247 CMR 13.00: NUCLEAR PHARMACY LICENSURE REQUIREMENTS AND PROFESSIONAL PRACTICE STANDARDS

Section

13.01: Authority and Purpose

247 CMR 13.00 is promulgated under the authority granted to the Board by M.G.L. c. 112, §§ 39, 39B, and 39J to license an establishment for transacting business as a nuclear pharmacy or non-resident nuclear pharmacy. The purpose of 247 CMR 13.00 is to establish professional standards for the practice of nuclear pharmacy in order to safeguard the public health and welfare.

13.02: Definitions

Authorized Nuclear Pharmacist means a pharmacist who is licensed by the Board pursuant to the provisions of M.G.L. c. 112, § 24 and who has met the training requirements of 105 CMR 120.526: *Training for an Authorized Nuclear Pharmacist*.

Authorized User means a practitioner who is legally authorized to receive and administer radiopharmaceuticals in accordance with 105 CMR 120.000.

Controlled Substance means any medication that is approved by the U.S. Food and Drug Administration (FDA) that may only be dispensed pursuant to a valid prescription as required by state or federal law. This includes Schedule VI controlled substances, as specified in M.G.L. c. 94C, § 3.

Nuclear Pharmacy means a pharmacy under the direction or supervision of an Authorized Nuclear Pharmacist that only engages in radiopharmaceutical services pursuant to M.G.L. c. 112, §§ 39B, 105 CMR 120.000, and 247 CMR 13.00. A nuclear pharmacy may prepare sterile and non-sterile (including complex level) compounded radiopharmaceuticals.

Radiopharmaceutical Services means, but shall not be limited to, the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceuticals.

13.03: General Requirements

(1) A nuclear pharmacy or non-resident nuclear pharmacy shall comply with all state and federal laws and regulations including 247 CMR 2.00 *et seq.* unless otherwise noted, as well as guidance issued by the U.S. Food and Drug Administration (FDA) and either the U.S. Nuclear Regulatory Commission (NRC) or Agreement State Program.

(2) A nuclear pharmacy or non-resident nuclear pharmacy shall adhere to United States Pharmacopoeia (USP) chapter <825> and all other applicable USP chapters.

(3) A nuclear pharmacy or non-resident nuclear pharmacy shall submit an application to the Board whenever there is a change of the Manager of Record or Designated Pharmacist-in-Charge, in accordance with 247 CMR 20.00.

(4) A nuclear pharmacy or non-resident nuclear pharmacy may only dispense radiopharmaceuticals and adjunct medications commonly used in nuclear medicine into, within, or from Massachusetts if it holds a nuclear pharmacy or non-resident nuclear pharmacy license.

(5) At least one Authorized Nuclear Pharmacist shall be present in a nuclear pharmacy during the entire time when said pharmacy is open for business.

(6) A nuclear pharmacy or non-resident nuclear pharmacy shall not dispense radiopharmaceuticals which do not comply with acceptable professional standards of radiopharmaceutical quality assurance.

(7) A nuclear pharmacy or non-resident nuclear pharmacy shall maintain, in readily retrievable form, detailed records of the acquisition, inventory, and disposition of all radiopharmaceuticals for at least three years.

(8) Unless otherwise permitted for emergency use, a nuclear pharmacy or non-resident nuclear pharmacy may only dispense radiopharmaceuticals and adjunct medications commonly used in nuclear medicine pursuant to a valid prescription.

(9) A nuclear pharmacy or non-resident nuclear pharmacy may provide radiopharmaceuticals to Authorized Users in amounts necessary for emergency use and shall maintain records regarding such to include:
(a) names of each Authorized User and institution;
(b) amounts of radioactive material and non-radioactive material provided; and
(c) dates provided.

(10) If a radiopharmaceutical provided pursuant to 247 CMR 13.03(9) has been used, the nuclear pharmacy or non-resident nuclear pharmacy shall, within 72 hours, obtain a valid prescription for each radiopharmaceutical administered that contains the date of administration and all information required by 105 CMR

721.000. The prescription shall be assigned a serial number.

(11) If a radiopharmaceutical provided pursuant to 247 CMR 13.03(9) has not been used, the nuclear pharmacy or non-resident nuclear pharmacy shall obtain and record verification to that effect from the Authorized User to whom it was provided.

(12) A nuclear pharmacy or non-resident nuclear pharmacy shall document in a readily retrievable record, the name and amount of any radiopharmaceutical that has been returned for disposal.

(13) In addition to any other labeling required by federal or state laws or regulations, each radiopharmaceutical shall be placed in an outer shielding container with a label bearing the following information:
(a) all information required by USP <825>;
(b) all information required by M.G.L. c. 94C, § 21 including the patient's name or space for patient's name; and
(c) lot number, if applicable.

(14) Environmental Monitoring (EM) Action Levels in International Standards Organization (ISO) Classified Areas
(a) Action levels shall be defined by USP <825> or Board policy, whichever is stricter.
(b) A nuclear pharmacy and non-resident nuclear pharmacy shall immediately respond to and properly remediate action level EM results.
(c) A nuclear pharmacy and non-resident nuclear pharmacy shall maintain a written policy and procedure for remediation of action level EM results.

(15) A nuclear pharmacy and non-resident nuclear pharmacy shall be exempt from the following regulations of the Board:
(a) 247 CMR 6.02(1), (2), (3), (5), (6), and (7);
(b) 247 CMR 6.13(4);
(c) 247 CMR 9.01(15);
(d) 247 CMR 9.01(19);
(e) 247 CMR 9.16(7);
(f) 247 CMR 9.18;
(g) 247 CMR 9.19(1) and (7);
(h) 247 CMR 9.19(9), (10), and (13);
(i) 247 CMR 17.00; and
(j) 247 CMR 18.00.

13.04: Licensure Requirements for a Nuclear Pharmacy or Non-Resident Nuclear Pharmacy

(1) A resident nuclear pharmacy shall have a Massachusetts-licensed Authorized Nuclear Pharmacist as the Manager of Record.

(2) A non-resident nuclear pharmacy shall have a Massachusetts-licensed Authorized Nuclear Pharmacist as the Designated Pharmacist-in-Charge.

(3) An application for a nuclear pharmacy or non-resident nuclear pharmacy shall be made on forms prescribed by, and available from the Board or its authorized agent and shall include:
(a) a completed application form;
(b) payment of a non-refundable fee;
(c) a controlled substance registration application and non-refundable fee for nuclear pharmacies that are to be located in Massachusetts in accordance with M.G.L. c. 94C, § 7;
(d) proof of good standing from the state where a non-resident nuclear pharmacy is located dated within three months of the application submission date; and
(e) any additional information, as required by the Board.

(4) The applicant shall provide and maintain the following on the premises:
(a) The most recent edition of USP, including the latest supplement thereto;
(b) access to laws and regulations governing the practice of pharmacy;
(c) current texts on the practice of nuclear pharmacy; and
(d) equipment and supplies necessary to prepare, compound, and dispense radiopharmaceuticals.

(5) The applicant shall achieve a satisfactory Board inspection of the proposed nuclear pharmacy or non-resident nuclear pharmacy prior to the issuance of a license. In the case of a non-resident nuclear pharmacy, the Board may require the inspection to be performed by an agent of the Board or by a Board-approved inspector. All costs associated with third-party inspections shall be paid by the applicant.

(6) If the Board is satisfied that an applicant complies with the requirements of 247 CMR 2.00 *et seq*. and will operate in compliance with regulations and guidance issued by the FDA, and either the NRC or Agreement State Program, it may issue a license.

13.05: Licensure Renewal for a Nuclear Pharmacy or Non-Resident Nuclear Pharmacy

(1) A nuclear pharmacy license or non-resident nuclear pharmacy license shall expire on December 31st of each odd numbered year.

(2) An application for renewal of a nuclear pharmacy or non-resident nuclear pharmacy license and controlled substance registration (if applicable) shall be made by a duly authorized representative of the pharmacy in the same manner as other pharmacies as specified in 247 CMR 6.00 including payment of non-refundable fees.

(3) A nuclear pharmacy or non-resident nuclear pharmacy shall achieve a satisfactory

Board inspection within the licensing period prior to renewal of the license. In the case of a non-resident nuclear pharmacy, the Board may require the inspection to be performed by an agent of the Board or by a Board-approved inspector. All costs associated with third-party inspections shall be paid by the licensee.

13.06: Remodeling, Change in Configuration, or Change in Square Footage

A resident nuclear pharmacy shall apply to the Board for approval to remodel or change the configuration or square footage of the Board-licensed area and may not commence any construction work or remodeling until it receives approval from the Board. An application shall be made in the same manner as other pharmacies as specified in 247 CMR 6.00.

13.07: Reporting Requirements

In addition to the applicable reporting requirements of 247 CMR 20.00, the following shall be reported in a manner and format determined by the Board:

(1) any defective compounded sterile or complex non-sterile preparation dispensed into, within, or from Massachusetts;
(2) any action level EM results; and
(3) any failure of certification of any primary or secondary engineering control.

REGULATORY AUTHORITY

247 CMR 13.00: M.G.L. c. 94C, §§ 6 and 7, M.G.L c. 112, §§ 24, 39, 39B, 39J, and 42A.