Requirements for Non-Resident Nuclear Pharmacies

Updated 1/6/2022

This guidance applies to non-resident (i.e., out-of-state) nuclear pharmacies that prepare radiopharmaceuticals that are distributed into Ohio. A separate guidance for in-state nuclear pharmacies is available here: www.pharmacy.ohio.gov/nuclear

Effective February 1, 2022, the following nuclear pharmacy rules will go into effect:

Rule Number	Type	Tagline
4729:5-6-01	New	Definitions - nuclear pharmacies and radiopharmaceuticals. (**NOTE:** These definitions are used in OAC 4729:5-8-05)
4729:5-8-05	New	Preparation, compounding, dispensing, and repackaging of radiopharmaceuticals by a nonresident pharmacy.

Important Reminders

Licensees should be aware of the following:

- These rules require compliance with USP 825. A free version of the USP 825 can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw
- These rules apply to non-resident nuclear pharmacies that distribute radiopharmaceuticals into Ohio. The rule prohibits non-pharmacies from dispensing or selling patient-specific radiopharmaceuticals into the state.
- Requires a non-resident pharmacy to have an Ohio licensed pharmacist as the pharmacy's responsible person. ***This provision does not take effect until June 30, 2022 (see Q5 of this document for more information).***

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For questions regarding radiopharmaceutical preparation standards by non-resident pharmacies, please review the frequently asked questions starting on the next page of this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) Rule 4729:5-8-05 requires compliance with USP 825 for preparation and handling of radiopharmaceuticals. Will the Board begin enforcing USP 825 on February 1, 2022?

Yes. As a reminder, a free version of the USP 825 can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw

Q2) How are radiopharmaceuticals defined?

As used in this rule chapter, "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.

See OAC 4729:5-6-01 for additional definitions.

Q3) Are there any new notification requirements for licensees preparing radiopharmaceuticals?

Yes. OAC 4729:5-8-05 (G) requires a nuclear pharmacy licensed as a nonresident terminal distributor to report to the State Board of Pharmacy, within seventy-two hours of receipt, any warning letters, injunctions, or decrees issued by the United States Food and Drug Administration or any other Federal or State Agency.

Notifications should be submitted via email to: compliance@pharmacy.ohio.gov.

Q4) Am I required to document proof of compliance with USP 825?

Yes. If a nuclear 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 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 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 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. ***At this time, the Board has not approved any alternative documentation. Licensees that wish to provide alternate methods to demonstrate compliance should submit requests to compliance@pharmacy.ohio.gov.***

Q5) Are there any other new requirements for non-resident nuclear pharmacies?

Yes. The following are new requirements for non-resident nuclear pharmacies:

- **Responsible Person Must be Ohio Licensed by 6/30/2022:** A pharmacy licensed as a non-resident pharmacy that is engaged in the preparation and distribution of radiopharmaceuticals shall have an Ohio licensed pharmacist as the responsible person on its license.

  NOTE: If a non-resident pharmacy engages in the preparation of radiopharmaceuticals but does not ship radiopharmaceuticals into Ohio, they are not required to have a responsible person who is an Ohio-licensed pharmacist.

  For more information on changing a responsible person, please use the following links:

  Change of Responsible Person – eLicense Guidance: https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/eLicense/Change%20 of%20Responsible%20Person.pdf

Change of Responsible Person – Attestation Form:
https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/Forms/General/Chang e%20of%20Responsible%20Person%20Form.pdf

Obtaining an Ohio Pharmacist License via Reciprocity:
https://www.pharmacy.ohio.gov/documents/licensing/pharmacist/general/ohio%20pharmacist%20licensure%20by%20reciprocity.pdf