

STATE OF KANSAS
KANSAS PHARMACY BOARD

NOTICE OF PUBLIC HEARING ON PROPOSED ARTICLE

A public hearing will be conducted at 9:00 a.m., on the 9th day of September, 2010, at the Via Christi Hospital on Harry Street, Conference Room A, 3600 E. Harry, Wichita, KS 67218 to consider the adoption of 68-10-4 through 68-10-6 of the Kansas Pharmacy Board.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed 68-10-4 through 68-10-6. All parties may submit written comments prior to the hearing to the Executive Secretary of the Kansas Pharmacy Board, Debra Billingsley, pharmacy@pharmacy.ks.gov or Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231. All interested parties will be given a reasonable opportunity to present their views orally on the proposed regulation during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request each participant to limit any oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056. Handicapped parking is available.

A summary of the amended regulation is as follows:

68-10-4. Definitions. This regulation defines various terms that are used in the nuclear pharmacy regulations, Chapter 68, Article 10.

68-10-5. General requirements. This regulation provides the general requirements for nuclear pharmacies.

68-10-6. Minimum equipment. This regulation establishes minimum equipment to be present in restricted areas of nuclear pharmacies.

The above regulations will have minimal economic impact.

Copies of the regulation and the economic impact statement may be obtained from the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056, or by accessing the Board's website at <http://www.accesskansas.org/pharmacy/leg.html>.

Debra Billingsley
Executive Secretary

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ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-420(b), the Kansas Pharmacy Board submits the following description of the economic impact of proposed regulation K.A.R. 68-10-4 through 68-10-6.

1. These regulations identify requirements for the provision of nuclear pharmacy services. This regulation will impact nuclear pharmacists, nuclear pharmacy technicians and nuclear pharmacies as it spells out standards of nuclear pharmacy practice and equipment.
2. The proposed regulations are not mandated by federal laws.
3. No new costs will be borne by pharmacists, pharmacy technicians, or others.
4. The Board is not aware of any less costly or less intrusive methods to achieve the stated purpose and thus none were considered.
5. This is not a proposed environmental regulation.

68-10-4. Definitions. As used in these regulations, the following terms shall have the following meanings specified in this regulation:

(a) "Authentication of product history" means the identification of the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Authorized nuclear pharmacist" means a pharmacist who holds a current license issued by the board and who is listed as an authorized user on a radioactive material user's license, certified as a nuclear pharmacist by the board of pharmaceutical specialties, or meets the following requirements:

(1) Meets minimal standards of training for status as an authorized nuclear pharmacist (ANP), as specified by the Kansas department of health and environment or, if in another state, the nuclear regulatory commission or that state's nuclear regulatory agency;

(2) has successfully completed at least 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or other training program recognized by the nuclear regulatory commission, with the following subjects covered:

(A) Radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) radiation biology; and

(E) radiopharmaceutical chemistry;

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JAN 20 2010

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(3) has attained at least 500 hours of clinical or practical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist in the following areas, as described in the current American pharmaceutical association (APhA) nuclear pharmacy practice standards:

- (A) Procuring radioactive materials;
- (B) compounding radiopharmaceuticals;
- (C) performing routine quality control procedures;
- (D) dispensing radiopharmaceuticals;
- (E) distributing radiopharmaceuticals;
- (F) implementing basic radiation protection procedures; and
- (G) consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(4) keeps documentation of experience and training available in the pharmacy for board review.

(c) "Compounding" means the act of combining two or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and the relationship between the practitioner, patient, and pharmacist. Compounding shall not mean the routine preparation, mixing, or assembling of drug products that are essentially copies of a commercially available product. Compounding shall occur only in the pharmacy where the drug or device is dispensed to the patient or caregiver. This term shall include the

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preparation of drugs or devices in anticipation of prescription orders based upon routine, regularly observed prescribing patterns.

(d) "Nuclear pharmacy" means a registered pharmacy that provides radiopharmaceutical services and has notified the board that the pharmacy provides these services at least 30 days before providing the services. For purposes of these regulations, a nuclear pharmacy is not a retail pharmacy.

(e) "Nuclear pharmacy technician" means a technician who holds a current pharmacy technician registration issued by the board and meets the requirements to qualify as a nuclear pharmacy technician in K.A.R. 68-5-16(c).

(f) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through ensuring the safe and efficacious use of radiopharmaceuticals and related drugs.

(g) "Pharmacist in charge" shall have the meaning specified in K.S.A. 65-1626 (cc) and amendments thereto. In addition, the pharmacist in charge for a nuclear pharmacy shall be an authorized nuclear pharmacist.

(h) "Quality assurance procedures" means all activities necessary to ensure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(i) "Quality control testing" means the performance of appropriate chemical and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting

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JAN 20 2010

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data to determine the suitability of these radiopharmaceuticals for use in humans and animals.

(j) "Radiopharmaceutical" means any substance that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. This term shall include any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance and any product that is labeled as containing a radionuclide or intended solely to be labeled as containing a radionuclide. This term shall not include drugs including carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

(k) "Radiopharmaceutical services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, recordkeeping, and disposal of radiochemicals, radiopharmaceuticals, and ancillary drugs. This term shall include quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(l) "Restricted area" means the area in a nuclear pharmacy in which radioactive material is present. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1630, K.S.A. 65-1634, and K.S.A. 2008 Supp. 65-1642; effective P-

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JAN 20 2010

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68-10-5. General requirements. (a) Each nuclear pharmacy shall employ an authorized nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of an authorized nuclear pharmacist, who shall be in attendance when the pharmacy is open for business. The pharmacist in charge shall be responsible for all operations of the pharmacy.

(b) Each nuclear pharmacy shall hold a current radioactive material license issued by the Kansas department of health and environment or, if in another state, the nuclear regulatory commission or that state's nuclear regulatory agency. Copies of inspection reports from the Kansas department of health and environment or, if in another state, the nuclear regulatory commission or that state's nuclear regulatory agency shall be available for board inspection.

(c) Each nuclear pharmacy shall have equipment, commensurate with the scope of services required and provided, that meets the equipment requirements established for all pharmacies in the state. Each nuclear pharmacy handling radiopharmaceuticals shall include a restricted area.

(d) The restricted area shall be secured from unauthorized personnel, totally enclosed, and lockable.

(e) The pharmacist in charge at each nuclear pharmacy shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with board and nuclear regulatory commission statutes and regulations.

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JAN 20 2010

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(f) All radiopharmaceuticals shall be compounded and dispensed in accordance with accepted standards of radiopharmaceutical quality assurance, including compounded sterile products.

(g) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Kansas department of health and environment or, if in another state, the nuclear regulatory commission or that state's nuclear regulatory agency authorized to possess, use, and administer the drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from the licensed practitioner. A radiopharmaceutical may be transferred to a person who is authorized to possess and use the drug for nonclinical applications.

(h) An authorized nuclear pharmacist or nuclear pharmacy technician working in a nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall have the prescription order reduced to writing or recorded in a data processing system. This writing or record shall contain at least the following:

- (1) The name of the institution and either the prescriber or the prescriber's agent;
- (2) the date of dispensing or calibration and the calibration time of the radiopharmaceutical;
- (3) the name of the procedure;
- (4) the name of the radiopharmaceutical;
- (5) the dose or quantity of the radiopharmaceutical;
- (6) the serial number assigned to the order for the radiopharmaceutical;
- (7) any specific instructions; and

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JAN 20 2010

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(8) the initials of the pharmacist who dispensed the order.

(i) If a prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded before dispensing.

(j) The outer container shield of each radiopharmaceutical to be dispensed shall be labeled with the following:

- (1) The name and address of the nuclear pharmacy;
- (2) the name of the prescriber;
- (3) the date of dispensing or calibration;
- (4) the serial number assigned to the order for the radiopharmaceutical;
- (5) the standard radiation symbol;
- (6) the words "Caution Radioactive Material";
- (7) the name of the procedure;
- (8) the name of the radionuclide and its chemical form;
- (9) the amount of radioactivity and the calibration date and time;
- (10) if a liquid, the volume;
- (11) if a solid, the number of items or weight;
- (12) if a gas, the number of ampules or vials;
- (13) the expiration date and time; and
- (14) the name of the patient or, in absence of the patient's name, the words "Per Physician's Orders."

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DEPT. OF ADMINISTRATION

JAN 20 2010

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(k) If the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall appear on the label. The requirements of this subsection shall be met if the name of the patient is readily retrievable from the patient's physician upon demand.

(l) The inner container label of a radiopharmaceutical to be dispensed shall be marked with at least the following:

- (1) The standard radiation symbol;
- (2) the identity of the radionuclide;
- (3) the amount of radioactivity and the calibration date and time;
- (4) the name of the procedure; and
- (5) the serial number of the radiopharmaceutical.

(m) If a radiopharmaceutical is dispensed under the authority of an investigational new drug (IND) application, the nuclear pharmacy records shall include the following:

- (1) An investigator's protocol for the preparation of the radiopharmaceutical;
- (2) a copy of the approval by an institutional radiation safety committee or an equivalent radioactive use oversight committee;
- (3) a copy of the institutional review board's approval form or letter; and
- (4) a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(n) Each nuclear pharmacy shall have a reference library that meets the requirements of K.A.R. 68-2-12a and a current copy of the state and federal regulations

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DEPT. OF ADMINISTRATION

JAN 20 2010

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governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(o) A quality control test in accordance with package insert or a validated alternate method meeting the current USP/NF guidelines shall be performed on each compounded product before releasing the product to the customer. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634, K.S.A. 2008 Supp. 65-1637, K.S.A. 2008 Supp. 65-1642, and K.S.A. 2008 Supp. 65-1643 as amended by L. 2009, ch. 131, sec. 9; effective P- _____.)

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68-10-6. Minimum equipment. The restricted area shall have at least the following equipment:

- (a) Radionuclide dose calibrator;
- (b) refrigerator;
- (c) single- or multiple-channel scintillation counter with solid state detector;
- (d) radiochemical fume hood and filter system with air sampling equipment when dispensing or preparing volatile radiopharmaceuticals;
- (e) area survey meter;
- (f) at least two Geiger-Müller (GM) survey meters, one of which shall be a high-range meter;
- (g) microscope and hemacytometer, when dispensing or preparing particle size-dependent radiopharmaceuticals;
- (h) laminar airflow hood and supplies to ensure sterile practices for parenteral solutions;
- (i) syringe and vial radiation shields;
- (j) shielded drawing station;
- (k) decontamination supplies;
- (l) supplies to perform quality assurance testing;
- (m) transport shields for syringes and vials; and
- (n) transport containers that meet the requirements of applicable U.S. department of transportation regulations and other labels and supplies for shipping radioactive

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DEPT. OF ADMINISTRATION

JAN 20 2010

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materials. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2008 Supp. 65-1642;
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JAN 20 2010

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