Ohio Administrative Code

Rule 4729:7-3-02 Exemptions.

Effective: April 16, 2021

(A) Licensing exemptions.

Persons listed in divisions (A)(1) to (A)(3) of section 4729.541 of the Revised Code shall be exempted from licensure as a terminal distributor of dangerous drugs as required in division (D)(1) of section 4729.541 of the Revised Code for any of the following:

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321 (12/13/2016), containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating.

(2) The preparation or reconstitution of non-hazardous, conventionally manufactured sterile dangerous drug products for direct administration with no intervening steps in accordance with the manufacturer's labeling for preparation, administration and beyond-use dating.

(3) The compounding, preparation, dilution or reconstitution of non-hazardous, non-sterile dangerous drug preparations.

(4) The possession of compounded dangerous drug preparations provided by an outsourcing facility.

(5) The dilution of non-hazardous, conventionally manufactured sterile dangerous drug products (e.g., diluting or mixing into a syringe to administer directly to the patient).

(B) Exemptions from the requirements of this chapter.

The following non-hazardous devices and drugs prepared by a licensed terminal distributor of dangerous drugs are exempted from the requirements of this chapter:

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321 (12/13/2016),

containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the device. 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. Unless administered immediately, the drug device described in this paragraph shall bear a label listing the name of the device (if not legible), date, and time prepared.

(2) The reconstitution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration, and the beyond-use dating indicated on the manufacturer's labeling. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond use date or timeframe 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. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(3) The preparation, 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. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond-use date exists, the dangerous drug product shall be assigned a beyond-use date in accordance with USP <795>. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(4) The dilution of a conventionally manufactured sterile dangerous drug product (e.g., diluting or mixing into a syringe to administer directly to the patient). The drug product 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. The dangerous drug product may only be used for up to six hours following preparation. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug, date, and time prepared.