Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
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REISSUED BUSINESS IMPACT ANALYSIS (BIA) – REPLACES BIA ISSUED 10/18/2024

NOTE TO COMMENTERS: Please provide any supporting materials or estimates outlining the costs associated with the rule.

Please send all comments to the following email address:
RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Reyburn
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Regulation/Package Title (a general description of the rules' substantive content):

Sterile and Non-Sterile Drug Compounding Standards

Rule Number(s): 4729:7-1-01; 4729:7-3-04; 4729:7-2-03

Date of Submission for CSI Review: 6/12/2025

Public Comment Period End Date: 7/15/2025

Rule Type/Number of Rules:

New/___ rules	No Change/__1__ rules (FYR? _Y__)
Amended/__2__ rules (FYR? _Y__)	Rescinded/____ rules (FYR? ___)

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 regulations that have an adverse impact on business 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.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

d. ☒ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4729:7-1-01 – Provides the standards for the drug compounding chapter. Since 2015, the Board has required compliance with national compounding standards, USP 795 (for non-sterile drug compounding) and USP 797 (for sterile drug compounding). New standards have been released (effective November 1, 2023) and this rule would require compliance with those updated standards. In addition to a long implementation window (1 year from effective date), the rule also includes a provision that allows the Board to grant additional extensions for licensees who are experiencing hardships.
- 4729:7-3-04 – Provides the requirements for immediate-use drug compounding by prescribers. Removes a reference to compounding risk levels (low, medium, high-risk) from the current version of USP 797 in anticipation of the adoption of new standards in proposed OAC 4729:7-1-01. Also, makes a correction to an incorrect cross reference.

No Change:

- 4729:7-2-03: Provides the standards for compounding in a pharmacy.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rule is authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. 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 does not implement a federal requirement.

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

   These rules exceed federal requirements because the regulation of pharmacy compounding has traditionally been done at the state level by legislatively created state boards of pharmacy.

   Such standards are necessary because compounded drugs are not FDA-approved. As such, the FDA does not verify their safety, effectiveness, or quality before they are marketed. In addition, poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient.

6. **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. These rules are necessary to ensure uniform standards for the compounding of dangerous drugs in Ohio.

   Such standards are necessary because compounded drugs are not FDA-approved. As such, the FDA does not verify their safety, effectiveness, or quality before they are marketed. In addition, poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. One such example is the New England Compounding Center meningitis outbreak in 2012, which sickened 798 individuals and resulted in the deaths of more than 100 people.

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

   The success of the regulations 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.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. 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.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy. The BIA was initially issued on 10/18/24 but is being reissued to accept the most up-to-date comments. Any previous comments will still be reviewed and addressed by the Board.

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

The Board did receive comments on this rule during the initial public comment process. While some comments were supportive, others raised concerns about the full implementation of the two new drug compounding standards (USP 797 & USP 795). Some commenters asked the Board to review the national standards to determine what should be applicable to Ohio. In general, the Board tends to defer to national experts who crafted these standards.

11. 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 new compounding standards (USP 797 & USP 795) were developed using an established process and expert committee.

The full rationale/data for the changes to USP 797 can be accessed here: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/797-

commentary-20221101.pdf?_gl=1*17di8j8*_gcl_au*NDg0Nzc0Mzc1LjE3MDQ3NDEwNjc.*_ga*MTkwOTQwMDAxLjE3MDQ3NDEwNjc.*_ga_DTGQ04CR27*MTcwNDc0MTA2Ny4xLjEuMTcwNDc0MTE5My4wLjAuMA..

The full rationale/data to support the changes to USP 795 can be accessed here: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/795-commentary-20221101.pdf?_gl=1*1dypnfl*_gcl_au*NDg0Nzc0Mzc1LjE3MDQ3NDEwNjc.*_ga*MTkwOTQwMDAxLjE3MDQ3NDEwNjc.*_ga_DTGQ04CR27*MTcwNDc0MTA2Ny4xLjEuMTcwNDc0MTI2OS4wLjAuMA..

12. **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?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and distribution of dangerous drugs, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **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 rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

14. **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 rules 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 rules. In addition, the Board's compliance agents 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 quarterly webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

Terminal distributors of dangerous drugs engaged in drug compounding.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

Violation of these rules may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

Amend:

- 4729:7-1-01 – Provides the standards for the drug compounding chapter. Since 2015, the Board has required compliance with national compounding standards, USP 795 (for non-sterile drug compounding) and USP 797 (for sterile drug compounding). New standards have been released (effective November 1, 2023) and this rule would require compliance with those updated standards. In addition to a long implementation window (1 year from effective date), the rule also includes a provision

that allows the Board to grant additional extensions for licensees who are experiencing hardships.

The cost of compliance is extremely variable, ranging from minimal cost for immediate-use exemption to thousands of dollars for lower-risk compounding (Category 1) and to more than $100,000 for higher-risk compounding (Category 3).

- 4729:7-3-04 – Provides the requirements for immediate-use drug compounding by prescribers. Removes a reference to compounding risk levels (low, medium, high-risk) from the current version of USP 797 in anticipation of the adoption of new standards in proposed OAC 4729:7-1-01. This minor amendment should not result in an overall increase to prescribers engaged in immediate-use drug compounding. Also, makes a correction to an incorrect cross reference.

  For the rule in general, prescribers who are engaged in immediate-use compounding only will not be required to purchase a hood or other specialized equipment. However, prescribers who normally prepare patient-specific compounded drugs in advance for more than 6-hours will experience an increase because of having to discard the medication to prevent bacterial growth. Prescribers will also be required to prepare drugs using aseptic technique which will require, at minimum, the use of gloves and proper hand hygiene. Additional costs also include staff time for training personnel in proper compounding techniques, cleaning and disinfecting compounding areas and ensuring compliance with the rule.

  The rule also requires the reporting of the following: (1) Adverse events or product recalls potentially associated with the quality of a compounded sterile preparation; and (2) Any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration. The Board plans to use its online reporting tool to allow for licensees to submit this information electronically. This reporting requirement is expected to take anywhere between 30-60 minutes to complete.

No Change:

- 4729:7-2-03: Provides the standards for compounding in a pharmacy. This rule requires compliance with national standards in OAC 4729:7-1-01. Those costs are outlined in the section above. This rule also requires the reporting of the following: (1) Adverse events or product recalls potentially associated with the quality of a compounded sterile preparation; and (2) Any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration. The Board uses an online reporting form to allow for licensees to submit this information electronically. This reporting requirement is expected to take anywhere between 30-60 minutes to complete.

16. **Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

    N/a.

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

    The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform requirements for the preparation of compounded drugs. Such standards are necessary because compounded drugs are not FDA-approved. As such, the FDA does not verify their safety, effectiveness, or quality before they are marketed. In addition, poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient. One such example is the New England Compounding Center meningitis outbreak in 2012, which sickened 798 individuals and resulted in the deaths of more than 100 people.

Regulatory Flexibility

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

These 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 regulation is uniform across Ohio. The Board has already committed to a 1-year implementation window (e.g., a one year effective date from the date the rule can be final filed) and the rule provides additional extensions for individuals who demonstrate hardship.

19. 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 Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure to meet standards for compounding 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.

20. 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.

The Board has also developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Rule 4729:7-1-01 | Compounding references and enforcement. (AMEND)

As used in this division and in agency 4729 of the Administrative Code:

(A) "The national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings" means publication number 2016-161 ~~**or any official supplement thereto**~~ (~~**March 10, 2020**~~ **May 9, 2023**).

(B) "United States Pharmacopeia Chapter <795>" or "USP <795>" means United States Pharmacopeia Chapter <795>~~**, USP 43-NF 38, or any official supplement thereto (March 10, 2020**~~ **(November 1, 2023**).

(C) "United States Pharmacopeia Chapter <797>" or "USP <797>" means United States Pharmacopeia Chapter <797>, ~~**USP 43-NF 38, or any official supplement thereto (March 10, 2020**~~ **(November 1, 2023**).

(D) "United States Pharmacopeia Chapter <800>" or "USP <800>" means United States Pharmacopeia Chapter <800>~~**, USP 43-NF 38, or any official supplement thereto (March 10, 2020**~~ **(December 1, 2022**).

(E) The board may grant extensions to the requirements to comply with the references listed in this rule if a licensee can demonstrate the following:

(1) Significant hardship in meeting the requirements of the references; and

(2) Sufficient progress towards compliance with the references.

Rule 4729:7-3-04 | Immediate-Use, Sterile Non-Hazardous Drugs Compounded by a Prescriber. (AMEND)

(A) The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring that compounded drug preparations maintain quality and sterility until administered;

(6) Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code;

(7) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(8) Ensuring aseptic technique for the preparation of all sterile compounded drugs.

(B) Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

(1) The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(2) Personnel shall adhere to appropriate aseptic technique, including all the following:

(a) Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure; and

(b) Compounding personnel shall don gloves prior to engaging in compounding activities.

(3) If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces.

(4) The beyond-use date for an immediate-use compounded drug preparation is as follows:

(a) Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug.

(b) For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug.

(5) If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code.

(6) Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

(a) Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name;

(b) The name and quantity of each ingredient;

(c) The beyond-use date and time prepared; and

(d) The name or initials of the person who prepared the compounded drug preparation.

(7) Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber.

(8) For an immediate-use compounded drug preparation administered via injection, a new sterile needle shall be used to administer the compounded drug preparations to the patient.

(C) Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins.

(D) Preparations that **do not meet the criteria listed in paragraph (B) of this rule** ~~**are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797>**~~ shall not be prepared as immediate-use.

(E) Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code.

(F) Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(G)

(1) Except as provided in paragraph (G)(2) of this rule, compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.

(2) A prescriber may compound preparations of buffered lidocaine containing antimicrobial preservatives for anticipated needs where multiple non-patient specific doses are produced in a single activity.

(H) Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code.

(I)

(1) Except as provided for in paragraph (I)(2) of this rule, this rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling hazardous drug preparations, a prescriber who is a veterinarian shall comply with rule 4729:7-3-05 of the Administrative Code.

(2) A veterinarian engaged in the compounding of immediate-use sterile drug preparations shall comply with the following:

(a) Unless administered immediately, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner, if applicable, and the name or identification of the animal;

(ii) The name and quantity of each ingredient;

(iii) The date and time prepared; and

(iv) The name or initials of the person who prepared the compounded drug preparation.

(J) For hazardous compounded drugs, the prescriber shall comply with rule 4729:7-3-05 of the Administrative Code.

(K) A prescriber may designate an appropriately trained agent to prepare compounded drug preparations.

(L) For all compounded drugs prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered.

(M) The requirements of paragraph (~~M~~L)(2) of this rule do not apply to either of the following:

(1) A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule; or

(2) A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule.

(N) All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

(1) Verify patient identification using at least two identifiers (e.g., last name, medical record number, DOB, etc.).

(2) Confirm with the patient the patient's planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed.

(5) A licensed prescriber is on-site and immediately available.

Rule 4729:7-2-03 - Drugs compounded in a pharmacy. (NO CHANGE)

(A) For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded preparations exempted from the requirements of this chapter in accordance with paragraph (C) of rule 4729:7-2-01 of the Administrative Code.

(B) For all sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <797>. This paragraph does not apply to sterile compounded drugs exempted from the requirements of this chapter in accordance with rule 4729:7-2-02 of the Administrative Code.

(C) For all antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with United States pharmacopeia chapter <800>.

(D) For all non-antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code and for all compounded hazardous drug preparations listed in table two or three on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with either:

(1) United States pharmacopeia chapter <800>; or

(2) All the following:

(a) Conduct a risk assessment for any hazardous drug preparations listed in paragraph (D) of this rule to determine if any additional containment strategies, work practices, and/or training is required to minimize occupational exposure. Risk assessments shall be made readily retrievable for review by an agent, inspector or employee of the state board of pharmacy. The risk assessment must be reviewed at least every twelve months and the review documented. If a risk assessment is not performed, the compounded drug preparations shall be prepared in accordance with paragraph (D)(1) of this rule. The risk assessment must, at a minimum, consider the following:

(i) Type of hazardous drug (e.g., non-antineoplastic or reproductive risk only);

(ii) Dosage form;

(iii) Risk of exposure;

(iv) Packaging; and

(v) Manipulation.

(b) Ensure that any employees of reproductive capability confirm in writing that they understand the potential risks of handling drugs listed in paragraph (D) of this rule.

(E) Comply with Title 21 U.S. Code section 353a (11/27/2013).

(F) Only the following may engage in compounding at a pharmacy:

(1) A pharmacist;

(2) A pharmacy intern under the personal supervision of a pharmacist;

(3) A certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee under the personal supervision of a pharmacist.

(G) For all compounded drug preparations, a pharmacist shall:

(1) Conduct the final check of the compounded drug preparation; and

(2) Be responsible for the dispensing of a compounded drug preparation.

(H) For all compounded drug preparations, a pharmacist shall be responsible for the following:

(1) All compounding records pursuant to rule 4729:7-2-04 of the Administrative Code;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

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

(J) In addition to the requirements of this rule, compounded drug preparations dispensed to an outpatient shall comply with the following requirements:

(1) Be labeled according to rule 4729:5-5-06 of the Administrative Code; and

(2) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(K) In addition to the requirements of this rule, compounded drug preparations dispensed to an inpatient shall be labeled according to the inpatient labeling requirements in agency 4729 of the Administrative Code; and

(L) Labels for a compounded drug that is prepared in anticipation of a patient-specific prescription shall also contain the following:

(1) The name, strength, and quantity of each active ingredient used in the compounded drug preparation;

(2) Pharmacy control number;

(3) The assigned beyond-use date;

(4) The identification of the repackager or outsourcing facility by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier;

(5) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(M) A prescription for a schedule II controlled substance narcotic to be compounded for the direct administration to a patient may be transmitted to a pharmacy by facsimile. The prescription shall comply with the requirements of 21 CFR 1306.11 (3/31/2010).

(N) The pharmacy shall maintain a system for the safe disposal of drug waste in accordance with all state and federal laws, rules and regulations.

(O) The pharmacy shall comply with the drug database reporting requirements pursuant to division 4729:8 of the Administrative Code.

(P) A pharmacy shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

(Q) A pharmacy shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.