



**August 25, 2016**

Mr. Mark Hamlin  
Director of Regulatory Policy  
Common Sense Initiative

RE: Physician Drug Compounding Rules 4729-16-04 & 4729-16-13

Dear Mr. Hamlin,

On July 20, 2016, the Board recently released a business impact analysis with amendments to rule 4729-16-04 and the proposed addition of rule 4729-16-13. The Board received a number of comments and concerns from individual healthcare providers as well as state and national provider organizations. As a result, the Board amended both rules at its August 9<sup>th</sup> meeting. Included with this letter, I have outlined the general concerns raised during the public input process as well as responses on how the new rules may address these concerns.

Prior to reviewing the feedback from stakeholders, I would like to provide background on the history of this rule.

Even before to the deadly 2012 outbreak of meningitis originating from steroids produced at a compounding pharmacy in Massachusetts, the Board already regarded sterile drug compounding as a high priority. For years, compounding pharmacies and prescribers in Ohio were required to adhere to certain standards when preparing sterile compounded drug products. In fact, since 1998, the Board has had a broad definition (exceeding that of the current federal definition) of drug compounding in the Ohio Revised Code.

When the Board reorganized its compounding rules chapter starting in late 2014, it went through an 18-month process of updating its rules to match national compounding standards (also known as USP 797), including updates to existing regulations for prescribers who were compounding drugs. In our various meetings around the country with other states, prescriber compounding was raised as an important issue. The [Pew Charitable Trust](#) convened an advisory committee of state regulators and experts to examine state oversight of compounding and develop best practices. The advisory committee affirmed that quality standards must be the same wherever compounding occurs and expressed concern that compounding in doctors' offices is not always regulated or tracked well. It went on to recommend that states should have a mechanism to identify and oversee in-office compounding.

During our rule update process, we worked with stakeholders representing the Ohio Hematology and Oncology Association (a profession that regularly compounds drugs in their offices) on commonsense patient and worker safety measures that were developed based on national compounding standards. However, we did not receive feedback from the rest of the prescriber

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community during this process (including two CSI comment processes and JCARR public rules hearings). Upon finalizing the rules in May 2016, we issued an FAQ document on the new rules that was disseminated to all stakeholder groups (including every physician via the Medical Board).

Following this notification, we received a substantial amount of feedback, particularly from the dermatological community.

Upon receiving these concerns, the Board immediately suspended enforcement of our licensing provisions for these concerned physicians in order to address the issues raised. We also had several in-person meetings with representatives from state and national organizations to try and identify the main points of contention regarding the rules. These actions demonstrate the Board's commitment to work with the prescriber community to find a viable solution that is in the best interest of Ohioans.

Thank you for the opportunity to provide a response to the comments received during the CSI public comment process. Please do not hesitate to contact me directly should you have any questions or need additional guidance.

Sincerely,



Cameron McNamee  
Director of Policy and Communications  
State of Ohio Board of Pharmacy

## **Feedback from CSI Process**

### **#1) Conflicts with Proposed Amendments to USP 797**

**COMMENT:** While the current version of USP 797 includes reconstitution in the definition of compounding, a proposed amendment to the chapter exempts reconstitution in accordance with the manufacturer's labeling. The proposed language reads as follows:

*Reconstituting or diluting a conventionally manufactured sterile product with no intervening steps strictly in accordance with the manufacturer's labeling for administration to an individual patient is not considered compounding. However, aseptic technique must be followed during preparation, and procedures must be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and must be performed in accordance with this chapter.*

Comments received by a number of prescriber organizations asked the Board to rescind current rules and wait for the adoption of the updated version of USP 797.

**RESPONSE:** Rule 4729-16-04 was recently amended by the Board to include similar wording from the proposed amendment to USP 797 that exempts both sterile and non-sterile reconstitution from the Board's definition of compounding. This change also exempts the requirement for licensure as a terminal distributor of dangerous drugs for solo practice prescribers and single shareholder LLCs that are solely engaged in reconstitution.

### **#2) Buffering of Lidocaine for Mohs Surgery and other in-office Procedures**

**COMMENT:** Prescriber groups also questioned whether or not the common practice of buffering lidocaine with epinephrine and sodium bicarbonate should fall under the provision of drug compounding. Additionally, prescribers who prepare these injections questioned the adherence to the 6-hour beyond use date listed in the proposed rule. They felt that such a BUD would interfere with current practice of preparing injections at the beginning of the day for procedures that are performed throughout the day.

**RESPONSE:** National standards (including the new amendments to USP 797) and federal law would consider this to be drug compounding, as essentially a new non-commercially manufactured drug is being created. Therefore, those prescribers engaged in this practice that are not already licensed by the Board would have to obtain licensure as a terminal distributor of dangerous drugs.

However, the Board did adopt an amended version of rule 4729-16-13 that would exempt prescribers from meeting most of the requirements in USP 797 (both current and proposed chapter), which includes major expenses such as the purchase and use of a hood.

Instead, prescribers will be required to adhere to the following when preparing buffered lidocaine for in-office procedures:

- Prepare the drug in a designated clean medication area;
- Perform a proper hand hygiene procedure prior to compounding; and
- Wear powder-free gloves.

It should be noted that the beyond-use-date on all drugs prepared in accordance with the rule is still 6-hours. The 6-hour window is consistent with data from the USP Committee on Analytical Microbiology. As the following chart demonstrates, the rate of microbial growth in a potentially contaminated drug product increases exponentially with time.

<b>Time (Hours)</b>	<b>Microbial Count (CFU per mL)</b>
6	10
9	640
12	41,000
18	$1.7 \times 10^7$
24	$6.9 \times 10^9$

*Cundell AM, USP Committee on Analytical Microbiology, Pharmacopeial Forum 2002; 28 (6) Stimuli to the Revision Process*

### #3) Procedures Performed Are Intradermal

**COMMENT:** The Board received a number of comments that reconstituted drugs which are intradermal or subcutaneous should be exempted from the definition of drug compounding.

**RESPONSE:** Rule 4729-16-04 was recently amended by the Board to include similar wording from the proposed amendment to USP 797 that exempts both sterile and non-sterile reconstitution from the Board’s definition of compounding. This change also exempts the requirement for licensure as a terminal distributor of dangerous drugs for solo practice prescribers and single shareholder LLCs that are solely engaged in reconstitution.

### 4) Botox

**COMMENT:** Prescribers raised issues regarding the cost of Botox. Many felt that it should not be limited to a 6-hour BUD. Some suggested that it could be used for several weeks if properly refrigerated (drug labeling indicates that it should be used within 24-hours).

**RESPONSE:** Rule 4729-16-04 was recently amended by the Board to include the exact wording from the proposed amendment to USP 797 that exempts both sterile and non-sterile reconstitution from the Board’s definition of compounding. This would include Botox. This change also exempts the requirement for licensure as a terminal distributor of dangerous drugs for solo practice

prescribers and single shareholder LLCs that are solely engaged in reconstitution. For those prescribers who are licensed by the Board, they would be required to adhere to the manufacturer's instructions.

#### #5) Tumescant Anesthesia for Liposuction

**COMMENT:** Tumescant anesthesia is a technique commonly used in cosmetic and dermatologic procedures. It involves subcutaneous infiltration of large volumes of tumescant fluid containing lidocaine (0.05% or 0.1%), saline, and epinephrine (1:1,000,000) to produce anesthesia, swelling, and firmness of targeted areas.

Individuals commented that regulations would interfere with this practice that they report has a demonstrated safety record with few adverse events.

**RESPONSE:** National standards (including the new amendments to USP 797) and federal law would consider this to be drug compounding, as essentially a new non-commercially manufactured drug is being created. Therefore, those prescribers engaged in this practice that are not already licensed by the Board would have to obtain licensure as a terminal distributor of dangerous drugs.

See response for comment #2 for additional information.

#### #6) Fillers

**COMMENT:** Commenters were concerned that the rules would negatively impact the use of fillers.

**RESPONSE:** Rule 4729-16-04 was recently amended by the Board to exempt the reconstitution or preparation of a drug device from its definition of compounding. The FDA classifies fillers as drug devices.

#### #7) Stringent Facility Requirements

**COMMENT:** Commenters also raised concerns regarding the "stringent facility requirements" that are associated with licensure by the Board of Pharmacy.

**RESPONSE:** Commenters did not specifically reference what these requirements are and how they could be mitigated in the rule. It should be noted that many entities will still be exempted from licensure due a recent proposed change in rule 4729-16-04 that does not include sterile and non-sterile reconstitution as part of the Board's definition of compounding.

#8) Rules prevent dermatologists from obtaining common anesthetic agents (in-office use exemption).

**COMMENT:** Several commenters suggested that the rules prevent them from obtaining compounded drug products for in-office use.

**RESPONSE:** The rules that were released for comment did not address this issue. It should be noted that the Board does have a rule allowing compounding pharmacies to provide such products for in-office use. It should also be noted that the FDA has commonly raised serious objections to this practice and have asked the states to ban this practice. After extensive discussions with FDA, the Board did limit the practice to in-state compounding pharmacies (see rule 4729-16-07) but did not prohibit the practice altogether as has happened in other states.

#9) 6-hour immediate use provision should be extended to permit prescribers to have individualized compounding plans based on manufacturing labeling and recommendations.

**COMMENT:** It was recommended that the immediate-use provision in the rule should be extended to permit prescribers to develop individualized compounding plans based on manufacturing labeling and recommendations.

**RESPONSE:** The 6-hour immediate use provision no longer applies to reconstituted drug products. For compounded drugs, see response for comment #2.

#10) \$120,000 cost to comply with regulations.

**COMMENT:** This figure was regularly quoted in a number of comments received by the Board.

**RESPONSE:** It was not made clear how this number was derived. There is speculation that some prescribers are under the impression they need what are commonly referred to as "clean rooms". These rooms include a hood and special ventilation when preparing medium and high-risk compounded drug products. However, the rules would not require such investments by prescribers, as they typically prepare what are commonly referred to as low-risk compounded drug products for immediate use.

#11) Local anesthesia will hurt more because the rules prevent it.

**COMMENT:** Several commenters stated that local anesthesia will hurt more because the rules prevent its buffering with other drug products.

**RESPONSE:** Amended rule 4729-16-04 and 4729-16-13 do not prohibit this practice. Please see response for comment #2 for further explanation regarding local anesthesia.

#12) Ativan will require a special license.

**RESPONSE:** Ativan is not a compounded drug product and these rules will not require obtaining a special license to possess Ativan.

#13) Physician representative on pharmacy board

**RESPONSE:** Such a comment cannot be addressed in the rule-making process.

#14) Questionable efficacy of CSTDs and cost of upwards of 7-10 dollars per unit.

**COMMENT:** Commenters questioned the efficacy of using a CSTD and the cost projections specified in the rule's business impact analysis.

**RESPONSE:** As a result of feedback provided, this requirement was removed from the amended rules.

#15) Retract or at least rewrite rules to allow physicians to practice medicine.

**COMMENT:** The goal of the regulations is to provide uniform standards to ensure the sterility and safety of drug administered to patients and not the regulation of the practice of medicine. The Board believes such regulations are consistent with its mission to protect the health and safety of the public.

## PROPOSED RULES (Amended August 9, 2016)

### 4729-16-01 Definitions.

(A) As used in this chapter of the Administrative Code:

(1) "Compounding" ~~has the same meaning as division (C) of section [4729.01](#) of the Revised Code.~~ except as provided in paragraph (A) of rule 4729-16-04, means the preparation sterile and non-sterile compounded drugs. Such preparations may be hazardous or non-hazardous.

(2) "Cytotoxic" means a drug that has been shown to be carcinogenic or mutagenic to humans through active or passive exposure.

(3) "Drug" has the same meaning as division (E) of section [4729.01](#) of the Revised Code.

(4) "Drug shortage" means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

(5) "Fluid therapy pharmacy" means a pharmacy where the primary purpose is to compound and dispense parenteral compounded sterile product prescriptions.

(6) "Hazardous drugs" has the same meaning as defined in the United States pharmacopeia ~~chapter <797> (08/01/2014).~~ chapter <800> USP 39 - NF 34, or any official supplement thereto (6/30/2016).

(7) "In-state health care facility" means any of the following that are licensed as a terminal distributor of dangerous drugs in the state of Ohio:

(a) A hospital registered with the department of health under section [3701.07](#) of the Revised Code;

(b) Ambulatory surgical facility as defined in section [3702.30](#) of the Revised Code; or

(c) Emergency medical service (EMS) organization as defined in section [4765.01](#) of the Revised Code.

(8) "In-state pharmacy" means any pharmacy, as defined in section [4729.01](#) of the Revised Code, located inside of Ohio that ships, mails, or delivers, in any manner, drugs at retail in or out of Ohio. An in-state pharmacy does not include a nuclear pharmacy as defined in rule [4729-15-01](#) of the Administrative Code.

(9) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as defined in division (I) of section [4729.01](#) of the Revised Code.

(10) "Medical director" means the physician who is responsible for managing and directing the provision of medical services at an in-state health care facility.

(11) "Non-resident pharmacy" means any pharmacy, as defined in section [4729.01](#) of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into

Ohio. A non-resident pharmacy does not include a nuclear pharmacy as defined in rule [4729-15-01](#) of the Administrative Code.

(12) "Non-sterile compounded drug" means a preparation intended to be non-sterile that is created by combining, reconstituting, diluting, pooling, or otherwise altering a dangerous drug product or bulk drug substance.

(13) "Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States food and drug administration section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(14) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.

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

(16) "Sterile compounded drug" means a preparation intended to be sterile that is created by combining, reconstituting, diluting, pooling, or otherwise altering a dangerous drug product or bulk drug substance.

(17) "Verified Pharmacy Program" means a program operated by the national association of boards of pharmacy that conducts inspections of pharmacies.

(18) "Licensed personnel approved by the responsible person" as used in paragraph (J) of rule 4729-16-04 and paragraph (G) of rules 4729-16-11 and 4729-16-13 means individuals licensed or registered pursuant to Chapters 4723., 4729., 4730., and 4731. of the Revised Code.

(19) "Beyond use date" means the date or time after which a compounded drug product shall not be administered, stored or transported. The date is determined from the date and time the preparation is compounded.

#### **4729-16-04 Drugs compounded by a prescriber.**

(A) As used in this rule, "compounding" means the preparation of non-hazardous sterile and non-sterile compounded drugs but does not include any of the following when administered to an individual patient:

(1) The preparation of a drug device designated as such and approved by the United States food and drug administration strictly in accordance with the manufacturer's labeling for administration and beyond use dating. These devices shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids.

(2) The reconstitution or dilution of a conventionally manufactured nonsterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond use dating. Any other reconstitution or dilution of a conventionally manufactured nonsterile product is considered compounding and shall be performed in accordance with United States Pharmacopeia Chapter <795>, USP 39-NF 34, or any official supplement thereto (6/30/2016).

(3) The reconstitution or dilution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond use dating. These drug products shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and shall be performed in accordance with this rule.

(B) A facility where a prescriber is compounding drugs shall be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.541 of the Revised Code. The responsible person on the license shall be an Ohio licensed prescriber as defined in section [4729.01](#) of the Revised Code and is responsible for all of the following:

(1) Developing and implementing appropriate procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;

(4) Ensuring competency of personnel; and

(5) ~~Assuring~~ Ensuring environmental control of the compounding areas-;

(6) Ensuring compounded drug products maintain their quality and sterility until administered or personally furnished.

(C) As used in this rule, a low-risk sterile compounded drug means all of the following:

(1) Does not involve any hazardous drugs as defined in rule [4729-16-01](#) of the Administrative Code.

(2) The drug is compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices.

(3) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile product.

(4) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(5) Administration of the drug shall commence within twelve hours of preparation or as recommended in the manufacturers' package insert, whichever is less.

(D) A prescriber who prepares low-risk sterile compounded drugs as defined in paragraph (B) of this rule shall meet all of the following requirements:

(1) A policy and procedure manual shall be prepared, maintained, and reviewed regularly by the responsible person regarding the compounding, safe handling, personally furnishing, and administration of compounded drugs.

The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education. The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent. ~~The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.~~

(2) Physical requirements

(a) The facility shall have a designated area with access limited to authorized personnel for preparing low risk sterile compounded drugs. This area shall be isolated from other areas; including areas used to prepare hazardous compounded products, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of low risk sterile compounded drugs and provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security. Cleaning and disinfecting of areas within the designated area including the primary engineering control device, counters, easily cleanable work surfaces and

floors shall occur each business day. If compounding is done less frequently than each business day (e.g., once a week or once a month), cleaning shall occur before and after each compounding session begins. Cleaning and disinfection agents must be selected and used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(b) The facility shall have:

(i) Appropriate primary engineering control devices capable of maintaining an ISO class 5 environment in the work place where critical objects are exposed and critical activities are performed. These devices shall be capable of maintaining an ISO class 5 environment during normal activity. Examples of such devices include laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

(ii) Infusion devices and equipment, if appropriate.

(iii) Appropriate temperature controlled transport containers.

(c) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(d) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.

(e) Low-risk sterile compounded drugs shall be prepared within an ISO class 5 environment and in accordance with all provisions of this rule except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized as document in the patient's medical record.

(3) Patient training

(a) Whenever possible, a prescriber shall be involved in discussing with each patient receiving a low-risk sterile compounded product, or the caregiver of such individual, the following matters:

(i) Dosage form, dosage, route of administration, and duration of drug therapy;

(ii) Special directions and precautions for preparation and administration;

(iii) Stability or incompatibilities of the medication.

(4) Quality assurance

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities. At a minimum, there shall be written quality assurance programs developed that address:

(i) Adequate training and continuing competency monitoring, including an initial skills assessment and examination as well as annual assessments, of compounding personnel in all of the following areas:

(a) Personal cleansing including proficiency of proper hand hygiene;

(b) Proper attire;

(c) Aseptic technique;

(d) Proper clean room conduct; and

(e) Clean room disinfecting procedures.

(ii) Continued verification of compounding accuracy including physical inspection of end products.

(iii) Continued verification of automated compounding devices.

(iv) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected.

(b) Instructors shall have the appropriate knowledge and experience necessary to conduct the training.

(c) All clean rooms and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.

(5) Personal protective equipment (PPE)

(a) The following PPE is required for compounding sterile drug products:

(i) Sterile powder-free gloves;

(ii) Gowns, head, hair, and shoe covers.

(E) For non-sterile compounded drugs, the prescriber shall comply with the United States Pharmacopeia Chapter <795>, USP 39-NF 34, or any official supplement thereto (6/30/2016).

(F) For low-risk with greater than twelve hour beyond use date, allergen extracts, medium and high-risk sterile compounded drugs as defined in United States Pharmacopeia Chapter <797>, the prescriber shall comply with United States Pharmacopeia Chapter <797>, USP 38 - NF 33, or any official supplement thereto (~~9/10/2015~~ 6/30/2016). (G) For hazardous compounded drugs, the

prescriber shall comply with rule 4729-16-11 of the Administrative Code. For immediate use compounded drugs, the prescriber shall follow rule 4729-16-13 of the Administrative Code.

(H) A prescriber may designate an appropriately trained agent to assist the prescriber in the compounding of drugs.

(I) For all compounded drugs prepared pursuant to this rule, the prescriber shall:

(1) Inspect and approve the compounding process.

(2) Perform the final check of the finished product.

(J) Paragraph (I) of this rule does not apply if either:

(1) a compounded product is being administered to a patient in the facility by a licensed health professional in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two licensed personnel approved by the responsible person to prepare or administer compounded drugs complies with the requirements in paragraph (K) of this rule do all of the following:

(2) a compounded drug product is being prepared and administered to a patient in the facility by a registered nurse in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, the same registered nurse complies with paragraph (K) of this rule.

(K) The following are required prior to the administration of a compounded drug product in accordance with paragraphs (J)(1) and (J)(2) of this rule:

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

(2) Confirm with the patient his/her planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form~~-dose~~;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Sign using positive identification pursuant to paragraph (N) of rule [4729-5-01](#) of the Administrative Code to indicate verification was completed;

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

(L) For all compounded drug products, the prescriber shall be responsible for:

(1) All compounding records pursuant to rule [4729-16-06](#) of the Administrative Code, including positive identification requirements pursuant to paragraph (N) of rule [4729-5-01](#) of the Administrative Code;

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

(3) Ensuring aseptic technique for the preparation of all compounded drug products.

(M) A compounded drug that is personally furnished by a prescriber must be labeled according to rule [4729-5-17](#) of the Administrative Code and must include the appropriate beyond use date, in accordance with United States Pharmacopeia Chapter <797> or <795> and complete list of ingredients. The statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

~~(N) A prescriber shall not compound drugs in anticipation of prescriptions based on routine prescribing patterns.~~ A prescriber shall not compound drugs for anticipated needs or engage in compounding practices where multiple non-patient specific doses are produced in a single activity.

(O) The prescriber shall comply with the drug database reporting requirements for Chapter 4729-37 of the Administrative Code.

(P) This rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729-16-11 of the Administrative Code.

**4729-16-13 Immediate Use Non-Hazardous Sterile Drugs Compounded by a Prescriber (NEW).**

(A) A facility where a prescriber is compounding dangerous drugs for immediate use shall be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.541 of the Revised Code. The responsible person on the license shall be an Ohio licensed prescriber as defined in section 4729.01 of the Revised Code and is responsible for all of the following:

- (1) Developing and implementing appropriate procedures;
- (2) Overseeing facility compliance with this rule;
- (3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;
- (4) Ensuring competency of compounding personnel; and
- (5) Ensuring that compounded drug products maintain their quality and sterility until administered.

(B) Immediate use sterile compounded drug products are exempt from the requirements in rule 4729-16-04 when all of the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous drug products 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 the appropriate aseptic technique, including all of the following:

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

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

(3) If not immediately administered, the finished drug product is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug products, and direct contact of outside surfaces.

(4) Unless supported using appropriate literature sources or direct testing and notwithstanding paragraph (B)(1) of rule 4729-9-01, the beyond-use date for an immediate use compounded drug product is no later than six hours.

(5) If administration has not begun within the beyond use dating described in paragraph (B)(5) of this rule, the drug shall be promptly, properly, and safely discarded.

(6) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded drug product shall bear a label listing the exact beyond use date.

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

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

(C) Preparations that are medium-risk level and high-risk level compounded drug products as defined in United States Pharmacopeia Chapter <797>, USP 39 - NF 34, or any official supplement thereto (5/1/2016) shall not be prepared as immediate use. Preparations that cannot meet any of the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729-16-04.

(D) Sterile compounded drug products for immediate use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. Cleaning and disinfecting of areas within the designated area including counters, easily cleanable work surfaces and floors shall occur each business day. If compounding is done less frequently than each business day (e.g., once a week or once a month), cleaning shall occur before and after each compounding session begins. Cleaning and disinfection agents must be selected and used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(E) A prescriber may designate an appropriately trained agent to assist the prescriber in the preparation of the sterile drug products.

(F) For all compounded drugs prepared pursuant to this rule, the prescriber shall:

(1) Inspect and approve the compounding process.

(2) Perform the final check of the finished product.

(G) Paragraph (F) of this rule does not apply if either:

(1) a compounded product is being administered to a patient in the facility by a licensed health professional in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two licensed personnel approved by the responsible person to prepare or administer compounded drugs complies with the requirements in paragraph (K) of this rule.

(2) a compounded drug product is being prepared and administered to a patient in the facility by a registered nurse in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, the same registered nurse complies with paragraph (K) of this rule.

(H) The following are required prior to the administration of a compounded drug product in accordance with paragraphs (G)(1) and (G)(2) of this rule:

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

(2) Confirm with the patient his/her 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) Sign using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code to indicate verification was completed;

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

(I) For hazardous compounded drugs, the prescriber shall comply with rule 4729-16-11 of the Administrative Code.

(J) This rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729-16-11 of the Administrative Code.

(K) Immediate-use compounded drug products shall be prepared in accordance with this rule except in an emergency situation 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.

(L) A prescriber shall not compound drugs for anticipated needs or engage in compounding practices where multiple non-patient specific doses are produced in a single activity.