

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 680 Department of Agency: Alabama State Board of Pharmacy

Rule No. 680-X-2-.20

Rule Title: **NUCLEAR PHARMACY**

 New xx Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule. NO

Are all facets of the rule making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer Mitzi G. Ellenburg
Mitzi G. Ellenburg, Director of Operations

Date: September 22, 2016

(DATE FILED)
(STAMP)

**ALABAMA STATE BOARD OF PHARMACY
NOTICE OF INTENDED ACTION**

AGENCY NAME: ALABAMA STATE BOARD OF PHARMACY

RULE NO. AND TITLE: 680-X-2-.20 NUCLEAR PHARMACY

INTENDED ACTION: AMENDED

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend this rule due to a typographical error in (1)(d) line 2. Reference should be §34-23-1(5) not §34-23-1 (11).

TIME, PLACE, MANNER OR PRESENTING VIEW:

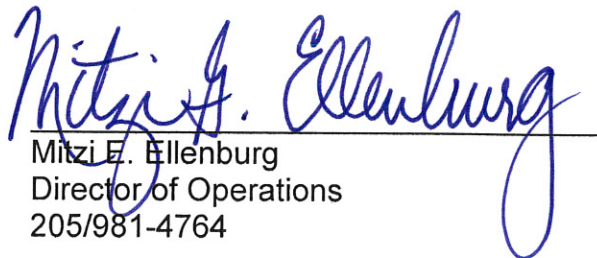
Comments can be presented at the public hearing scheduled at 9:00 a.m. on November 16, 2016 at the Alabama State Board of Pharmacy located at 111 Village Street, Birmingham, Alabama 35242. Additionally, written comments may be addressed to Mitzi Ellenburg, Director of Operations, Alabama State Board of Pharmacy, at the same address. Written comments must be received in the Board Office no later than 4:00 p.m. on December 5, 2016.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

December 5, 2016

CONTACT PERSON AT AGENCY:

Mitzi Ellenburg
Director of Operations
205/981-4764


Mitzi E. Ellenburg
Director of Operations
205/981-4764

680-X-2-.20. NUCLEAR PHARMACY.

(1) Purpose and Scope: It is unlawful to receive, possess or transfer radioactive drugs, except in accordance with appropriate pharmacy statute(s) and rule(s). It is also unlawful for any person to provide radiopharmaceutical services unless he/she is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with appropriate pharmacy statute(s) and the State Board of Pharmacy rule(s) and rules of the State Board of Health relating to radiation control. No person may receive, acquire, possess, use, transfer or dispose of any radioactive materials except in accordance with the conditions of a radioactive materials license issued by the State Board of Health. The requirements of these Nuclear Pharmacy Regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Board of Health.

(2) Definitions: For the purpose of this rule, the following words and phrases pertaining to the practice of nuclear pharmacy shall have the respective meanings ascribed by this action:

(a) Nuclear Pharmacy - A pharmacy which provides a radiopharmaceutical service.

(b) Nuclear Pharmacist - An actively licensed pharmacist who has met the training qualifications as described in the rule.

(c) Radiopharmaceutical Service - Shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping or disposal of radiopharmaceuticals.

(d) Radiopharmaceutical - Any substance defined as a drug in Code of Alabama 1975, §34-23-1(44 5) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium containing salts which contain trace quantities of naturally occurring radionuclides.

(e) Radiopharmaceutical Quality Assurance - Includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(f) Authentication of Product History - Includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

(3) Registration and Certification of Pharmacies: The application for a certificate to operate a nuclear pharmacy shall only be issued to a pharmacy registered by the Alabama State Board of Pharmacy and to a licensed, certified nuclear pharmacist. Re-certification shall be biennially which shall expire on

December 31 of even-numbered years on forms provided by the Board. Each nuclear pharmacy shall designate a licensed, certified nuclear pharmacist as the Supervising Pharmacist.

(4) **Registration and Certification of Pharmacists:** All pharmacists engaged in the practice of nuclear pharmacy shall have training or shall have demonstrated previous training in the safe handling of radioactive pharmaceuticals. They must be registered with and certified by the Alabama State Board of Pharmacy. Applications and re-certification with the Board is required biennially which shall expire on December 31 of even-numbered years on forms provided by the Board. Satisfactory completion of no less than two (2) hours of continuing education prior to re-certification earned in the previous calendar year related to nuclear pharmacy shall be required.

(5) **General requirements:** A licensed, certified nuclear pharmacist shall personally supervise the operation of only one nuclear pharmacy during all times the radiopharmaceutical services are being performed.

(a) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(b) Each nuclear pharmacist shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(c) All nuclear pharmacies shall provide a secure radioactive storage and decay area.

(d) All nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(e) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order, from a licensed medical practitioner or his/her authorized agent authorized to possess, use and administer radiopharmaceuticals.

(f) A nuclear pharmacist may transfer radioactive materials to an *authorized user in accordance with all applicable laws and regulations.

(g) A nuclear pharmacy, upon receiving an oral order for a radiopharmaceutical, shall immediately have the order reduced to writing or recorded in a data processing system which writing or records shall contain at least the following:

1. The name of the authorized user or his/her agent.
2. The date of distribution and the time of calibration of the radiopharmaceutical.
3. The name of the procedure.

(*) *"Authorized user" means a practitioner of the healing arts who is identified as an authorized user on a license issued by the State Board of Health that authorizes the medical use of radioactive material, hazards, and the applicable regulations of the U.S. Nuclear Regulatory Commission.*

4. The name of the radiopharmaceutical.
5. The dose or quantity of the radiopharmaceutical.
6. The prescription number assigned to the order for the radiopharmaceutical.
7. Any specific instructions.
8. The initials of the person dispensing the radiopharmaceutical.
9. Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded.

(h) In addition to other labeling requirements of the state laws and rules of the Board of Pharmacy for nonradioactive pharmaceuticals, the immediate outer shield of a radiopharmaceutical to be distributed shall also be labeled with:

1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".
3. The name of the procedure.
4. The prescription number of the radiopharmaceutical and a suitable lot number for traceability.
5. The radionuclide and chemical form.
6. The amount of radioactivity and the calibration date and time.
7. The expiration date and time.
8. The volume dispensed if liquid chemical form.
9. The number of items or weight if solid chemical form.
10. The number of ampules or vials if gaseous chemical form.
11. Molybdenum-99 content to USP limits.
12. The name of the patient, or the words, "Physician's Use Only", in the absence of a patient name.

(i) The immediate inner container label of a radiopharmaceutical to be distributed shall also be labeled with:

1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".
3. The radionuclide.
4. The chemical form.
5. The name of the procedure.
6. The prescription number of the radiopharmaceutical.

(6) Minimum Requirement for Space, Equipment, Supplies, and Publication: In order to insure compliance with general safety requirements as set forth above, the following minimum requirements shall be met by a nuclear pharmacy, which operates pursuant to a permit issued by the Alabama Board of Pharmacy, and engages in providing radiopharmaceutical services. These requirements are in addition to the minimum requirements for space, equipment and supplies for other types of pharmacies, and those requirements of the State of Alabama Department of Public Health, Radiological Health Branch, for the control of radiation. Such minimum permit requirements are set forth as follows:

(a) Space - The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such nonradioactive pharmaceuticals from pharmacy areas.

(b) Equipment:

1. Fume hood
2. Shielded radiation containment drawing section
3. Dose calibrator
4. Well scintillation counters
5. Area rate meters
6. Geiger-Mueller (GM) survey meters
7. Refrigerator
8. Microscope
9. Hemocytometer
10. Leaded glass syringe and vial shields
11. Personnel radiation detection devices
12. Radioactive storage container and/or storage vault for waste materials

(c) Supplies:

1. Syringes and vials required to perform practice
2. Disposable gloves and protective lab coats
3. Appropriate supplies to ensure aseptic technique
4. Appropriate supplies to perform thin layer chromatography
5. Lead transport shields for syringes and vials
6. D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(7) Training Qualifications: A pharmacist licensed to practice pharmacy in this state, who performs a radiopharmaceutical service, shall, prior to engaging in such specialized practice, meet the minimum training requirements of didactic study, training and experience in the handling of radioactive material.

(a) A licensed pharmacist seeking to practice nuclear pharmacy in this state, shall submit to the Board of Pharmacy, a certificate of training and a course outline from an accredited college of pharmacy, or other program recognized by the State of Alabama Department of Public Health, Radiological Health Branch and the Alabama Board of Pharmacy, and a certificate of such training which provides a minimum of 200 clock hours of formal didactic training. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation
2. Radiation Protection
3. Mathematics pertaining to the use and measurement of radioactivity
4. Radiation Biology

5. Radiopharmaceutical chemistry

(b) The minimum on-the-job training which shall be included in a radiopharmacy internship is five hundred (500) hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:

1. Ordering, receiving and unpackaging radioactive material safely, including performing related radiation surveys.
2. Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.
3. Calculating, preparing and verifying patient doses while maintaining radiation safety standards of shielding.
4. Following appropriate internal control procedures to prevent mislabeling.
5. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures and surveys.
6. Eluting Technetium-99 from generator systems, assaying the eluate for technetium-99m, for molybdenum-99 contamination, and processing the eluate with reagent radiopharmaceuticals.
7. Clinical practice concepts.

Author: ~~Herb Bobo, R.Ph.~~ Dr. Susan P. Alverson, Secretary
Statutory Authority: Code of Alabama 1975, § 34-23-92.
History: Adopted: June 8, 1989; Effective July 31, 1989;
Amended July 18, 2012; Effective August 27, 2012; Amended.

APA-6

**ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 41-22-23(f))**

Control No. 680 Department of Agency: Alabama State Board of Pharmacy

Rule No.: 680-X-2-.20

Rule Title: **NUCLEAR PHARMACY**

 New XX Amend Repeal Adopt by Reference

 X This rule has no economic impact.

 This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:
2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:
3. EFFECT OF THIS RULE ON COMPETITION:
4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:
7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:
8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:
10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

**** Additional pages may be used if needed.**