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STATE OF OHIO BOARD OF PHARMACY

Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding

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Effective April 1, 2017, all prescribers that possess compounded drugs or engage in the compounding of dangerous drugs (i.e. prescription drugs) must obtain a license as a terminal distributor of dangerous drugs (ORC 4729.541).

On or after April 1, 2017, any facility possessing compounded drugs or engaging in drug compounding without being properly licensed as a terminal distributor will be in violation of Ohio law. In addition, a facility that is not licensed as a terminal distributor will not be able to purchase any compounded medications or drugs used for the purpose of compounding from any wholesaler or pharmacy. **All potential applicants are encouraged to apply as soon as possible to ensure their license application is processed prior to the statutory deadline.**

NOTE: This requirement applies to all locations and includes previously exempted prescriber practices (dentist, solo-practitioners, etc.) if they possess compounded drugs or engage in drug compounding.

For questions regarding this licensing requirement, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) How does the Board define compounding?

In rule 4729-16-01 (effective 4.1.2017), compounding is defined as, "…the preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance."

However, compounding **DOES NOT** include the following, pursuant to rule 4729-16-04 (effective 4.1.2017), as it relates to **NON-HAZARDOUS DRUGS ONLY** when administered to an individual patient:

- 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.

- 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. NOTE: 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, USP 39-NF 34, or any official supplement thereto.

- 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. NOTE: Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and shall be performed in accordance with rule 4729-16-04 or 4729-16-13 of the Ohio Administrative Code.

If a prescriber office is engaged in any of the three activities previously described, the office is not required to obtain licensure as a terminal distributor of dangerous drugs.

NOTE: If any activities involve the compounding, combining, admixing, mixing, diluting, or reconstituting of hazardous drugs, then the prescriber practice is required to obtain a terminal distributor license pursuant to rule 4729-16-11 of the Administrative Code.

Q2) I compound drugs in my office, what rules am I required to follow?

In addition to security and recordkeeping requirements in Chapters 4729-5 and 4729-9 of the Ohio Administrative Code, prescribers engaged in compounding are required to comply with the following Board of Pharmacy regulations:

OAC 4729-16-04: This rule provides the requirements for prescribers that prepare non-hazardous compounded drug products. This rule does not apply to prescribers preparing hazardous compounded drug products (OAC 4729-16-11) or non-hazardous compounded drug products for immediate-use (OAC 4729-16-13).

OAC 4729-16-11: This rule provides the requirements for prescribers that prepare and handle hazardous compounded drug products. More information on this rule can be accessed by visiting: www.pharmacy.ohio.gov/hazardous

OAC 4729-16-13: This rule provides the requirements for prescribers that prepare immediate-use non-hazardous compounded drug products. Immediate-use drug products must meet all the following criteria:

(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 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) 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 following preparation of the drug.

(5) If administration has not begun within the beyond-use dating described in paragraph (B)(4) of rule 4729-16-13, 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.

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 rule 4729-16-13 must comply with the requirements in rule 4729-16-04.

Q3) How does the Board define a hazardous drug?

The Board uses the definition of hazardous drugs that is found in USP 800. USP 800 defines hazardous drugs as any drug identified by at least one of the following criteria:

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals
- Genotoxicity or new drugs that mimic existing HDs in structure or toxicity

The National Institute for Occupational Safety and Health maintains a list of hazardous drugs used in healthcare settings. The list can be accessed here: https://www.cdc.gov/niosh/docs/2016-161/.

For more information on hazardous drug compounding by prescribers, visit: www.pharmacy.ohio.gov/hazardous

Q4) How do I know if I am ordering compounded drugs to my office?

Compounded drugs are those medications that are not commercially available in the strength, concentration, or form needed for a prescriber office or specific patient. The medications are provided by a pharmacy (usually a specialty or compounding pharmacy) or an FDA registered outsourcing facility.

Please note: The terminal distributor licensure requirement applies if the prescriber is ordering patient-specific compounded drugs to their location to be picked up by the patient in accordance with rule 4729-5-10 of the Ohio Administrative Code.

A list of Ohio licensed outsourcing facilities can be accessed here: www.pharmacy.ohio.gov/outsourcing

Q5) What if I already have a license?

If you currently possess a terminal distributor license, then you are already compliant with the requirements of the law.

Application Information

- To obtain a license as a terminal distributor of dangerous drugs, please visit the Pharmacy Board's licensing page: http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx
- Scroll down to the APPLICATIONS header and select "Facility or Practitioner Application"
- On question 5 of the application, be sure to select "Category II" or "Category III" license.
    a. Category II licenses are for non-controlled drugs;
    b. Category III licenses are for the possession of both non-controlled and controlled substance medications.
- For more information regarding the legal questions (8 & 9), there is a guidance document included at the end of the application. This guidance document can also be accessed here: www.pharmacy.ohio.gov/legal
- If you are engaged in the practice of compounding, make sure to complete the prescriber compounding survey in the application.
- Applications must be signed using a wet-ink signature and original copies must be submitted to the Board with the correct payment. The Board will not process incomplete or scanned copies of applications.

Responsible Person on an Application

Every terminal distributor license is required to have a responsible person at all times. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of dangerous drugs (i.e. prescription drugs). For a prescriber office or clinic, the responsible person must be any of the following: MD, DO, APRN, RPH, DDS or DPM.

Pursuant to rule 4729-5-11 of the Administrative Code:

Unless otherwise approved by the Board, no responsible person for locations licensed as a terminal distributor of dangerous drugs shall:

(a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(b) Have been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(c) Have been convicted of any of the following: (i) a felony; (ii) a misdemeanor related to, or committed in, the person's professional practice; (iii) an act of moral turpitude; or (iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

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

(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 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) 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 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 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. 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 (H) 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 (H) 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.

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

(I) 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.

(J) 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.

(K) 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.

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Rule Amplifies: 4729.55, 4729.01, 4729.54, 4729.541

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

~~(A) A facility where a prescriber is compounding drugs shall be licensed as a terminal distributor of dangerous drugs. 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 environmental control of the compounding areas.~~

(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. If no such beyond use date exists, the dangerous drug product may only be used for up to six hours following preparation. 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. If no such beyond use date exists, the dangerous drug product may only be used for up to six hours following preparation. 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. If no such beyond use date exists, the dangerous drug product may only be used for up to six hours following preparation. 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;

(5) Ensuring environmental control of the compounding areas;

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

~~(B)~~(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~~personally furnishing.

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

~~(C)~~(D) A prescriber who prepares low-risk sterile compounded drugs as defined in paragraph (~~B~~C) 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. 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 documented 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.

~~(D)~~(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).~~.~~

~~(E)~~(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).~~).~~For immediate use compounded drugs, the prescriber shall comply with rule 4729-16-13 of the Administrative Code.

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

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

~~(H)~~(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; or

(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.

~~(I)~~(K) ~~Paragraph (H) of this rule does not apply if 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 do all of the following:~~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.

~~(J)~~(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.

(K)(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 for anticipated needs or engage in compounding practices where multiple non-patient specific doses are produced in a single activity.

(L) A prescriber shall not compound drugs in anticipation of prescriptions based on routine prescribing patterns.

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

(N)(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.

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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, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance,

(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 drug preparation intended to be non-sterile.

~~(12)~~(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).

~~(13)~~(14) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.

~~(14)~~(15) "Sterile" means a dosage form free of living microorganisms (aseptic).

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

~~(15)~~(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.

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Certification

02/01/2017

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