 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:
1. Name and description of the medication;
 2. dosage form, dosage, route of administration and duration of therapy;
 3. special directions and instructions for preparation, administration and use by the patient;
 4. common severe side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications which the pharmacist deems relevant;
 5. techniques for self-monitoring drug therapy;
 6. proper storage;
 7. prescription refill information; and
 8. action to be taken in the event of a missed dose or adverse reaction.
- (e) The offer to counsel shall be made to the patient, or the person acting on behalf of the patient when confidentiality can be maintained, either by face to face communication or telephone. If the patient does not pick up the prescription at a pharmacy or the offer is not made by telephone then the offer must be made in writing. This offer must provide a toll-free telephone service to facilitate communication between such person and the pharmacist and must state the following: "Dear patient, 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". Printed material containing information on the drug may accompany this written offer to counsel provided the patient is informed that said information is not comprehensive and that the patient should call for further information if needed.
- (f) Counseling must be made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist if deemed appropriate by the pharmacist.
- (g) Counseling must be available at all times when a pharmacy is open for business.
- (h) The provisions of 247 CMR 9.07 shall apply to pharmacists who directly dispense medications to outpatients and patients being discharged from hospitals, institutions and clinics.
- (i) The provisions of 247 CMR 9.07 shall not apply to any drug dispensed to an inpatient at a hospital, nursing home or any other setting where medication is administered by an authorized individual, except to the extent required by the Federal Health Care Financing Administration pursuant to the provisions of 42 USC 1396r-8.

REGULATORY AUTHORITY

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

NON-TEXT PAGE