Hazardous Drug Compounding by Prescribers

Updated 2/02/2017

Rule 4729-16-11 provides requirements for the compounding of hazardous drug products by prescribers. To assist licensees in complying with the regulation, the Board of Pharmacy has developed the following guidance document.

For non-hazardous drugs, prescribers are required to comply with rule 4729-16-04 or rule 4729-16-13 (effective April 1, 2017). In addition, all prescribers who order compounded drugs or compound drugs on-site are required to obtain a license as a terminal distributor of dangerous drugs. For more information about this requirement please visit: www.pharmacy.ohio.gov/prescribercompound

NOTE: Veterinary practices that engage in hazardous drug compounding are required to adhere to rule 4729-16-11.

For questions regarding hazardous drug compounding by prescribers, please review the guidance document. 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.

1) How does the Board define drug compounding?

In rule 4729-16-01, 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."

There are some exceptions to this definition for prescribers that prepare **non-hazardous drugs only**. For more information, please visit: www.pharmacy.ohio.gov/prescribercompound

2) Does hazardous drug compounding include the reconstitution of drugs in accordance with the manufacturer's instructions?

Yes. Rule 4729-16-11 does not differentiate between reconstitution and compounding for hazardous drugs.

3) What is the definition of 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/.

4) Does this rule also apply to the compounding of hazardous drugs in a pharmacy?

No. Hazardous drugs compounded in a pharmacy must continue to follow rule 4729-16-03.

5) Paragraph (B)(5)(a) of the rule states the following: Personnel shall use an appropriately fitted national institute for occupational safety approved N95 or equivalent respiratory protection during spill cleanup and whenever there is a significant risk of inhalation exposure to hazardous drug particulates. Does this require initial and annual fit testing?

Yes. OSHA rule CFR 1910.134(f)(2) requires that an employer shall ensure that an employee using a tight-fitting face piece respirator is fit tested prior to initial use of the respirator, whenever a different respirator face piece (size, style, model or make) is used, and at least annually thereafter.

6) Are closed-system drug transfer devices required during both admixture and administration?

For administration of hazardous drugs: When the dosage form allows, the rule requires the use of a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system. These devices are commonly known as a closed-system transfer device (CSTD).

For admixture (i.e. compounding): The rule does not require the use of closed-system transfer devices when compounding, however, they are highly recommended (when the dosage form allows) in order to limit employee exposure to hazardous drugs.

7) For the purpose of verification of the final compounded drug product prior to administration in paragraph (G) of the rule, are pharmacy technicians considered licensed healthcare personnel?

No. Pharmacy technicians are not licensed in Ohio. Pursuant to paragraph (A)(18) of rule 4729-16-01, licensed healthcare personnel must be limited to individuals licensed pursuant to Chapters 4723 (Nursing Practice Act), 4729 (Pharmacy Practice Act), 4730 (Physician Assistants) or 4731 (Medical Practice Act) of the Revised Code.

8) Are immunotherapy drugs considered hazardous or non-hazardous?

Please see question 3.

9) Do hazardous and non-hazardous drugs have to be kept in totally separate cabinets and refrigerators or just separated from each other in a single cabinet and refrigerator?

The rule requires hazardous drugs to be stored separately from other inventory. Therefore, the drugs are required to be stored in a separate area away from non-hazardous drug stock. The goal to is minimize employee exposure to hazardous drugs.

10) What is the required personal protective equipment (PPE) for compounding and administering hazardous drugs?

The following is the required PPE for compounding and administering hazardous drugs:

Hazardous Drug Activity	Personal Protective Equipment (PPE)
Sterile Compounding	Sterile chemotherapy gloves*, gowns, head covers, hair covers, shoe covers, eye and face protection.
Non-Sterile Compounding	Chemotherapy gloves* (sterile or non-sterile), gowns, head covers, hair covers, shoe covers, eye and face protection.
Patient Administration	Chemotherapy gloves* (sterile or non-sterile) and gowns.

** Double gloving is recommended. Chemotherapy gloves must be tested to ASTM standard D6978 (or its successor) and must be powder-free.*

11) What does the Board consider appropriate personal protective equipment (PPE) for other hazardous drug activities?

For all hazardous drug handling, the rule requires the use of chemotherapy gloves* and gowns.

The Board considers the following PPE to be appropriate for the following hazardous drug activities:

Hazardous Drug Activity	Personal Protective Equipment (PPE)
Receipt (i.e. delivery from wholesaler or manufacturer)	Chemotherapy gloves* (sterile or non-sterile), gowns, eye and face and respiratory protection**.
Storage and Transport	Chemotherapy gloves* (sterile or non-sterile) and gowns.
Deactivation or decontamination, cleaning, and disinfecting	Sterile chemotherapy gloves*, gowns, head covers, hair covers, shoe covers, eye, face and respiratory protection+.
Spill Control	Chemotherapy gloves* (sterile or non-sterile), gowns, head covers, hair covers, shoe covers, eye, face and respiratory protection.

** Double gloving is recommended. Chemotherapy gloves must be tested to ASTM standard D6978 (or its successor) and must be powder-free.*

*** Respiratory protection should be worn if hazardous drugs are not contained in plastic upon receipt or until the receiver ensures no damage occurred during transport. If there is no detectable damage during shipping/delivery, the person unpackaging can remove the respiratory protection.*

+ Respiratory protection is only required when deactivating, decontaminating, disinfecting and cleaning underneath the work surface of a C-PEC.

12) Is a full-face respirator considered appropriate eye and face protection?

Yes. A full-face respirator provides the required eye and face protection.

13) Is a surgical N95 respirator considered appropriate respiratory protection?

Yes. A surgical N95 respirator is a NIOSH-approved N95 respirator that has also been cleared by the Food and Drug Administration (FDA) as a surgical mask.

A surgical N95 respirator provides the respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier to splashes, droplets, and sprays around the nose and mouth.

For more information, please visit:
http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3healthcare.html

NOTE: A surgical respirator does not provide appropriate eye protection. If using a surgical N95 respirator, goggles and face shields are required.