August 2025 – Rules and Resolutions

Appreciation of Service – Isabella Blankenship

BE IT RESOLVED that we, the undersigned Members of the Ohio Board of Pharmacy, in the Board's one hundred fortieth year, do hereby express our appreciation to Pharmacist Isabella "Bella" Blankenship for her contributions and service to the Board during her Pharmacy Practice Advancement and Advocacy Fellowship with The Ohio State University College of Pharmacy.

BE IT FURTHER RESOLVED that this resolution be spread upon the minutes of the Ohio Board of Pharmacy and a copy presented to:

Isabella "Bella" Blankenship, PharmD
On this 4th day of August 2025
at the Ohio Board of Pharmacy, Columbus, Ohio

Resolution Requesting the Emergency Filing of Rule 4729-8-02 of the Administrative Code

The Ohio Board of Pharmacy hereby determines that rule 4729-8-02 requires immediate adoption upon the effective date of section 4729.261 of the Revised Code (HB 96 – 136th General Assembly) and hereby requests the Governor to issue an order pursuant to section 119.03(G)(1) of the Revised Code.

Licensure of Investigational New Drug/Product Suppliers

Pursuant to the definition of investigational drug or product in Section 4729.01 of the Revised Code, those engaged in the sale of investigational drugs or products that are currently in

phase one of U.S. Food and Drug Administration (FDA) clinical trials are not required to obtain licensure from the Ohio Board of Pharmacy.

Those entities engaged in the sale or distribution of investigational drugs or products that are in phase two or three of FDA clinical trials are required to obtain appropriate licensure from the Ohio Board of Pharmacy in accordance with section 4729.51 of the Revised Code.

To ensure that there are no disruptions to existing phase two or three clinical trials, the Board shall exercise its enforcement discretion to provide a six-month grace period (to expire on 2/4/26) for all current suppliers of investigational new drugs or products or those conducting such trials to obtain appropriate Ohio licensure.

This enforcement discretion shall only apply to those engaged in phase two or three clinical trials and does not confer any rights or immunities to any person, applicant, or licensee that fails to comply with the Board's licensure requirements for dangerous drugs that are not investigational new drugs or products undergoing phase two or three clinical trials.

For Filing with CSI and JCARR

Rule 4729:7-1-01 | Compounding references, definitions, 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 **2025-103** ~~**2016-161 or any official supplement thereto**~~ (~~**March 10, 2020**~~ **July 17, 2025**).

(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 a temporary extension to the requirements to comply with the standards listed in paragraphs (B) and (C) of this rule to an existing licensee, if the licensee can demonstrate all the following:

(1) The licensee was compliant with the standards in effect immediately prior to the effective date of this rule;

(2) Significant hardship in meeting the standards; and

(3) Sufficient progress towards compliance with the standards.

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 **products** ~~**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.

States that Have Adopted the Latest Versions of USP 797 and 795

Alabama	Yes	Yes
Alaska	Yes	Yes
California	Yes	Yes
Colorado	Yes	Yes
Connecticut	Yes	Yes
Delaware	Yes	Yes
District of Columbia	Yes	Yes
Florida	Yes (Effective 11/16/2025)	No
Georgia	Yes	Yes
Iowa	Yes	Yes
Kansas	In process	In process
Kentucky	Yes (effective January 2026)	Yes (effective January 2026)
Louisiana	Yes	Yes
Maryland	Yes	Yes
Massachusetts	Yes	Yes
Michigan	Yes	Yes (except flavoring)
Minnesota	Yes	Yes
Mississippi	Yes	Yes
Montana	In process	In process
Nebraska	Yes	Yes
Nevada	Yes	Yes
New Hampshire	Yes	Yes
New Jersey	In process	In process
New Mexico	Yes	Yes
North Carolina	Yes	Yes
Pennsylvania	Yes	Yes
Rhode Island	Yes	Yes
South Dakota	Yes	Yes
Tennessee	Yes	No
Utah	In process	In process
Vermont	Yes	No
Virginia	Yes	Yes
Washington	Yes	Yes
West Virginia	Yes	Yes
Wisconsin	In process	In process

USP 797 – (30 Adopted / 5 in Process) | USP 795 – (27 Adopted / 5 in Process)

CSI Comments from October 2024 and July 2025

Comment	DRAFT RESPONSE
Overall Comment (Nationwide Children's) We support the proposed rule changes as written.	Supportive comment.
Batch Size (Alliance for Pharmacy Compounding, Revelation Pharma, Lee Silsby Compounding Pharmacy) ▪ The new Chapter <797> restricts batch sizes for CSPs to 250 units and curtails beyond-use dating of CSPs based on no substantiable evidence those restrictions enhance patient safety by reducing the risk of contamination. ▪ By reducing the batch size to 250 units in the new chapter, some compounders will now need to prepare multiple batches instead of fewer larger batches, increasing the number of manipulations for components and traffic into and inside the cleanroom. Increasing manipulations and activity create more potential opportunities for contamination and may increase operator fatigue which may lead to poor aseptic technique.	**USP Scientific Rationale[1] [2]:** Sterile compounding within 503A facilities (e.g., pharmacies and clinics) is largely a manual process. The chapter sets a minimum standard for quality assurance that encompasses a wide variety of practice sites. These quality assurance parameters are not intended for outsourcing facilities or pharmaceutical manufacturers, as they were created to accommodate the equipment and processes normally performed by 503A facilities. The risk of contaminating a compounded sterile product (CSP) is likely to increase as the batch size increases, especially for a manual process. For example, equipment limitations (such as the size of a PEC) may only permit a portion of a large batch to be packaged in one continuous process. If 25 units are packaged in one continuous process, a batch of 250 units would require repeating this process 10 times. A batch of 1000 units would require repeating this process 40 times.

[1] https://go.usp.org/USP_GC_797_FAQs

[2] https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/797-commentary-20221101.pdf

▪ Limiting batch size – which will require more batches – increases costs associated with preparing these medications including testing cost per batch and the quantity of consumables used in the compounding lab. This will ultimately result in higher costs for patients. ▪ Setting an arbitrary maximum number of batch units does not effectively consider the risk associated with the process. The current 250-unit limitation fails to demonstrate the potential risk reduction by this new requirement. Compounding pharmacies only prepare stock on established anticipatory patient needs. Therefore, under this new standard, if a need was demonstrated for 1,000 units the pharmacy would have to repeat the batch four times to meet the anticipatory need, whereas the same measure of quality controls could be demonstrated in an optimized, perhaps larger, batch size while still meeting all compendial quality standards for final release.	Smaller batches reduce the potential for operator error due to fatigue. To help ensure sterility assurance, batch size is limited to 250 final dosage units for CSPs that require sterility testing. Sterility testing does not guarantee that an entire batch is sterile, only the units tested. The possibility of detecting a contaminated preparation is about 10% for batch sizes between 10 and 100 but drops to about 4% for a batch size of 250 and only 2% for a batch size of 500. The limit of 250 final yield units is based on USP 71 *Table 3*, which provides the minimum number of items to be tested in relation to the number of items in the batch. This table specifies that 10 containers are to be tested for quantities greater than 100 to up to 500 containers, leading the Compounding Expert Committee to specify 250 as the maximum batch size for CSPs requiring sterility testing. USP General Chapter 71 Sterility Tests falls under the Microbiology Expert Committee and was created for facilities that follow current good manufacturing practices (CGMP). USP 797 sets a minimum standard for quality assurance that encompasses a wide variety of practice sites. These quality assurance parameters are not intended for outsourcing facilities or pharmaceutical manufacturers, as they were created to accommodate the equipment and processes normally performed by 503A facilities. The risk of contaminating a CSP

	increases as the batch size increases, particularly for manual processes. For example, equipment limitations (such as the size of a PEC) may only permit a portion of a large batch to be packaged in one continuous process. Smaller batches reduce the potential for operator error due to fatigue. The process of sterility testing leads to destruction of the CSP used in testing, as the container closure system has to be breached, and therefore not all units within a batch can be tested for sterility. Sterility testing does not guarantee that an entire batch is sterile, only the units tested. Contamination within a batch may not be uniformly distributed across all units. The probability of detecting contamination during sterility testing decreases as batch size increases, and risk for unidentified contamination increases. **Manufacturing and Compliance with Federal Law:** The New England Compounding Center outbreak from 2012 spurred changes to federal and state compounding laws after the deaths of more than 100 patients.[3] To ensure that larger quantities of compounded medications are prepared safely and to reduce the possibility of mass contamination, Congress and the Ohio General Assembly authorized the licensure

[3] https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison

	and regulation of outsourcing facilities. Federal and state law allows outsourcing facilities to produce larger batches of compounded medications. This is permissible because they comply with the same standards (Current Good Manufacturing Practices - CGMP) as drug manufacturers. If the commenters wish to produce large quantities of dangerous drugs, then there must be some specific cut-off in terms of how much can be batched before they are considered an outsourcing facility or manufacturer. Additionally, Congress nor the Ohio General Assembly intended for compounding pharmacies or prescribers to operate as manufacturers or outsourcing facilities. Rather, 21 U.S. Code § 353a authorizes the compounding of drugs as follows: *(A) Is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and* *(B) Is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been*

	generated solely within an established relationship… The patient-specific focus of federal law shows that Congress intended for compounding to be performed in very specific instances and not for pharmacies and clinics to operate as manufacturers or outsourcing facilities. Furthermore, that same section of federal law requires compliance with "United States Pharmacopoeia chapter on pharmacy compounding" and includes restrictions on what is permissible to compound when medications are commercially available. Therefore, incongruity between federal law and state standards may also put Ohio compounders at risk of federal sanctions if the state's compounding standards have exceptions that permits these entities to act more like outsourcing facilities and/or manufacturers. **Interstate Business & Inspection Compliance:** By adopting standards that are different from 30 other states Ohio compounding pharmacies will be put at a disadvantage when trying to conduct business across state lines. This will also impact the Board's efforts to create uniform pharmacy inspection processes across stateliness (known as NABP Blueprint).

	The USP standards were developed over the course of many years by experts and were the subject of several rounds of public comments. Given the risk to the public, the Board did not feel it was appropriate or safe to overrule the limitations set by the USP Expert Committee.
Beyond-Use Dating (Alliance for Pharmacy Compounding, Revelation Pharma, Lee Silsby Compounding Pharmacy) ▪ Restrictions on beyond-use dating to less than 180 days – with no scientific basis for the restriction – will require compounders to compound CSP more frequently to meet patient need, increasing the number of batches. ▪ The CEC itself is acknowledging the need for CSPs to be assigned a BUD of up to 180 days, but in doing so is misrepresenting the proposed <797> as allowing Category 3 CSPs *in general* to be assigned a BUD of up to 180 days, when in fact the proposed <797> only allows one type of Category 3 CSP – a terminally sterilized Category 3 CSP stored frozen – a maximum BUD of 180 days. ▪ USP 795 Section 10.5 and USP 797 section 14.4.3 requirements to	**USP Scientific Rationale[4] [5]:** USP's Compounding Expert Committee, made up of independent volunteer experts, relied on the previously published chapters as well as input from stakeholders to revise the (beyond-use date) BUD limits. The revisions to the BUD limits were established based on a risk-based approach since it is difficult to predict the stability and microbial susceptibility for all the different types of nonsterile and sterile preparations (e.g., some preparations may degrade more quickly than others and some preparations may be more susceptible to microbial proliferation than others). The Compounding Expert Committee replaced risk levels with categories based on criteria other than just starting ingredients and number of manipulations. In addition to starting ingredients, BUDs are also based on environmental quality, personnel hygiene and garbing,

[4] https://go.usp.org/USP_GC_797_FAQs

[5] https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/797-commentary-20221101.pdf

support extension of a BUD with a complex stability study presents an undue hardship on traditional compounders. Furthermore, we don't feel that USP provided an evidence-based reason for adding this requirement. ▪ Historically, compounders have provided scientific peer-reviewed literature to support formulation BUDs and product stability. Now, the new standards are imposing Current Good Manufacturing Practice ("cGMP") standards, requiring that, "the analytical method [must] be validated based on characteristics such as those described in USP ⟨1225⟩." ▪ Method development and validation for stability studies is an arduous process that may take up to 7 months to complete. This validation is not reasonable for the variety of formulations that are uniquely customized to meet a specific patient's need; this flexibility is the core practice model of a 503A facility. ▪ USP 795 Section 10 and USP 797 Section 14: Establishing Beyond-Use Dates also sets new default Beyond-Use dates for sterile and non-sterile preparation. The basis for these changes is factors that affect the compound's susceptibility to microbial contamination or that may impact the sterility assurance for sterile compounds. New default BUDs would limit the pharmacies'	physicochemical stability, and requirements for release testing. Generally, longer BUDs are permitted for compounded sterile products (CSPs) stored in colder conditions than for CSPs stored at controlled room temperature as colder temperatures have been shown to slow the growth of most microorganisms. Temperature affects chemical reaction rates; thus, storage at higher temperatures will accelerate degradation and reduce a BUD. The accepted rule of thumb is reaction rates increase two-fold for every 10 degree increase in temperature. This means that 1 year storage at 30 °C is equivalent to approximately 6 months at 40 °C and approximately 3 months at 50 °C. Correlating this concept to a refrigerated product (stored at 5 °C) estimates the BUD to be one-fourth at room temperature (25 °C). The exact mechanism of degradation and rate of reaction will determine the actual difference, which can only be determined through a stability evaluation over time. The BUD limits are based on several considerations, such as the minimum time periods necessary to perform required tests, CSP chemical and physical stability, the potential for microbial proliferation, the exponential growth rate of microorganisms with increasing temperatures, and the risk of microbial contamination or not achieving

	ability to support anticipated stock needs. Patient dispensing would be contingent upon release of the batch, to meet a 30 days' supply. This subjects a patient to the pharmacy's production schedule versus the pharmacy proactively working to meet the patient's need.	and maintaining sterility despite implementation of the requirements in the chapter. A diversity of practice settings, environments, processes, raw materials, analytical approaches, and few cases in practice which require greater than a 6-month supply resulted in the limit of 180 days. If there is a USP–NF compounded preparation monograph for the CSP, and the preparation is labeled to indicate that it meets the monograph specifications, the BUD must not exceed the BUD specified in the monograph. The USP standards were developed over the course of many years by experts and were the subject of several rounds of public comments. As a reminder, compounded medications are not FDA-approved and are made under conditions less stringent than manufacturers or outsourcing facilities. Therefore, putting in place standardized BUDs protects the public from unnecessary harm. Given the risk to the public, the Board did not feel it was appropriate or safe to overrule the limitations set by the USP Expert Committee. **Interstate Business & Inspection Compliance:** By adopting standards that are different from 30 other states Ohio compounding pharmacies will be put at a disadvantage when trying to conduct

	business across state lines. This will also impact the Board's efforts to create uniform pharmacy inspection processes across stateliness (known as NABP Blueprint).
Media Fill Validations **(Lee Silsby Only)** ▪ Under new USP standards, newly categorized "Category 3" sterile compounds require quarterly validation of media fills and aseptic techniques. For Lee Silsby, this subjects 6 supervising pharmacist, 9 sterile compounding technicians, and quality assurance personnel, to unnecessary multi-day scheduling for validation. ▪ In addition, the revised media fill incubation periods and cycles also impact the pharmacy, as there is not sufficient space to store the in-process the media fill vials. This requires that pharmacies either invest in costly new equipment, where space and capital may be limited, or adopt a continuous media fill rotation, that takes away from necessary production shifts and adds increased risk to the environment with the constant introduction of media fill components (e.g., soy growth broth). ▪ Lee Silsby believes that the current standard of media fill validation every 6 months effectively	**USP Scientific Rationale[6]:** Media-fill testing is an objective way to demonstrate aseptic practices, and this must be performed to assess personnel proficiency in compounding. The USP chapter is intended to provide the minimum standard to help ensure the quality of compounded drugs. The chapter requires media-fill testing with post gloved fingertip and surface sampling at least every 6 months. Personnel are the main source of contaminants, and Category 3 compounded sterile products (CSPs) have longer BUDs, which increases the risk of microbial contamination and proliferation, as well as chemical degradation, physical incompatibilities, and the compromising of the container closure system. To address these risks and maintain a higher state of environmental control, additional requirements must be met if compounding Category 3 CSPs. A frequency of every 3 months for the garbing competency helps ensure continued proper hand hygiene and garbing procedures.

[6] https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/797-commentary-20221101.pdf

	demonstrates the proficiency of compounding personnel. In addition, daily quality controls are maintained and documented to demonstrate proper environmental controls, garbing, aseptic technique, and cleaning and disinfecting procedures.	Lastly, USP does not dictate that media-fill tests must be completed by all personnel at the same time. Therefore, businesses with space limitations can stagger the required training to avoid having to invest in additional space. The USP standards were developed over the course of many years by experts and were the subject of several rounds of public comments. Given the risk to the public with category 3 CSPs (assigned as the highest-risk by USP), the Board did not feel it was appropriate or safe to lessen the standards set by the USP Expert Committee.

For Filing with JCARR:

4729-8-02 – Approval of instruments to reduce drug poisoning

(A) Pursuant to sections 4729.261 and 2925.14 of the Revised Code, the state board of pharmacy hereby determines that drug testing strips and reagent kits are effective at reducing drug poisoning by determining the presence of the following compounds:

(1) Fentanyl and fentanyl-related compounds;

(2) Xylazine;

(3) Medetomidine;

(4) Benzimidazole-opioids or nitazenes; and

(5) Benzodiazepines and benzodiazepine-related compounds.

(B) The board may approve additional instruments via resolution. The board shall consider the following when deciding on whether to approve additional instruments:

(1) Drug poisoning data, including data from other states;

(2) Reports provided by established forensic laboratories as defined in rule 4729:9-1-01 of the Administrative Code;

(3) Reports from harm reduction organizations operating within the state;

(4) Any other information as determined by the board.

(C) A resolution issued in accordance with paragraph (B) of this rule shall exempt the instrument from the definition of drug paraphernalia under section 2925.14 of the Revised Code.

(D) This rule shall be updated periodically to reflect any new instruments approved via paragraph (B) of this rule.

(E) In accordance with section 4729.261 of the Revised Code, none of the instruments approved pursuant to this rule shall measure the proportion of a controlled substance within the total mixture.

Public Comments – Instruments to Reduce Drug Poisoning

Name	Organization	Comment
Mandie Knight	Sanctuary Night	On behalf of Sanctuary Night, a harm reduction nonprofit serving vulnerable women impacted by sex work, homelessness, and substance use in Columbus, Ohio, I am writing to express our strong support for the proposed rule under ORC 4729.261 that would authorize the approval of additional instruments proven to reduce drug poisoning. We commend the Board's commitment to public health and safety by recognizing that tools such as fentanyl test strips and reagent kits play a critical role in overdose prevention. Expanding access to drug checking instruments that detect the presence of compounds like xylazine, medetomidine, nitazenes, and benzodiazepines is an essential step forward in responding to the evolving overdose crisis in our communities. At Sanctuary Night, we see firsthand the devastating impact of unintentional drug poisoning among the people we serve. Legal clarity around the use and possession of these life-saving tools enables us, and others engaged in direct service work, to provide more comprehensive harm reduction strategies without fear of criminalization. We also urge the Board to: • Continue engaging with harm reduction organizations and people with lived experience to identify emerging substances and practical tools being used on the ground. • Ensure that approved instruments are accessible, affordable, and easily distributed through community-based programs.

		• Recognize the urgent need for legal protections for people who use drugs and the organizations that support them. Thank you for taking this critical step toward evidence-based, compassionate public health policy. We are grateful for the opportunity to contribute to this conversation and stand ready to collaborate as these rules are implemented.
Albert Barber	Portage County Mental Health and Recovery Board	I would like to register my full support for ORC 4729.261
Linda Smolak	SOAR Initiative	My name is Linda Smolak and I am a Projects Director at The SOAR Initiative. In my work, I write and administer several grants that provide harm reduction services throughout the state of Ohio. SOAR distributes tens of thousands of fentanyl test strips (FTS) as part of this work. I am writing to support in the strongest possible terms the Ohio Board of Pharmacy's Approval of Instruments to reduce Drug Poisoning (Date issued: 7/2/2025). We know from empirical data and direct experience that People Who Use Drugs (PWUD) want and use drug test strips to assess the presence of unexpected substances in the drug supply. Evidence further indicates that PWUD alter their behavior in ways that increase their safety and reduce the risk of overdose based on the results of the test strips. Laboratory evidence has definitively shown the presence of xylazine, medetomidine, and nitazenes in the drug supply in various locations throughout Ohio. Since the test strips for these drugs are considered illegal drug paraphernalia in Ohio,

		funding agencies will not pay for them. Therefore, we have been unable to supply test strips for these drugs to PWUD despite the dangers and risks these drugs present. PWUD routinely request test strips for xylazine, medetomidine, and nitazenes. They will use these strips to reduce risks. The availability of these test strips will save lives. I not only urge the Board to approve this proposal but to do so quickly. A new round of state funding is scheduled to start on September 30, 2025. If the additional test strips are fundable then, we can start getting the test strips to PWUD yet this year. Please let me know if you need any additional information. Thank you.
Nichole L. Michaels, PhD and Gary A. Smith, MD, DrPH	Nationwide Children's Hospital	We are writing on behalf of Nationwide Children's Hospital to express our support for the Ohio Board of Pharmacy's adoption of rules to legalize the use of drug testing products, including, but not limited to, drug testing strips and reagent kits to detect the presence of xylazine, medetomidine, nitazene, and benzodiazepine. Expanding the legalization of drug testing tools to include drugs other than fentanyl will be a significant step forward for local communities and organizations working to prevent drug overdose deaths in the state. As faculty in the Center for Injury Prevention and Policy at Nationwide Children's Hospital, we currently lead two statewide research projects funded by the Centers for Disease Control and Prevention and the National Institute on Drug Abuse at the National Institutes of Health evaluating the use of fentanyl test strips by individuals who use drugs. These studies are the largest federally funded randomized controlled trials of fentanyl test strips in the United States, involving more than 3,000 Ohioans who use drugs, and we anticipate

		the findings will help inform future overdose prevention efforts. Expanding access to drug testing tools that allow individuals to check their drugs for adulterants and unanticipated ingredients can help prevent harm and save lives. Many of our community partners have asked our study staff whether we can supply them with testing strips for drugs such as xylazine to pass on to their clients. In addition, we are currently preparing for publication data from a recent survey of 229 Ohioans with criminal justice involvement and a history of illicit stimulant use. Seventy-five percent of survey respondents indicated that it is "very important" to know if xylazine is in their drugs and 84% indicated they "do not use xylazine and try to avoid it." Only 3% of study participants indicated a preference for xylazine over other drugs. In addition, two-thirds of respondents indicated they would be "very likely" or "somewhat likely" to use xylazine test strips if they were available to them at no cost. Drug testing strips are easy to use, low-cost, and highly accurate. Creating an exemption for drug testing strips for personal use in Ohio's drug paraphernalia laws will alleviate fear of legal penalties, reduce stigma, and expand access to important interventions that can save lives. On behalf of Nationwide Children's Hospital, we strongly support the implementation of 4729-8-02, Approval of Instruments to Reduce Drug Poisoning by the Ohio Board of Pharmacy.
	Community Overdose Action Team	***(7/21/25)*** **Regarding ORC 4729.261 and ORC 2925.14 that concern the Board of Pharmacy process for approval and legalization of additional types of drug-testing strips used to reduce drug poisoning,** Public Health - Dayton & Montgomery County's Community Overdose Action Team

		(COAT) is in support of the proposed change. This comment aims to provide supportive evidence for the role of legalizing additional types of drug test strips in reducing overdose death and improving overall community health outcomes. **The prevalence of various substances in the drug supply changes over time.** COAT collects extensive data on overdose deaths every year, including which drugs were present in each overdose death. COAT data comes from multiple sources, including Public Health – Dayton & Montgomery County, Dayton Police Department, ADAMHS, the Montgomery County Coroner' Office, the Montgomery County Probation Office, the Montgomery County Sheriff's Office, Project Dawn, and Wright State University. According to COAT's Montgomery County data[1], rates of overdose deaths involving fentanyl are going down, but other substances' percentages are going up. **Monitoring drug trends and approving the use of drug testing strips that are consistent with current drug trends will have the biggest impact.** From 2023 to 2024, fentanyl went from being present in 81% of overdose deaths to being present in 69% of overdose deaths. However, xylazine, one of the drugs for which new test strips approval is included in this bill, went from being present in 33% of deaths in 2023, up to being present in 47% of deaths in 2024. This shows the value of being able to screen for other drugs beyond fentanyl. **Test strips are easy to use and are associated with a higher rate of future harm reduction behaviors after use.** In a Rhode Island study, 98% of participants were confident in using test strips, whether it be through testing their urine after using drugs or testing the drug sample itself, showing that they're convenient and easy to use.[2] A study that focused on introducing fentanyl test strips to a population of female sex workers in Baltimore showed that 86% of them had at least

		one fentanyl-positive result, and that 69% of all participants made an effort to engage with more harm reduction efforts after receiving the result.[3] Harm reduction, defined as "a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use[4]" has been associated with positive health outcomes, including lower HIV and Hepatitis C Virus transmission, and greater linkage to treatment. **Drug test strips are positively received by the population of people who use drugs.** According to a qualitative study done by conducting interviews with PWUD in Philadelphia, if they had access to fentanyl test strips, they "would use them every time."[5] Furthermore, in another study where fentanyl test strips were introduced to a population of young adults who use drugs in Rhode Island, 95% of participants stated that they wanted to use the test strips even after the study ended.[6] COAT supports the Board of Pharmacy intent to have a developed process to legalize additional tools able to prevent drug overdose through determining the presence of certain harmful substances. In addition, information about drug trends in overdose deaths from COAT and other entities can be shared with the Ohio Board of Pharmacy in order to determine which drug testing strips and reagent kits will be most impactful to approve by resolution in the future in order to successfully reduce overdose deaths in Ohio communities. <u>*About the Community Overdose Action Team:*</u> *The Community Overdose Action Team seeks to reduce the number of people dying from drug overdoses and drug abuse. The Community Overdose Action Team was established in the fall of 2016 to address the opioid/heroin epidemic in Montgomery County. Montgomery County Alcohol, Drug Addiction & Mental Health Services, Public Health – Dayton &*

		Montgomery County, and Montgomery County Administration are the lead agencies in the effort to combat the epidemic. COAT has over 200 members representing all sectors within our community including government, healthcare, faith-based, civic/volunteer organizations, law enforcement, fire/EMS, youth-serving organizations, schools, media, substance abuse organizations, concerned citizens, those in recovery, and families/friends of those in recovery. The COAT Project Manager is Dawn Schwartz, (937) 225-6026. [1] COAT, "Data Unit 2024 Annual Report," April 24, 2025. [2] Maxwell S. Krieger et al., "Use of Rapid Fentanyl Test Strips among Young Adults Who Use Drugs," *International Journal of Drug Policy* 61, no. 61 (November 2018): 52–58, https://doi.org/10.1016/j.drugpo.2018.09.009. [3] Ju Nyeong Park et al., "A Fentanyl Test Strip Intervention to Reduce Overdose Risk among Female Sex Workers Who Use Drugs in Baltimore: Results from a Pilot Study," *Addictive Behaviors* 110 (November 2020): 106529, https://doi.org/10.1016/j.addbeh.2020.106529. [4] National Harm Reduction Coalition, "Principles of Harm Reduction" https://harmreduction.org/about-us/principles-of-harm-reduction/ [5] Megan K. Reed et al., "'If I Had Them, I Would Use Them Every Time': Perspectives on Fentanyl Test Strip Use from People Who Use Drugs," *Journal of Substance Abuse Treatment* 140 (May 2022): 108790, https://doi.org/10.1016/j.jsat.2022.108790. [6] Maxwell S. Krieger et al., "Use of Rapid Fentanyl Test Strips among Young Adults Who Use Drugs," *International Journal of Drug Policy* 61, no. 61 (November 2018): 52–58, https://doi.org/10.1016/j.drugpo.2018.09.009.
Mysheika Roberts, MD, MPH	Columbus Public Health	On behalf of Columbus Public Health, I thank you for this opportunity to provide comments on proposed rule 4729-8-02, regarding instruments to reduce drug poisoning. We

		commend the Board for its leadership in advancing harm-reduction strategies that will save lives and improve community safety across Ohio. Columbus Public Health supports the adoption of a framework that allows for the approval of tools to detect and prevent drug poisoning, particularly those capable of identifying contaminants such as fentanyl and xylazine. These instruments are essential additions to Ohio's broader overdose prevention efforts as they reflect national best practices in public health and harm reduction. **Support for Instrument Approval and Implementation** The proposed rule appropriately authorizes the Board to approve instruments that are demonstrated to reduce drug poisoning through compound detection. As the rule is implemented, we encourage consideration of the following items to support effective and practical access for those who need them most: • Provide clear guidance for pharmacies and community organizations on how approved instruments can be distributed or sold. • Ensure broad eligibility for use, including in community-based settings such as public health clinics, harm-reduction programs and outreach teams. • Establish protocols that allow for timely evaluation and approval of new drug-checking technologies as they become available in response to emerging public health threats. **Coordination with Local Harm Reduction Programs** Coordination between pharmacies, local health departments and existing harm-reduction providers is essential to avoid duplication and ensure comprehensive care for those with the

		brain disease of addiction. Columbus Public Health, through the Columbus Board of Health, provides oversight to Franklin County's syringe services program and serves as a lead agency in the Columbus and Franklin County Addiction Plan. As such, we recommend: • Aligning implementation timelines with local capacity and training needs. • Encouraging collaboration between pharmacies and public health departments to increase public awareness and access to new tools. **Conclusion** Overall, the proposed rule is a welcome and necessary step to reduce overdose deaths in Ohio through comprehensive harm reduction. When paired with naloxone access, syringe services and strong local partnerships, detection tools can play a critical role in preventing fatal poisonings and connecting individuals to care. Columbus Public Health looks forward to continued collaboration with the Board and the broader pharmacy community to protect the health and safety of all residents. Thank you for your consideration of these comments.
Individual Commenter	N/a	Allowing all test strips is amazing! Only allowing Fentanyl and not others, like Xylazine, Is just assanine., when people are dying from both. My infant nephew died over a year ago, because he some how got ahold of something that had zylazing in it. His dad only had fentanyl tests strips, and did not even know himself. If he would have taken it, I wouldve been burying both.

Other Supporting Documentation:

Sedative 'dex' is replacing 'tranq' in illegal drug supply and causing excruciating withdrawal (https://www.statnews.com/2025/05/01/medetomidine-replacing-xylazine-in-fentanyl-increases-overdose-danger-withdrawal-risks/)

- *In Philadelphia in particular, reports of medetomidine have skyrocketed. When the city first began testing for the substance in May 2024, it found medetomidine in 29% of fentanyl samples analyzed, according to data from the city's public health department. Six months later, medetomidine's prevalence had increased threefold to 87% — while xylazine's dropped from 100% early in the year to 42% in November.*

***Notes from the Field:* Suspected Medetomidine Withdrawal Syndrome Among Fentanyl-Exposed Patients — Philadelphia, Pennsylvania, September 2024–January 2025 (https://www.cdc.gov/mmwr/volumes/74/wr/mm7415a2.htm)**

- *During September 2024–January 2025, 165 patients at three Philadelphia health systems were hospitalized for fentanyl withdrawal complicated by profound autonomic dysfunction, including severe hypertension and tachycardia. This syndrome was resistant to medications that had previously been effective in managing fentanyl and xylazine withdrawal but was responsive to dexmedetomidine.*

Responding to medetomidine: clinical and public health needs (https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(25)00063-8/fulltext)

- *First identified in Maryland's illicit opioid supply in July 2022, medetomidine was frequently co-adulterated with xylazine.[1,2] By mid-2023, it had spread to Missouri, Colorado, Pennsylvania, and California, and by early 2024, it was linked to overdose clusters in Philadelphia, Pittsburgh, and Chicago.[1,2] This trajectory mirrors the early epicenters of the xylazine overdose crisis—Maryland and Philadelphia—which may serve as bellwethers for emerging drug trends.[1–3] These patterns emphasize the importance of applying lessons from the nation's response to xylazine to address medetomidine's growing threat.*

- *However, medetomidine is not included in standard toxicology panels, underscoring the need for expanded early detection strategies in clinical and harm reduction settings. Point-of-care test strips for medetomidine offer a practical solution, with BTNX Inc. test strips reliably detecting medetomidine at concentrations above 1000 ng/mL.7 These test strips should be distributed in regions with identified medetomidine overdoses to enhance real-time surveillance. Federal agencies, including the Substance Abuse and Mental Health Services Administration, have endorsed fentanyl and xylazine test strips, setting a precedent for similar strategies for medetomidine. Although expensive, confirmatory testing with liquid chromatography–mass spectrometry remains essential for accurately characterizing medetomidine-involved polysubstance overdoses.*

Drug Lab Statistics – Calendar Year 2024*

Xylazine	**4,268**	In the top 5 most reported substances in 2025. Most commonly appears with fentanyl.
Medetomidine	**185**	Not a controlled substance so may not be tested by all labs.
Benzimidazole-opioids or nitazenes	**255**	
Benzodiazepine	**73** non-traditional. Additional **893** for clonazepam, alprazolam and diazepam.	

**These figures are not a complete representation of drug lab statistics, as not all Ohio crime labs are represented in this information.*

4729:5-13-03 - Security, control, and storage of dangerous drugs.

(F) Thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. government class V security container from all other controlled substances.

(M) Dangerous drugs shall only be administered by a licensed health care professional, acting within the scope of the professional's practice, in accordance with a prescriber's order or protocols authorized by a prescriber pursuant to ~~agency~~ rule 4729:5-3-12 of the Administrative Code. A copy of the protocols shall be maintained on-site for immediate inspection by an agent, officer, or inspector of the board.

4729:5-16-02 - Security, control, and storage of dangerous drugs.

(B) Except as provided in paragraph (H) of this rule, controlled substances shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access.

(1) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

4729:5-23-01 - Limited facilities - definitions.

As used in Chapter 4729:5-23 of the Administrative Code:

(A) "Limited facility" means a facility licensed as a limited category II or limited category III terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where drugs are possessed on-site for administration, ~~, dispensing,~~ or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

(1) A limited facility includes any of the following:

(a) Dog trainers affiliated with an Ohio law enforcement agency;

(b) Home health care providers, including those offering in-home services;

(c) Hospice care providers of in-home services;

(d) Physical therapy providers;

(e) Teaching institutions; and

(f) Any other facility as determined by the board.

(2) A limited facility does not include any of the following:

(a) Non-limited facilities as defined in Chapter 4729:22 of the Administrative Code; or

(b) Any other person or facility licensed as a terminal distributor of dangerous drugs that is specifically defined and required to comply with security, control, and record keeping requirements of another chapter of this division (EMS organization, pain management clinic, animal shelter, etc.).

4729:5-23-03 - Record keeping.

(G) Records of disposal of controlled substances that are not dangerous drugs shall comply with the requirements of paragraph (~~P~~Q) of rule 4729:5-23-02 of the Administrative Code.

4729:5-22-01 - Non-limited facilities - definitions.

As used in Chapter 4729:5-22 of the Administrative Code:

(A) "Non-limited facility" or "unlimited facility" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where drugs are possessed on-site for administration, ~~dispensing,~~ or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

4729:5-21-02 - Personally furnishing dangerous drugs from an opioid treatment program.

~~(3)~~ A prescriber may designate an unlicensed person, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (F) of this rule. An unlicensed person shall not prepare and package ~~any of the following dangerous drugs:~~

~~(a) Anesthesia;~~

~~(b) Controlled substances; or~~

~~Drugs administered intravenously.~~controlled substances.

(3) Pursuant to rule 4729:7-3-04 of the Administrative Code, a prescriber shall not personally furnish immediate-use compounded drug preparations.

4729:5-21-03 - Security and control of dangerous drugs.

(E) Controlled substances administered for the treatment of opioid dependence or addiction may be administered directly to the patient by any of the following:

(1) A licensed prescriber, in accordance with the prescriber's scope of practice and as authorized by federal or state law.

(2) A ~~registered~~ nurse licensed under Chapter 4723. of the Revised Code~~or licensed practical nurse~~ pursuant to a valid order issued by a licensed prescriber.

(3) A pharmacist in accordance with a consult agreement pursuant section 4729.39 of the Revised Code. The pharmacist shall only administer the drug pursuant to a valid order by ~~the consulting physician~~ a licensed prescriber.

4729:5-21-05 - Mobile opioid treatment programs.

(iv) All approvals from the DEA shall be maintained at the licensed location and made immediately available for immediate inspection by an agent, officer, or inspector of the state board of pharmacy.

4729:5-20-04 - Record keeping.

(C) Records of temperature control monitoring described in paragraph (~~J~~K) of rule 4729:5-20-03 of the Administrative Code shall include any of the following:

4729:5-14-01 **Emergency medical services - definitions.**

As used in Chapter 4729:5-14 of the Administrative Code:

(A) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(B) ~~"Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01, 4765.011 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.~~"Certificate to practice" means the certificate to practice as an emergency medical responder, emergency medical technician, advanced emergency medical technician, or paramedic issued by the division of emergency medical services within the department of public safety pursuant to section 4765.30 of the Revised Code and Chapter 4765-8 of the Administrative Code.

(C) "Direct supervision" or "personal supervision" means EMS organization personnel shall be physically present at the licensed location or within the immediate proximity of an EMS unit to deter and detect the diversion of dangerous drugs.

(D) "Electronic signature" means any of the following attached to or associated with an electronic drug administration record by EMS organization personnel to authenticate the drug administration record:

(1) A private, unique personal identifier and secure passcode consisting of a combination of letters, numbers, and symbols that is adapted or executed by an individual as that individual's electronic signature.

(2) An electronic image of an individual's handwritten signature that is captured following drug administration and is created by using a writing apparatus (i.e. stylus). The signature shall be legible and include the person's first name, last name and credentials.

(3) Any other method approved by the board.

(E) "Emergency medical service organization" or "EMS organization" has the same meaning as in section 4765.01 of the Revised Code.

(F) "Medical director" means a physician to whom an EMS organization has designated, pursuant to section 4765.42 of the Revised Code, to perform the duties of medical director including establishing medical protocols that must be followed in the delivery of emergency medical services.

The program medical director shall be registered with the United States drug enforcement administration pursuant to 21 U.S.C. 823 (12/7/2023).

(G) "Mutual aid" means a formal written agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage, including having access to dangerous drugs during the emergency.

(H)

(1) "Positive identification" means a method of identifying EMS personnel that does not rely solely on the use of a private personal identifier such as a password, but must also include 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~~.

~~(I) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for less than twenty-four hours and where the EMS unit is under the direct supervision of the EMS personnel on duty.~~

~~(J) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for more than twenty-four consecutive hours pursuant to a formal agreement with the sponsors of the event and where the EMS unit is under the direct supervision of the EMS personnel on duty.~~

~~(1) Posting up at a special event requires notification to the board. Notification shall be provided prior to the special event in a manner determined by the board.~~

~~(2) The requirements of this paragraph do not apply in the event of an emergency management assistance compact or an emergency declared by the governor.~~

~~(K)~~(I) ~~"Protocol" or "standing order" means a definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized and signed by the EMS organization's medical director. A protocol may be used only by licensed or certified EMS personnel, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.~~"Protocol" or "standing order" means a definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized and signed by the EMS organization's medical director. A protocol may be used only by licensed or certified EMS personnel or individuals licensed in accordance with Chapter 4723. of the Revised Code, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.

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

~~(M)~~(K) "Responsible person" has the same meaning as defined in agency 4729 of the Administrative Code and is responsible for the 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.

~~(N)~~(L) "Satellite" means a location licensed by the state board of pharmacy as a terminal distributor of dangerous drugs that is separate from the licensed headquarters of the EMS organization.

~~(O)~~(M) "Scope of practice" has the same meaning as defined as in section 4765.35 of the Revised Code and ~~rule~~ Chapter 4765-12~~-04~~ of the Administrative Code for an

emergency medical responder or first responder, section 4765.37 of the Revised Code and ~~rule~~ Chapter 4765-15~~-04~~ of the Administrative Code for an emergency medical technician or emergency medical technician-basic, section 4765.38 of the Revised Code and ~~rule~~Chapter 4765-16~~-04~~ of the Administrative Code for an advanced emergency medical technician or emergency medical technician-intermediate, and section 4765.39 of the Revised Code and ~~rule~~ Chapter 4765-17~~-03~~ of the Administrative Code for a paramedic or emergency medical technician-paramedic.

~~(P)~~(N) "Tamper-evident" means a package, storage container, or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(O) "Verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a dangerous drug, including a controlled substance, to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

4729:5-14-03 **Security and control of dangerous drugs.**

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license. The responsible person may delegate the day-to-day tasks to EMS organization personnel who hold appropriate certification/licensure to access the dangerous drugs for which the personnel are responsible. A responsible person shall comply with the requirements set forth in rule 4729:5-2-01 of the Administrative Code.

(B) A licensed EMS organization shall provide effective controls and procedures to deter and detect the diversion of dangerous drugs.

(1) Except as provided in paragraph (B)(2) of this rule, only the following may have access to controlled substance dangerous drugs maintained by the EMS organization:

(a) A paramedic (emergency medical technician-paramedic) certified in accordance with Chapter 4765. of the Revised Code;

(b) An advanced emergency medical technician (emergency medical technician-intermediate) certified in accordance with Chapter 4765. of the Revised Code; and

(c) A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization.

(2) An emergency medical technician (emergency medical technician-basic) certified in accordance with Chapter 4765. of the Revised Code may have access to buprenorphine to administer an initial dose pursuant to paragraph (C) of rule 4729:5-14-05 of the Administrative Code. Buprenorphine maintained in accordance with this paragraph shall:

(a) Be physically secured with access limited to persons listed in paragraphs (B)(1) and (B)(2) of this rule.

(b) Stored in a manner that does not permit an emergency medical technician access to other controlled substance dangerous drugs maintained by the EMS organization.

(3) A certified emergency medical responder (emergency medical responder) and emergency medical technician certified in accordance with Chapter 4765. of the

Revised Code may have supervised access to controlled substance dangerous drugs as follows:

(a) For the purpose of documenting the disposal of an unused portion of a controlled substance resulting from administration to a patient in accordance with paragraph (K) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(b) For the purpose of documenting the disposal of controlled substances in accordance with paragraph (J) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(C)

(1) All non-controlled dangerous drugs maintained by the EMS organization shall be maintained under the direct supervision of licensed or certified EMS personnel employed or affiliated with the EMS organization to deter and detect the diversion of dangerous drugs.

(2) If direct supervision is not possible, the licensed location is not currently in use, or the facility is being utilized to hold an event attended by persons other than licensed or certified EMS personnel, all non-controlled dangerous drugs shall be physically secured with access limited to licensed or certified EMS personnel, except for the following if stored in a sealed, tamper-evident manner:

(a) Solutions labeled for irrigation use;

(b) Dextrose solutions;

(c) Saline solutions;

(d) Lactated ringers;

(e) Sterile water; and

(f) Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.

(D) Except as provided in paragraph (B)(2) of this rule, all controlled substance dangerous drugs maintained by the EMS organization shall be physically secured with access limited to persons listed in paragraph (B)(1) of this rule.

(E) All areas where dangerous drugs and devices are stored shall be dry, well-lit well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be

maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(F) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

(G) A dangerous drug that is stored improperly, expired, damaged, tampered, or otherwise adulterated shall be separated from active stock to prevent possible administration to patients. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by the EMS organization. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons as required by this rule.

(H) A non-controlled dangerous drug that is expired or adulterated shall be disposed of in a manner that renders the drug unavailable and unusable.

(I) Unless the EMS organization is registered with the United States drug enforcement administration (DEA), any controlled substance that is expired or otherwise adulterated shall be returned to the institutional pharmacy or facility that is owned or operated by a hospital acting as the EMS organization's responsible DEA registrant.

(J) Except as provided in paragraph (K) of this rule, the disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code. The disposal of controlled substances shall be conducted by two licensed or certified

EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(K) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method. The on-site method does not have to meet the definition of non-retrievable in rule 4729:5-3-01 of the Administrative Code but must render the drug unavailable and unusable.

The destruction of partially used controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(L) If there is a recall of oxygen by the manufacturer, all portable oxygen tanks affected by the recall shall be handled in accordance with the manufacturer's recall instructions.

4729:5-14-05 **Protocols and Verbal Orders for Drug Administration.**

(A) An emergency medical services professional with a certificate to practice and acting within their scope of practice may administer directly (but not prescribe) a dangerous drug, including controlled substances, outside the physical presence of a medical director or authorizing prescriber in accordance with the following:

(1) A protocol or standing order that is issued and adopted by one or more medical directors of the EMS organization; or

(2) A verbal order that is:

(a) Issued in accordance with a policy of the organization; and

(b) Provided by a medical director or an authorizing prescriber in response to a request by the emergency medical services professional with respect to a specific patient in any of the following circumstances:

(i) In the case of a mass casualty incident; or

(ii) To ensure the proper care and treatment of a specific patient.

(B) An emergency medical services professional with a certificate to practice and acting within their scope of practice may administer directly (but not prescribe) an initial dose of buprenorphine, or another medication for opioid use disorder approved by the board, to a patient who is experiencing opioid use disorder in accordance with a protocol approved by the organization's medical director. Such a protocol shall ensure that the EMS organization is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy.

(C) A controlled substance administered in accordance with paragraph (B) of this rule is exempted from reporting to the drug database established in section 4729.75 of the Revised Code.

4729:5-16-03 **Record keeping.**

(A) A laboratory shall keep a record of all dangerous drugs and controlled substances received, administered, personally furnished, used (i.e. chemical analysis or research), disposed, destroyed, or transferred.

(B) The acts of administering, using (~~i.e.~~ e.g., chemical analysis or research), and destroying or disposing controlled substances shall be documented with positive identification.

(C) Records of receipt shall contain a description of the drug or substance and all the following if obtained from a person licensed in accordance with section 4729.52 or 4729.54 of the Revised Code:

(1) The name, strength, dosage form, and quantity of the drug;

(2) The name and address of the seller;

(3) The name and address of the recipient; and

(4) The date of receipt.

(D) Except as provided in paragraph (E) of this rule, records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished~~,~~; the positive identification of the person personally furnishing the drug~~,~~; the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished~~,~~; the date the drug is personally furnished; and, if applicable, the date the drug is received by the patient or patient's caregiver.

(E) Records of personally furnishing for animal use shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished~~,~~; the positive identification of the person personally furnishing the drug~~,~~; the name of the animal or group of animals (e.g., herd, parliament, flock, flamboyance)~~,~~; the name and address of the ~~animal's~~ owner of the animal or animals~~,~~; the date the drug is personally furnished; and, if applicable, the date the drug is received by the animal's owner or~~patient or patient's~~ caregiver.

(F) Except as provided in paragraphs (G) and (H) of this rule, records of administration shall contain the name, strength, dosage form, and quantity of the drugs administered~~,~~; the name and date of birth of the person to whom or for whose use the drugs were administered~~,~~; the identification of the person administering the drug~~,~~; and the date of administration.

(1) Records of ~~non-controlled substances~~drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substances administered ~~which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if~~ shall be documented using positive identification.

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order or protocol issued by a prescriber authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification.

(G) Except as provided in paragraph (H) of this rule, records of administration for animal use shall contain the name, strength, dosage form, and quantity of the drugs administered~~,~~; the name or identification number of the animal to whom or for whose use the drugs were administered~~,~~; the identification of the person administering the drug~~,~~; and the date of administration.

(1) Records of ~~non-controlled substances~~drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substances administered shall be ~~which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if~~ documented using positive identification.

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order or protocol issued by a prescriber authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification.

(H) Records of administration for non-human research purposes shall contain the name of the drugs administered~~,~~; the name or identifier of the animal, group of animals, or group of cells for whose use the drugs were administered~~,~~; the identification of the person administering the drug; and the date the research protocol began. Administration to an animal or group of animals shall be pursuant to an institutional

animal care and use committee (IACUC) protocol which outlines the name, strength, dosage form, and quantity of the drug to be administered, and a timeline for subsequent administration(s). Documentation within a lab notebook or research record ~~of~~ shall be deemed to meet the requirements of this paragraph.

(1) The laboratory shall have the current IACUC protocol available for immediate inspection by an agent, inspector, or employee of the board.

(2) Records of controlled substances administered shall be documented using positive identification.

(I) A laboratory conducting chemical analysis or research with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance:

(1) The name of the drug or controlled substance.

(2) The form (e.g., powder, granulation, tablet, capsule, or solution) and the concentration in such form (e.g., "C.P.," "U.S.P.," "N.F.," ten-milligram tablet, or ten-milligram concentration per milliliter).

(3) The quantity utilized in any manner by the laboratory including the date and manner of utilization.

(4) The identification of the person or persons conducting the chemical analysis or research. If a controlled substance, the positive identification of the person or persons conducting the chemical analysis or research.

(5) This paragraph does not apply to records relating to known or suspected controlled substances or dangerous drugs received as evidentiary material.

(J) A laboratory conducting chemical analysis of anonymous samples of suspected controlled substances or dangerous drugs shall maintain records, to the extent known and reasonably ascertainable by the person conducting the analysis, containing the following information:

(1) Date the sample is received;

(2) Purported contents and actual identification;

(3) Quantity received;

(4) Form of sample (i.e., powder, liquid, tablets, etc.);

(5) Description of sample;

(6) Quantity utilized in analysis; and

(7) The identification of the person or persons conducting the analysis.

(K) Records of dangerous drug disposal, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed~~,~~; the date destroyed~~,~~; the method of disposal~~,~~; and the identification of the person that performed the disposal.

(L) Records of controlled substance dangerous drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance dangerous drug inventory is performed on-site, records shall also include the positive identification of two laboratory employees conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.

(2) If conducting the disposal of an unused portion of a controlled substance dangerous drug, records shall also include the positive identification of two laboratory employees conducting and witnessing the disposal.

(M) Records of the disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample shall be maintained in accordance with paragraph (Q) of rule 4729:5-16-02 of the Administrative Code.

(N) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

(O) Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, ~~expiration date~~ and quantity of the dangerous drug transferred or sold~~,~~; the address of the location where the drugs were transferred or sold~~,~~; and the date of transfer or sale.

(P) Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-16-02 of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(Q) All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(R) 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 shall be scanned in full color via technology designed to capture information 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.

For Filing with CSI and JCARR:

4729:1-3-03 – Administration of Drugs by Injection (AMEND)

(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer by subcutaneous or intramuscular injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner and the individual to whom the drug was prescribed has an ongoing physician-patient or nurse-patient relationship with the physician or nurse:

~~**(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer, by injection, any of the following dangerous drugs if the dangerous drug that is to be administered has been prescribed by a physician and the individual to whom the dangerous drug was prescribed has an ongoing relationship with the physician, an advanced practice registered nurse who has entered into a standard care arrangement with the physician, or a physician assistant who has entered into a supervision agreement with the physician:**~~

(1) An addiction treatment drug administered in a long-acting or extended-release form, which may include any medication indicated for relapse prevention; ~~**An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States food and drug administration.**~~

(2) An antipsychotic drug administered in a long-acting or extended-release form**;**

(3) A human immunodeficiency virus treatment or prevention drug administered in a long-acting or extended-release form;

(3) Hydroxyprogesterone caproate for pregnant women**;**

(4) Medroxyprogesterone acetate for non-pregnant women**;**

(5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States food and drug administration**;**

(6) Antibiotics;

(7) Denosumab or romosozumab;

(8) Methotrexate for non-emergent conditions;

(9) Heparin, low molecular weight heparin, and factor Xa inhibitors; and

~~**(6)**~~ (**10)** Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

(B) To be authorized to administer drugs pursuant to this rule, a pharmacist shall comply with all the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (L) of this rule.

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(3) Practice in accordance with a protocol that meets the requirements of paragraphs (F) and (G) of this rule.

(C) Each time a pharmacist administers a drug pursuant to this rule, the pharmacist shall comply with all the following:

(1) For each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain written permission from the individual.

(2) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain written permission from the individual's parent or other person having care or charge of the individual.

(3) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain written permission from the person authorized to make such decisions on the individual's behalf.

(4) Permission obtained in accordance with this paragraph shall also include notification of the patient's right to request a private area in accordance with paragraph (J) of this rule.

(5) In the case of an **addiction treatment drug described in paragraph (A)(1) of this rule** ~~**opioid antagonist**~~, obtain, in accordance with paragraph (D) of this rule, test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(6) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug.

(7) Notify the physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** who prescribed the drug within seven days that the drug has been administered to the individual. Notification ~~**of the physician**~~ shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) A pharmacist may obtain the test results described in paragraph (C)(5) of this rule:

(1) From the prescribing physician**, certified nurse-midwife, clinical nurse specialist, certified nurse practitioner**; ~~**or the physician's agent; or**~~

(2) From an agent of the prescribing physician, certified nurse-midwife, clinical nurse specialist, certified nurse practitioner; or

(**3**) By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.

(E) If a pharmacist orders blood and urine tests pursuant to paragraph (D) of this rule, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the **addiction treatment drug** ~~**opioid antagonist**~~. A pharmacist's authority to evaluate test results pursuant to this rule does not authorize the pharmacist to make a diagnosis.

(F) A ~~**physician-established**~~ protocol for the administration of dangerous drugs in accordance with section 4729.45 of the Revised Code shall include the following:

(1) For the dangerous drugs listed in paragraph (A) of this rule:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration;

(g) Injection sites; ~~**and**~~

(h) The type of tests that may be ordered in accordance with paragraph (E) of this rule**;**

(i) Any special handling instructions or precautions, if applicable.

(2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on standards of care established by the **authorizing** physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner**. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) The locations that a pharmacist shall engage in the administration of dangerous drugs in accordance with paragraph (J) of this rule.

(5) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist.

(G) All ~~**physician-established**~~ protocols pursuant to this rule and section 4729.45 of the Revised Code shall comply with the following:

(1) The protocol shall be signed and dated by the **authorizing** physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** prior to implementation

and shall be readily available to the administering pharmacist. The protocol shall be renewed by **~~the physician~~** on a biennial basis.

(2) A physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(3) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for **immediate** inspection by an agent, inspector**,** or employee of the state board of pharmacy.

(4) The protocol must be established by a physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** who has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(H) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for administration of drugs in accordance with this rule. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(I) A pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(J) Dangerous drugs administered in accordance with this rule shall be administered in a location that ensures the privacy and dignity of the patient and is consistent with state and federal privacy laws and regulations. When necessary to protect patient privacy, or if requested by the patient, this shall include a private area located outside of the pharmacy.

For all dangerous drugs requiring administration in the gluteal muscle or any other administration requiring the removal of clothing, the administering pharmacist shall:

(1) Offer a chaperone to patients and/or provide a chaperone upon the patient's request;

(2) Employ disrobing, draping, and positioning practices that protect a patient's privacy and dignity; and

(3) Administer in a private area and minimize patient exposure by only exposing the specific injection site.

(K) Administration records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(L) A course in the administration of dangerous drugs developed pursuant to section 4729.45 of the Revised Code shall meet the following requirements:

(1) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(2) The course must include the following components:

(a) A minimum of ~~**an hour and a half**~~ **five hours** (~~**0.15**~~ **0.5** C.E.U.s) of live or home study coursework for ~~**each category of**~~ **the** dangerous drug**s** listed in paragraph (A) of this rule that is covered by the course and shall include:

(i) A review of the conditions treated or prevented;

(ii) Mechanisms of action;

(iii) Routes of administration;

(iv) Injection sites and ensuring patient privacy;

(v) Dosages and administration schedules;

(vi) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(vii) Patient populations;

(viii) Precautions and contraindications; and

(ix) Proper storage requirements.

(b) A minimum of thirty minutes (0.05 C.E.U.s) of live or home study coursework that includes:

(i) A review of sterile technique in injectable dosage preparation and administration;

(ii) A review of the proper disposal procedures for contaminated needles and dangerous drugs; and

(iii) A review of the proper procedures for accidental needle sticks.

(c) A minimum of one hour (0.1 C.E.U.s) of live and supervised physical participation in **subcutaneous and intramuscular** administration techniques**.** ~~**for the categories of drugs covered by the course.**~~

~~**(d) If the course includes instruction on administration of an opioid antagonist, a minimum of one hour (0.1 C.E.U.s) of live or home study coursework that includes a review of the tests necessary to comply with paragraph (C)(5) of this rule and the evaluation of such tests.**~~

~~**(3) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(b) of this rule if the pharmacist has met the training requirements in paragraphs (A)(4)(c), (A)(4)(e) and (A)(4)(f) of rule 4729:1-3-02 of the Administrative Code;**~~

~~**(4) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(c) of this rule if all of the following apply:**~~

~~**(a) The pharmacist has met the training requirements in paragraph (A)(4)(d) of rule 4729:1-3-02 of the Administrative Code; and**~~

~~**(b) The instruction on administration techniques provided in accordance with rule 4729:1-3-02 of the Administrative Code includes the same techniques necessary to administer each category of dangerous drug covered by the training.**~~

(~~**5**~~ **3**) The course must provide a method to evaluate the successful comprehension of the content.

(~~**6**~~ **4**) The course must provide a method to demonstrate the pharmacist has successfully completed the course.

(~~**7**~~ **5**) All live coursework shall be taught by an instructor that is a licensed health care professional who has the appropriate education and experience to teach a course in the administration of the dangerous drugs included in the categories listed in paragraph (A) of this rule.

(M) Courses may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(N) A pharmacist who has not successfully completed a course in drug administration that meets the requirements set forth in this rule must complete a course that meets the requirements specified in this rule prior to the administration of a dangerous drug listed in paragraph (A) of this rule.

(O) A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers dangerous drugs in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (L) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(2) of this rule.

(P) A pharmacist shall not intravenously administer any drug listed in paragraph (A) of this rule.

(Q) Failure to adhere to the standard of care for the administration of a dangerous drug listed in paragraph (A) of this rule shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.

(R) A pharmacist who completed a course in the administration of drugs that complied with the training requirements in effect immediately prior to the adoption of this rule shall be deemed to have met the training required by section 4729.45 of the Revised Code.

CSI Comments – Administration of Injectable Drugs and Dispensing Drugs to an Alternate Location

Name	Organization	Comment	DRAFT Response
Kristen Monarch-Mocek, PharmD, BCPS, RPh	ProMedica Health System	For the proposed changes to 4729:1-3-03: --the methotrexate administrations would require quite a bit of additional control for patient safety as unlike the other medications it is a NIOSH category 1 medication. I suggest additional considerations for receiving and maintaining training and competency for hazardous drug handling / storage be added to help prevent accidental harmful pharmacist or non-prescribed patient exposure.	Propose adding a requirement to protocol instructions to include: **(i) Any special handling instructions, precautions, or use of personal protective equipment if applicable.**
David E. Burke, RPh, MBA	Ohio Pharmacists Association	**Proposed Rule 4729:1-3-03** We support the additions and changes to this rule and applaud the Board of Pharmacy. The increased access to allowed administration of medications by pharmacists and the	Supportive comment.

		expansion of permitting additional prescribers to exercise this privilege increases patient access and assists to maintain the quality of care intended by the prescriber in the outpatient setting. **Proposed Rule 4729:5-3-24 (rescind 4729:5-5-14)** The Board of Pharmacy continues to clarify and adjust the rules related to the movement of medications between entities. We support the rule change and the Board's consistent work in modernizing these provisions.	
David E. Burke, RPh, MBA	Ohio Pharmacists Association	In total, the training requirement for everything at OPA would likely be: • 5 hours for dangerous drugs – live or home study • 30 mins for sterile technique, proper disposal, needlesticks – live or home study – same requirement as before	The rule was amended to align the required training with the recommendation provided by OPA.

		• 1 hour for injection technique – live and supervised – generally same requirement as before	
State Medical Board of Ohio	State Medical Board of Ohio	**(1) Methotrexate** In the practice of obstetrics, methotrexate is used to treat an ectopic pregnancy, a pregnancy outside of the uterus. Patients who are given this medication are carefully chosen because they must be reliable (have available transportation to the same provider and lab), monitored closely (serial labs which need to interpreted are drawn on days 0, 4, and 7), and meet strict requirements to receive methotrexate (not have liver or renal disease, blood disorders, infections, alcoholism, or receiving radiation therapy). In addition, for the provider administering the medication, it is an absolute contraindication	This medication must be prescribed by a physician or nurse practitioner prior to administration and administered in accordance with a prescriber-established protocol. As stated in the comments received by pharmacists, this will allow pharmacists to assist patients for self-administration. To address these concerns, the Board clarified that the methotrexate must be ***for non-emergent conditions.*** The Board did add additional requirements for the prescriber authorized protocol to include precautions to prevent unnecessary exposure.

		for them to be pregnant, breastfeeding, or have a history of a severe allergic reaction to methotrexate. For the protection of patients, the complexity of this medical treatment including patient selection, monitoring, and review of contraindications, necessitates that the injection of this drug occurs in a physician's office rather than a pharmacy.	
State Medical Board of Ohio	State Medical Board of Ohio	**(2) Medroxyprogesterone acetate** Although we are aware that this drug is specifically named in R.C. 4729.45, patient safety concerns compel the Medical Board to share the following concerns. In the practice of gynecology, medroxyprogesterone acetate (AKA depo provera or DMPA) is most commonly administered as contraception. Prior to administration, it is necessary to confirm the	This medication must be prescribed by a physician or nurse practitioner prior to administration and administered in accordance with a prescriber-established protocol. This drug is authorized specifically under the Ohio Revised Code and has been in law since 2017.

		patient is not currently pregnant. This may require more than a urine pregnancy test such as bloodwork or a follow up visit because of recent intercourse. Also, there is close monitoring of the administration site (on a patient's body) and timing (every 12-14 weeks). This information is charted and reviewed prior to every injection to avoid undue harm to patients. For the protection of patients, the complexity of this treatment including testing, follow-up visits, monitoring, and timing requirements, warrants that the injection of this drug occur in a physician's office rather than in a pharmacy.	
State Medical Board of Ohio	State Medical Board of Ohio	**(3) Hydroxyprogesterone caproate** Although we are aware that this drug is specifically named in R.C. 4729.45, patient safety concerns compel the Medical Board to share	This medication must be prescribed by a physician or nurse practitioner prior to administration and administered in accordance with a prescriber-established protocol.

		the following concerns. Hydroxyprogesterone caproate for pregnant women is no longer FDA approved for usage to prevent preterm birth. However, Hydroxyprogesterone caproate is still approved to help regulate menstrual periods and uterine cancer. These are diagnoses which need to be treated by a women's healthcare provider.	This drug is authorized specifically under the Ohio Revised Code and has been in law since 2017.
State Medical Board of Ohio	State Medical Board of Ohio	**(4) Antibiotics** While the rule lists antibiotics generally, the comments provided to the Medical Board with the proposed rule specifically list two antibiotics Ceftriaxone and penicillin G benzathine. It would be more consistent with the rest of the rule to specifically list these two drugs requested rather than include such an expansive category which includes antibiotics that would not fit this rule. Also, there should be additional protections in	This medication must be prescribed by a physician or nurse practitioner prior to administration and administered in accordance with a prescriber-established protocol. As such, there are already safeguards to determine what is appropriate for pharmacist administration. The Board addressed privacy concerns by incorporating the commenter's suggestions (see paragraph J).

		the rule to prevent sexual misconduct for injections of all drugs in the gluteal muscle including (1) offering a chaperone to patients and providing a chaperone upon the patient's request; (2) employing disrobing and draping practices that protect a patient's privacy; and (3) requiring a private location within the pharmacy to administer the gluteal injection.	
State Medical Board of Ohio	State Medical Board of Ohio	**(5) HIV prevention drug administered in a long-acting or extended release form** An injection of this drug is an intramuscular injection in the gluteal muscle. There should be additional protections in the rule to prevent sexual misconduct for injections of all drugs in the gluteal muscle including (1) offering a chaperone to patients and providing a chaperone upon the patient's request; (2) employing disrobing and draping practices that	The Board addressed privacy concerns by incorporating the commenter's suggestions (see paragraph J).

		protect a patient's privacy; and (3) requiring a private location within the pharmacy to administer the gluteal injection.	
State Medical Board of Ohio	State Medical Board of Ohio	**(7) Defining injection** While we appreciate the addition of paragraph (P) prohibiting intravenously administering the drugs in this proposed rule, defining injection in paragraph (A) to specifically mean "subcutaneous or intramuscular" would provide additional needed clarification in this area. **(8) Defining "ongoing physician-patient or nurse-patient relationship"** "Ongoing physician-patient or nurse-patient relationship" in paragraph (A) should be specifically defined to exclude patient relationships with physicians, certified nurse midwives, clinical nurse specialists, and certified nurse practitioners from emergency departments, urgent care, or one	Subcutaneous or intramuscular was added to paragraph (A) of this rule. This would negatively impact conditions that require immediate response and care such as post-exposure prophylaxis or sexually transmitted infections. This medication must be prescribed by a physician or nurse practitioner prior to administration and administered in accordance with a prescriber-established protocol. As such, there are already safeguards to determine what is

		episode telehealth encounters. The complexity of the drugs that this rule deals with should require prescribing by only those physicians and specified APRNs who have a long-standing relationship and understanding of their patients and their patients' medical conditions.	appropriate for pharmacist administration.
		(9) Recognizing and treating adverse reactions Due to the serious consequences of adverse reactions for the drugs in the proposed rule, the Medical Board has concerns about the sufficiency of the training of a pharmacist compared to that of a physician or the specified APRNs in the rule to monitor, diagnose, and correctly treat the adverse reactions.	The statute and rule require specific information about monitoring and responding to adverse reactions as well as 6.5 hours of training. Additionally, the rules require the administering pharmacist to be CPR and BLS certified. These are more stringent requirements than are listed in the Medical Board's own rules on unlicensed persons administering injections (OAC 4731-23). For which there are no training requirements.
		(10) Addiction treatment drug references References to "opioid antagonist" are changed	All references to opioid antagonist have been changed to "addiction treatment drug."

		to “addiction treatment drug” throughout the proposed rule.	
Tracy L. Vannemann, CAE	Ohio Association of Physician Assistants	On behalf of the Ohio Association of Physician Assistants (OAPA), I am writing to request that the Ohio Board of Pharmacy restore language in the proposed rule *4729:1-3-03 Administration of Drugs by Injection* that recognizes physician assistants (PAs) who have entered into supervision agreements with physicians as authorized prescribers. In a prior version of ORC 4729.45, only physicians were explicitly referenced; however, the Board took the appropriate and pragmatic step of recognizing that PAs functioning under valid supervision agreements were also authorized prescribers in the Ohio Administrative Code. This interpretation aligned with the statutory framework governing PA practice in Ohio and	New amendments to the statute now specify which mid-level practitioners are able to prescribe injectable medications for administration by pharmacists. If the legislature intended on allowing PAs to have such authority it would be specified in statute with all other mid-level prescribers. Therefore, the commenter should seek a legislative fix to address the absence of PAs from the statute. With the updated legislative language, the Board cannot exercise its authority beyond what is specifically stated in statute.

		supported collaborative, team-based care. Although the revised statute (ORC 4729.45) again does not explicitly name PAs, it also does not preclude their inclusion. The current rule proposal removes this previously granted recognition, which could create confusion and barriers to efficient patient care. We respectfully urge the Board to restore language that acknowledges PAs in supervision agreements as authorized prescribers, consistent with past practice and the intent of team-based care models.	

Rule 4729:5-18-06 – Technology requirements for a telepharmacy system. (NEW)

(A) There shall be a fully functioning telepharmacy system in the remote dispensing pharmacy that is operational at all times that pharmacy personnel are working in the pharmacy.

(1) The telepharmacy system shall utilize positive identification and comply with the record keeping requirements for outpatient pharmacies in accordance with Chapter 4729:5-5 of the Administrative Code.

(2) All pharmacy personnel must complete a training program on proper use of the telepharmacy system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.

(3) In the event that the telepharmacy system is not functional for more than one-business day, the supervising pharmacist or another pharmacist employed by the supervising pharmacy shall be required to be physically on-site to allow for prescriptions to be dispensed during normal business hours of the remote dispensing pharmacy.

(4) The supervising pharmacy shall have backup procedures to ensure prescriptions may be dispensed in the event of a telepharmacy system outage that is greater than one business day.

(5) In the event of a temporary telepharmacy system outage of less than the duration of one business day, the supervising pharmacist may direct the certified pharmacy technicians and/or pharmacy interns at the remote dispensing pharmacy to complete activities not requiring pharmacist verification or use of the telepharmacy system. Staff at the remote dispensing pharmacy may continue to sell prescriptions that have already been dispensed by the pharmacist. In this case, patients shall be provided with a phone number where they can obtain patient counseling in accordance with rule 4729:5-5-09 of the Administrative Code.

(6) The telepharmacy system shall comply with all the following:

(a) Chapter 3798. of the Revised Code;

(b) 42 U.S.C. 1320d et. seq.; and

(c) 45 C.F.R. parts 160, 162, and 164 for individually identifiable health information (HIPAA).

(C) The telepharmacy system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device, and sufficient data retention capabilities to investigate any quality-related events.

(1) The telepharmacy system must produce images that are high definition in that the image resolution is at least 300 pixels per inch.

(2) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing:

(a) A clear ~~copy~~ image of the prescription label ~~and~~ affixed to the medication or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragarph (C)(3) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of of the Administrative Code used to fill the prescription, if applicable; and

(d) Clear markings present on the pill or capsule, if applicable.

(3) The board may waive or modify the requirements listed in paragraph (c)(2)(c) of this rule if the remote dispensing pharmacy can provide an alternative method that accurately captures information from the medication stock bottle and/or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(4) Images associated with the verification of the prescription will be retained and become part of the patient's profile and maintained for one year.

(D) There shall be a working computer link, video link and audio link to the supervising pharmacist at a supervising pharmacy whenever the remote dispensing pharmacy is open to the public. The required technology must allow the supervising pharmacist to provide the

personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed.

(E) Written prescriptions presented to the remote dispensing pharmacy shall be scanned into the telepharmacy system to ensure initial dispensing and each refill and the original prescription may be viewed at both the remote dispensing pharmacy and the supervising pharmacy.

(1) All information in the prescription shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user.

(2) A prescription record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(F) Certified pharmacy technicians and/or pharmacy interns shall use barcoding technology when filling prescriptions at the remote dispensing pharmacy to ensure the accuracy of prescriptions dispensed in accordance with this chapter. Barcodes shall be scanned, and not manually typed, into the system.

The board may waive or modify the barcode technology requirements listed in this paragraph if the remote dispensing pharmacy can provide an alternative method to ensure the accuracy of prescriptions dispensed in accordance with this chapter

(G) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing pharmacy and shall be maintained for three years after the filling of the prescription.

Name	Organization	Comment	DRAFT RESPONSE
Mark Johnston RPh, PharmD (Honorary)	CVS Health	I am writing to you in my capacity as Executive Director of Advocacy and Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Ohio through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to provide comments regarding proposed rule 4729:5-18-06 – Technology requirements for a telepharmacy system. It is my understanding that the Board discussed public comments received during the initial filing of these rules at their June 2025 meeting, and the Board directed the Board's staff to research CVS Health's request to strike or modify the proposed requirement for an image of the stock bottle during the verification process. It is also my understanding that these	The Board incorporated a provision that does allow for the Board to modify or waive the specific requirement to capture the image of the stock bottle if the remote dispensing pharmacy can provide an accurate alternative. Additionally, based on additional feedback the Board also made sure that the stock bottle image capture also includes medications that have been returned to stock (which by rule cannot be returned to stock). It should be noted that the Board has been told by CVS Health and Pharmacist Johnston that they are not intending on opening any remote dispensing pharmacies in the state.

		proposed rules were refiled prior to the conclusion of the research; thus, said image requirement remains in this refiled version. The submission of this letter and the subsequent attachment of the original letter dated 5/9/2025 was suggested by the Board's staff, so that the Board would consider the topic again, during this refiled comment period. (Previous comment below) I am writing to you in my capacity as Executive Director of Advocacy and Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Ohio through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to provide comments regarding proposed rule 4729:5-18-06 –	

		Technology requirements for a telepharmacy system. The proposed rule currently includes a requirement that telepharmacy system images contain, among other things, the "medication stock bottle used to fill the prescription, if applicable." However, this provision does not account for advancements in the industry that make the requirement largely unnecessary. Historically, prescription drug verification included a pharmacist's manual check of the stock bottle against the product to be dispensed. However, pharmacy operating systems have evolved, as has the pharmaceutical industry, driving more streamlined processes with higher reliability. One such advancement is the implementation of two-dimensional data matrix codes ("2D codes") on prescription drug packaging as mandated under the Drug Supply Chain Security Act. These 2D codes include the product's standardized	

		numerical identifier (composed of the NDC and a unique - to individual manufacturer bottle/package - alphanumeric serial number), lot number, and expiration date[1] enabling pharmacies to use 2D code scanning to accurately capture individual package information in the dispensing process, thus making the imaging of stock bottles unnecessary. Therefore, CVS Health respectfully requests that the Board revise proposed rule 4729:5-18-06(C)(2) to eliminate subparagraph (c) as follows: 4729:5-18-06(C)(2): The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing: (a) A clear copy of the prescription label and the medication or device; (b) The full quantity of the filled prescription;	

		(c) ~~The medication stock bottle used to fill the prescription, if applicable;~~ and Clear markings present on the pill or capsule, if applicable. Alternatively, we ask the Board to provide for an exception to the requirement where a pharmacy captures the relevant information through 2D code scanning by adding to proposed rule 4729:5-18-06(C)(2) the following: <u>(d) The requirement under subparagraph (c) shall not apply to any prescription for which the manufacturer's or repackager's 2-dimensional data matrix code was scanned and the product's standardized numerical identifier, lot number, and expiration date recorded by the</u>	

		terminal distributor of dangerous drugs. 1: Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), June 2021, Labeling.	
Various Pharmacist Representatives	Ohio Association of Community Health Centers	How are items without a scannable barcode—such as those with damaged labels or certain OTC products exempt from DSCSA 2D barcode requirements—managed within the telepharmacy workflow? Is there a designated bypass or override function for these scenarios, and if so, is it clearly flagged or highlighted to ensure the verifying pharmacist is fully aware during the verification process? But (C)(3) says we only keep the image for 1 year. Why not	The Board added a waiver provision to the barcode requirement whereby an alternative method may be approved. Image storage is only required for a year to avoid added costs of

		have it consistent across the board	storing such images. This requirement does coincide with the Board's requirement to maintain a patient profile for one-year.
		While I align CVS's position that maintaining documentation of the scanned DSCSA-compliant 2D barcode generally eliminates the need to photograph the stock bottle, I do have some reservations. Specifically, for liquid medications or products lacking distinguishable markings, a 2D barcode scan alone may not provide sufficient assurance that the correct medication was used. In these cases, the absence of visual identifiers makes verification more challenging. As a practicing pharmacist, we continue to require the stock bottle to be included in the basket for verification when such situations arise. Given the increased liability associated with this remote role, I advocate for continuing to scan the stock bottle as an	The Board is maintaining the stock bottle provision requirement unless it approves an alternative method.

		added layer of verification. This practice enhances both remote pharmacist confidence and patient safety. Is the telepharmacy system capturing an actual photograph of the final dispensed product—with the prescription label physically affixed to the medication bottle—or does it simply generate a computer-rendered image of the label? If it's the latter, how can we ensure that the label has been correctly matched to the appropriate medication container for the correct patient? This also raises the question of whether pharmacies will need to implement scanning of the actual prescription bottle at the point of sale to verify that the correct medication is being dispensed. Currently, practices vary widely: some pharmacies scan each individual bottle, while others scan only the receipt attached to the patient's bag. The	Rule was clarified to provide actual picture of label affixed to container. The Board's goal in implementing these rules is to ensure that processes closely mirror what occurs in traditional retail pharmacy. There are no point-of-sale requirements for outpatient pharmacies.

		latter assumes that the pharmacist was the one who performed the final bagging of the medication. In scenarios where the pharmacist is not the one bagging the prescriptions, I would strongly advocate for a system that requires scanning of each individual bottle at the point of sale. This would ensure that, even if a medication were inadvertently placed in the wrong patient's bag by the bagging technician, the system would detect the mismatch and prevent the sale from proceeding. This becomes especially critical when prescriptions involve multiple bottles, as each must be verified independently to maintain patient safety and compliance.	

4729:5-3-24 – Dispensing Dangerous Drugs to an Alternate Location (NEW)

NOTE: This is intended to replace the current pick up station rule OAC 4729:5-5-14, which would be rescinded.

(A) As used in this rule, "alternate location" means a location other than a patient or caregiver's address on file with the pharmacy that complies with the requirements set forth in this rule.

(B) This rule does not apply to a central fill pharmacy as defined in rules 4729:5-5-19 and 4729:5-9-02.13 of the Administrative Code.

(C) A pharmacy licensed as a terminal distributor of dangerous drugs may dispense dangerous drugs to an alternate location in accordance with this rule. An alternate location may include either:

(1) A pharmacy as defined in section 4729.01 of the Revised Code; or

(2) A location licensed as a terminal distributor of dangerous drugs or who is exempted from licensure in accordance with section 4729.541 of the Revised Code and all the following apply:

(a) The dispensing pharmacy maintains a record keeping system that provides accountability for the delivery, return, and, if returned, the disposal of all dangerous drugs dispensed in accordance with this division of the administrative code.

(b) There is clear and convincing evidence that delivery of a dangerous drug directly to the patient would result in:

(i) Danger or harm to public health or safety;

(ii) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(c) The receipt, storage, control, and distribution of the dispensed dangerous drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code and in accordance with the professional's scope of practice.

(d) There is a documented method in place to ensure compliance with rule 4729:5-5-09 of the Administrative Code.

(e) The dispensing complies with federal law, rules, and regulations.

(D) A terminal distributor of dangerous drugs that serves as an alternate location shall comply with the following:

(1) Maintain a record keeping system that will provide accountability for the receipt, disposal, and return of all dangerous drugs dispensed by the pharmacy in accordance with this division of the administrative code.

(2) Unless donated to a drug repository program pursuant to section 3715.87 of the Revised Code, a dangerous drug that is not distributed or administered to a patient shall either:

(a) Be returned to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code.

(3) Only receive drugs from the dispensing pharmacy if there is clear and convincing evidence that the delivery of a dangerous drug directly to the patient would result in:

(a) Danger or harm to public health or safety; or

(b) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(4) The location acknowledges that any patient specific dangerous drug dispensed by a pharmacy is the property of that patient, except that a dangerous drug that is not distributed or administered to ~~**a**~~ **that** patient within six months shall be deemed abandoned. A terminal distributor of dangerous drugs may do any of the following with an abandoned drug:

(a) Return the drug to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code;

(c) Donate to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code. For the purposes of meeting the requirements under division (H) of section 3715.873 of the Revised Code and rule 4729:5-10-06 of the Administrative Code, a terminal distributor of dangerous drugs that possesses an abandoned drug shall be deemed as the owner of the drug for the sole purpose of providing consent for the drug's donation to a drug repository program; or

(d) If dispensed by a pharmacy under common ownership and control as the receiving terminal distributor of dangerous drugs, the drug may be returned to stock in accordance with 4729:5-5-22 of the Administrative Code.

(5) Nothing shall authorize a terminal distributor of dangerous drugs to return to inventory or otherwise repurpose an abandoned drug for use on another patient, unless the terminal distributor:

(a) Operates a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code; or

(b) Returns the drug in accordance with paragraph (D)(4)(d) of this rule.

(E) The state board of pharmacy may restrict a site from acting as an alternate location if it has clear and convincing evidence that the activities of that location present the following:

(1) Danger or harm to public health or safety; or

(2) Danger or harm to the patient.

(F) No prescriber or pharmacy that provides a patient with a drug pursuant this rule shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(G) Paragraph (F) of this rule does not prohibit a prescriber or pharmacy from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber or pharmacy.

(H) Except as otherwise required by Ohio law, a patient or patient's caregiver shall have the exclusive right to determine if a pharmacy may sell or deliver dangerous drugs that have been dispensed by the pharmacy in the name of that patient to an alternate location.