7/11/2019

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

Rescind:

- 4729-15-01: Provides definition section for radiopharmaceuticals (nuclear pharmacy) chapter of the OAC.
- 4729-15-02: Requires a nuclear pharmacist to be in charge or a nuclear pharmacy and to be the responsible person on a nuclear pharmacy license.
- 4729-15-03: Provides the minimum standards for the operation of a nuclear pharmacy.
- 4729-15-04: Provides the record keeping requirements for a nuclear pharmacy.
- 4729-15-05: Includes general prohibitions regarding the operation of a nuclear pharmacy.

New:

- 4729:5-6-01: Provides definition section for radiopharmaceuticals (nuclear pharmacy) chapter of the OAC.
- 4729:5-6-02: Specifies the provisions of the Administrative Code that would apply to licensees using radiopharmaceuticals.
- 4729:5-6-03: Provides the standards for the preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals. This includes adherence to USP <825>.
- 4729:5-6-04: Provides the record keeping requirements for licensees engaged in the preparation and use of radiopharmaceuticals.
- 4729:5-8-05: Provides the requirements for non-resident licensees that prepare radiopharmaceuticals.

Comments on the proposed rules will be accepted until close of business on **July 26, 2019**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

In addition, please copy your comments to: **CSIPublicComments@governor.ohio.gov**

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Agency Contact Info: Ali Simon (ali.simon@pharmacy.ohio.gov)

Regulation/Package Title: Radiopharmaceuticals (Nuclear Pharmacy)

Rule Number(s): Rescind: 4729-15-01; 02; 03; 04; 05

New: 4729:5-6-01; 02; 03; 04 and 4729:5-8-05

Date: 7/11/2019

Rule Type:

X New
X Rescinded

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

Rescind:

- 4729-15-01: Provides definition section for radiopharmaceuticals (nuclear pharmacy) chapter of the OAC.
- 4729-15-02: Requires a nuclear pharmacist to be in charge or a nuclear pharmacy and to be the responsible person on a nuclear pharmacy license.
- 4729-15-03: Provides the minimum standards for the operation of a nuclear pharmacy.
- 4729-15-04: Provides the record keeping requirements for a nuclear pharmacy.
- 4729-15-05: Includes general prohibitions regarding the operation of a nuclear pharmacy.

New:

- 4729:5-6-01: Provides definition section for radiopharmaceuticals (nuclear pharmacy) chapter of the OAC.
- 4729:5-6-02: Specifies the provisions of the Administrative Code that would apply to licensees using radiopharmaceuticals.
- 4729:5-6-03: Provides the standards for the preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals. This includes adherence to USP <825>.
- 4729:5-6-04: Provides the record keeping requirements for licensees engaged in the preparation and use of radiopharmaceuticals.
- 4729:5-8-05: Provides the requirements for non-resident licensees that prepare radiopharmaceuticals. This includes adherence to USP <825>.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   The rules are authorized by section 4729.26 of the Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   This rule package does not implement a federal requirement nor is it required to obtain/maintain federal approval.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This rule package exceeds federal requirements because the regulation of the practice of nuclear pharmacy has traditionally been shared between the federal government and the states.

   The federal government (i.e. nuclear regulatory commission) sets forth the standards on to the handling (including proper disposal) of radioactive materials where the states are expected to set regulations necessary to ensure that the drugs are prepared in a sterile environment and are safe for patient use.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Without this regulation, the Board would not be able to provide uniform standards for the preparation of radiopharmaceuticals. There have been published reports of patient harm from mishandled radiopharmaceuticals. Patel, et al. reported 16 patients who developed hepatitis C virus infections from contaminated radiopharmaceuticals used in myocardial perfusion studies (Patel PR, et al. Hepatitis C Virus Infections From a Contaminated Radiopharmaceutical Used in Myocardial Perfusion Studies. JAMA. 2006; 296(16):2005-2011.) Moore, et al. reported several patients who developed hepatitis C virus infections from improper handling practices in a nuclear cardiology clinic (Moore ZS, et al. Transmission of Hepatitis C Virus During Myocardial Perfusion Imaging in an Outpatient Clinic. Am J Cardiol. 2011:108;126-132.)

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the regulation will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Board posted the proposed rules to its website for public comment on 5/30/2019. The rule was also distributed to the Board's CSI stakeholder distribution list and to pharmacists who work at nuclear pharmacies.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   The Board received the following comments that were incorporated into the draft rules:

   - Requested definitions should align with the definitions listed in USP 825.
   - Requested exemption for institutional facilities from having a nuclear pharmacist as the responsible person on the facility's license.
   - Requested clarification on the required reporting of adverse events to the Board. To clarify this issue, the rule draft was updated to mirror federal notification requirements.
   - Requested delay for the requirement that out-of-state pharmacies must have an Ohio-licensed pharmacist listed as the responsible person on their non-resident terminal distributor license (provision delayed until April 1, 2021).

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   The rules require adherence to USP 825. USP is a not-for-profit, science-driven organization that has an established process for convening independent experts for the development and maintenance of quality standards. The process is public health focused, leveraging current science and technology, and draws on the expertise of scientists and healthcare practitioners while providing opportunities for public input from stakeholders throughout the standard setting process.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    As the rule package is essential to protecting the public's safety by ensuring uniform standards for the preparation of radiopharmaceuticals, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform standards for the preparation of radiopharmaceuticals. At this juncture, it was the determination of the Board that the rule did not lend itself to performance-based regulations.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rule to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation. The current regulations on the preparation of radiopharmaceuticals (OAC 4729-15) are proposed for rescission as part of this rule package.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance staff are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;
Licensed terminal distributors of dangerous drugs (TDDDs) that prepare radiopharmaceuticals.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
Violation of this rule may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

- 4729:5-6-01: Provides definition section for radiopharmaceuticals (nuclear pharmacy) chapter of the OAC. This rule requires institutional facilities to submit notification to the Board of when they are engaged in the preparation of radiopharmaceuticals. It also requires the institutional facility to submit notification to the Board of the designated person that is responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, personally furnish, and repackage radiopharmaceuticals. The Board will use its existing eLicense platform to allow for notification forms to be uploaded. It is estimated that the time to complete submit each form will be between 10-20 minutes.
- 4729:5-6-02: Specifies the provisions of the Administrative Code that would apply to licensees using radiopharmaceuticals. While the rule itself does not include any additional requirements, as it serves as a reminder of the other applicable rules and regulations a licensee is subject to, a violation of this rule could result in administrative discipline for the licensee.
- 4729:5-6-03: Provides the standards for the preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals. This includes adherence to USP <825>. <USP 825> may require significant site improvements, including clean room, separation from other semi-sterile work areas, pass-through boxes, improved air filtration systems, laminar flow hoods, and changes to workflow and operational procedures. Depending on

the required updates, estimates for compliance may be upwards of $100,000. It should be noted that USP 825 was developed at the request of those involved in the preparation of radiopharmaceuticals. It also requires the submission to the Board a report relating to any "medical event." However, this is the same reporting that must be submitted to the nuclear regulatory commission so it should only take 5-10 additional minutes to submit the report to the Board of Pharmacy.

- 4729:5-6-04: Provides the record keeping requirements for licensees engaged in the preparation and use of radiopharmaceuticals. Licensees preparing radiopharmaceuticals will experience administrative costs associated with maintaining records in accordance with this rule. It should be noted that except for the addition of documenting the final check with positive identification, the requirements are similar to those currently in effect. As stated previously, the cost of implementing positive identification can range given that it can be accomplished using simple methods (i.e. a paper record with a hard copy signature) to more technologically sophisticated methods (i.e. biometric scans).
- 4729:5-8-05: Provides the requirements for non-resident licensees that prepare radiopharmaceuticals. This includes adherence to USP <825>. This includes adherence to USP <825>. <USP 825> may require significant site improvements, including clean room, separation from other semi-sterile work areas, pass-through boxes, improved air filtration systems, laminar flow hoods, and changes to workflow and operational procedures. Depending on the required updates, estimates for compliance may be upwards of $100,000. It should be noted that USP 825 was developed at the request of those involved in the preparation of radiopharmaceuticals. It also requires the submission to the Board a report relating to any "medical event." However, this is the same reporting that must be submitted to the nuclear regulatory commission so it should only take 5-10 additional minutes to submit the report to the Board of Pharmacy.

  The rule also requires all nonresident pharmacies that are selling radiopharmaceuticals into Ohio to have a responsible person who is an Ohio licensed pharmacist. Pharmacists licensed in Ohio may apply to the Board for reciprocity. The cost of an initial license by reciprocity is $337.50. This provision goes into effect April 1, 2021 (to coincide with license renewal).

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board believes that the regulatory intent of the proposed rule is necessary to protect the health and safety of all Ohioans by ensuring uniform rules for the preparation of radiopharmaceuticals. The standards set forth in this proposed rule chapter include strategies

to maintain patient safety while also ensuring the safety of individuals performing these activities.

There have been published reports of patient harm from mishandled radiopharmaceuticals. Patel, et al. reported 16 patients who developed hepatitis C virus infections from contaminated radiopharmaceuticals used in myocardial perfusion studies (Patel PR, et al. Hepatitis C Virus Infections From a Contaminated Radiopharmaceutical Used in Myocardial Perfusion Studies. JAMA. 2006; 296(16):2005-2011.) Moore, et al. reported several patients who developed hepatitis C virus infections from improper handling practices in a nuclear cardiology clinic (Moore ZS, et al. Transmission of Hepatitis C Virus During Myocardial Perfusion Imaging in an Outpatient Clinic. Am J Cardiol. 2011:108;126-132.)

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulations are uniform across Ohio.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations.

However, any failure of a standard of care in the practice of pharmacy or the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:5-6 – Nuclear Pharmacies & Radiopharmaceuticals

(NOTE: Rescinds Chapter 4729-15)

4729:5-6-01 – Definitions – Nuclear Pharmacies & Radiopharmaceuticals

As used in Chapter 4729:5-6 of the Administrative Code:

(A) “Radiopharmaceutical,” “radiopharmaceutical preparation,” or “radioactive drug” means a finished dosage form of a dangerous drug that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms “radiopharmaceutical” and “radioactive drug” are commonly used interchangeably.

(B) “Authorized nuclear pharmacist” means a licensed pharmacist that meets the requirements 10 CFR 35.55 (7/16/2018).

(C) “Authorized user prescriber” or “authorized user” means a licensed physician, dentist or podiatrist that meets the definition of authorized user in 10 CFR 35.2 (7/16/2018). Pursuant to section 4729.541 of the Revised Code any authorized user prescriber engaged in the compounding of radiopharmaceuticals, which includes preparation, shall be licensed as a terminal distributor of dangerous drugs.

(D) "Beyond-use date" means the assigned date and time beyond which the radiopharmaceutical must not be administered.

(E) "Compounding" has the same meaning as in USP <825>.

(F) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(G) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(H) “Final check” means the final verification check for accuracy and conformity to the formula of the compounded preparation or product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(I) “Kit” means a commercially manufactured package containing all ingredients required to prepare a radiopharmaceutical with the exception of the radionuclide.

(J) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(K) "Non-sterile compounded drug" means a dangerous drug preparation intended to be non-sterile.

(L) "Nuclear pharmacy" is a pharmacy licensed as a terminal distributor of dangerous drugs where prescriptions for radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. A nuclear pharmacy shall also be licensed by the United States nuclear regulatory commission or the appropriate state nuclear regulatory agency.

(M) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring and provide personal review and approval of all professional activities.

(N) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting. All dispensing requirements (i.e. records, processes, etc.) in USP <825> shall also apply to personally furnishing.

(O)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(P) “Preparing” or “preparation” means the act of combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.

(Q) “Product” means a drug in a commercially manufactured pharmaceutical dosage form that has been evaluated for safety and efficacy by the United States food and drug administration. Products are accompanied by full prescribing information, which is commonly known as the United States food and drug administration-approved manufacturer's labeling or product package insert.

(R) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(S) “Responsible person” has the same meaning as in rule 4729:5-2-01 of the Administrative Code who is responsible for supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(1) Except as provided in paragraph (S)(3) of this rule, a nuclear pharmacy shall have an authorized nuclear pharmacist as its responsible person. Responsible person shall also mean the “designated person” as used in USP 825.

(2) Except as provided in paragraph (S)(3) of this rule, a terminal distributor of dangerous drugs that is not a nuclear pharmacy but is engaged in the preparation, compounding, personally furnishing, or repackaging of radiopharmaceuticals shall have an authorized user prescriber or nuclear pharmacist as its responsible person. Responsible person shall also mean the “designated person” as used in USP 825.

(3) An institutional facility licensed as a terminal distributor of dangerous drugs that is engaged in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals shall comply with the following:

(a) Submit notification to the board, in a manner determined by the board, that the facility is engaged in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals.

(i) For new facilities, the institutional facility shall notify the board within ten days of the date the facility engages in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals.

(ii) For existing facilities, the institutional facility shall notify the board within ten days of the effective date of this rule.

(b) An institutional facility that ceases to engage in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals shall submit notification to the board, in a manner determined by the board, within ten days of cessation.

(c) The facility shall have a designated person who is an authorized user prescriber or nuclear pharmacist employed by the facility that is responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, personally furnish, and repackage radiopharmaceuticals. For a nuclear pharmacy, the designated person shall be a nuclear pharmacist.

(i) For new facilities, the institutional facility shall notify the board of the designated person within ten days of the date the facility engages in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals.

(ii) For existing facilities, the institutional facility shall notify the board of the designated person within ten days of the effective date of this rule.

(iii) If there is a change in the designated person, the board shall be notified within ten days of the effective date of the appointment of the new designated person.

(T) "Sterile" means a dosage form free of living microorganisms (aseptic).

(U) "Sterile compounded drug" means a dangerous drug preparation intended to be sterile.

(V) “United States Pharmacopeia Chapter <825>” or “USP <825>” means United States Pharmacopeia Chapter <825>, USP 42-NF 37 2S, or any official supplement thereto (12/1/2019).

4729:5-6-02 – Applicability

(A) The provisions in this chapter apply to the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals for humans and animals prepared by a pharmacy or prescriber licensed as a terminal distributor of dangerous drugs. These standards apply to all radiopharmaceuticals, including those with radionuclides that emit a single photon, a positron, or a therapeutic particle, and intravascular radioactive devices (e.g. radioactive microspheres).

(B) This chapter applies to all the following:

(1) Nuclear pharmacies located in this state; and

(2) Facilities located in this state where an authorized user prescriber is engaged in the preparation, compounding, personally furnishing, or repackaging of radiopharmaceuticals. Such facilities shall maintain all applicable licenses as required by federal and state laws, rules and regulations.

(C) This chapter does not apply to the preparation, compounding, dispensing, personally furnishing, and repackaging of non-radioactive drugs, including those used as pharmacologic adjuncts for certain nuclear medicine procedures. These drugs shall be prepared in accordance with the applicable provisions of division 4729:7 of the Administrative Code.

(D) Except if specifically stated in this chapter, an outpatient pharmacy shall also comply with chapter 4729:5-5 of the Administrative Code.

(E) Except if specifically stated in this chapter, an institutional pharmacy shall also comply with chapter 4729:5-9 of the Administrative Code.

(F) An authorized user prescriber shall also comply with chapter 4729:5-19 of the Administrative Code.

(G) Except if specifically stated in this chapter, a nonresident nuclear pharmacy shall comply with the requirements of rule 4729:5-8-05 of the Administrative Code.

(H) All terminal distributors of dangerous drugs engaged in the preparation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals for humans and animals shall comply with 10 CFR Part 35 (7/16/2018).

4729:5-6-03 – Preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals.

(A) A terminal distributor of dangerous drugs engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals for humans and animals shall comply with USP <825>.

(B) All radiopharmaceuticals shall be dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs. A limited quantity may be prepared in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(C) All radiopharmaceuticals are exempt from labeling requirements of division 4729:5 of the Administrative Code.

(1) Radiopharmaceuticals shall be labeled in accordance with USP <825> and the outer shielding must also be labeled with the following:

(a) If a pharmacy, the name and telephone number of the pharmacy;

(b) The name of the ordering prescriber;

(c) The lot number of the preparation; and

(d) The prescription number.

(2) The patient's name (first and last or first initial and last name) shall be included on the label for the outer shielding and inner container for all therapeutic and blood-products.

(D) The terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) The terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) All personnel trained to work with radiopharmaceuticals shall do so under the personal supervision of an authorized nuclear pharmacist or an authorized user prescriber.

(F) A terminal distributor shall report to the state board of pharmacy, immediately upon discovery and in a manner determined by the board, adverse events potentially associated with the quality of a radiopharmaceutical preparation.

(G) A terminal distributor shall report any event as a medical event, except for an event that results from patient intervention, to the state board of pharmacy that meets the criteria listed in 10 CFR 35.3045 (7/16/2018).

(1) The terminal distributor shall notify by telephone the state board of pharmacy no later than the next calendar day after discovery of the medical event.

(2) The terminal distributor shall submit a written report, in a manner determined by the board, within fifteen days after discovery of the medical event. The written report shall include the following:

(a) The licensee's name;

(b) The name of the prescriber;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the individual(s) who received the administration;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

4729:5-6-04 – Record keeping.

(A) In addition to the record keeping requirements of rules 4729:5-5-04, 4729:5-9-04, or 4729:5-19-04 of the Administrative Code, a terminal distributor shall maintain records in compliance with USP <825> for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, dispensing, or personally furnishing radiopharmaceuticals.

(B) In addition to the requirements set forth in paragraph (A) of this rule, there shall be positive identification of the authorized nuclear pharmacist or authorized user prescriber conducting the final check of the radiopharmaceutical.

(C) All records maintained in accordance with this rule shall be readily retrievable and uniformly maintained for at least three years.

(1) Except as provided in paragraph (C)(2) of this rule, all records maintained in accordance with this rule shall be kept on-site.

(2) A pharmacy located in this state intending to maintain records pursuant to this rule at an alternate location must first send a written request to the state board of pharmacy. The request shall contain the pharmacy's name and license number and the name and address of the alternate location. The state board of pharmacy will send written notification to the pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to authorized personnel or contractors of the pharmacy.

(D) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features, such as unique user names and passwords, to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.

(E) All records required in accordance with this rule shall be maintained under appropriate supervision and control to restrict unauthorized access.

4729:5-8-05 – Preparation, compounding, dispensing, and repackaging of radiopharmaceuticals by a nonresident pharmacy.

(A) Except as otherwise provided in this rule, terms used in this rule have the same meaning as in rule 4729:5-6-01 of the Administrative Code.

(B) Only a pharmacy licensed as a nonresident terminal distributor of dangerous drugs may dispense or sell patient-specific radiopharmaceuticals in this state and shall comply with all the following:

(1) All radiopharmaceuticals shall be dispensed pursuant to a patient-specific prescription or order issued by a licensed health professional authorized to prescribe drugs. A limited quantity may be prepared in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(2) Comply with the requirements of USP <825>; and

(3) Shall have an authorized nuclear pharmacist licensed in this state as its responsible person. The requirement for the responsible person to obtain Ohio licensure shall take effect on April 1, 2021.

(C)

(1) Radiopharmaceuticals shall be labeled in accordance with USP <825> and the outer shielding must also be labeled with the following:

(a) If a pharmacy, the name and telephone number of the pharmacy;

(b) The name of the ordering prescriber;

(c) The lot number of the preparation; and

(d) The prescription number.

(2) The patient's name (first and last or first initial and last name) shall be included on the label for the outer shielding and inner container for all therapeutic and blood-products.

(D) A pharmacy licensed as a nonresident terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) A pharmacy licensed as a nonresident terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) A pharmacy licensed as a nonresident terminal distributor shall report any event as a medical event, except for an event that results from patient intervention, to the state board of pharmacy that meets the criteria listed in 10 CFR 35.3045 (7/16/2018).

(1) The terminal distributor shall notify by telephone the state board of pharmacy no later than the next calendar day after discovery of the medical event.

(2) The terminal distributor shall submit a written report, in a manner determined by the board, within fifteen days after discovery of the medical event. The written report shall include the following:

(a) The licensee's name;

(b) The name of the prescriber;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the individual(s) who received the administration;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(G) A pharmacy licensed as a nonresident terminal distributor shall report to the state board of pharmacy, within seventy-two hours and in a manner determined by the board, any warning letters, injunctions, or decrees issued by the United States food and drug administration or any other federal or state agency.

(H) If a pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or their license has lapsed, the pharmacy shall provide any of the following, in a manner prescribed by the board, as part of the initial or renewal application:

(1) The most recent inspection report that is less than two years old that demonstrates applicable compliance with USP <825> conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction;

(2) The most recent inspection report that is less than two years old that demonstrates applicable compliance with USP <825> rule by the national association of boards of pharmacy's verified pharmacy program; or

(3) Any other documentation of compliance as determined by the state board of pharmacy.

(I) The state board of pharmacy's executive director or the director's designee may grant a one-year, one-time extension to pharmacies licensed as nonresident terminal distributors in the event an inspection report is not available at the time of application or renewal and documentation, as specified by the board, is presented verifying intent to comply with this rule.

(J) This rule does not apply to a pharmacy licensed as a nonresident terminal distributor of dangerous drugs that prepares compounded drug preparations in accordance with rule 4729:5-8-04 of the Administrative Code.