Ohio Dermatological Association

March 2021

Ohio In-Office Dermatology Compounding Practices- Frequently Asked Questions

The State of Ohio Board of Pharmacy's (SOBP) newest set of compounding rules will go into effect on March 31, 2021. The Ohio Dermatological Association (ODA) has been actively following the formation and implementation of the compounding rules for several years. Many practices have contacted ODA for additional information about rule compliance. We have directed those practices to the pharmacy board's compounding guidance document for more information. Taking into consideration that the board's guidance document is very lengthy and addresses all facets of office compounding, we have worked with the pharmacy board to provide answers to our most frequently asked questions.

I compound in my office. How do I know whether I need to obtain a TDDD from the pharmacy board?

Pursuant to section 4729.541 of the Revised Code all healthcare providers must obtain TDDD licensure from the Board of Pharmacy if engaged in the practice of drug compounding.

However, there are exceptions. Rule 4729:7-3-02 further clarifies this provision by exempting the following from the Board's licensure requirements:

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321, containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. **(Example, Preparing Restylane per manufacturer's instructions)**

NOTE: A Terminal Distributor of Dangerous Drugs, TDDD license, may still be required even if drug compounding does not occur on-site or if you are only performing the "exempted" compounding procedures.

For instance, even if you are only compounding non-hazardous, dangerous drug preparations for immediate use or only preparing devices strictly in accordance with the manufacturer's labeling instructions, you may still have to obtain a TDDD for reasons other than compounding.

You need a TDDD if you are "distributing" drugs. Distribution includes on-site administration of drugs to patients as well as handing drugs to patients to take away from the facility for later use (commonly known as personally furnishing). *This includes any samples of prescription medication.*

There are very few exceptions to Ohio's TDDD licensure rules and physicians need to review the board's TDDD prescriber compliance document at http://www.pharmacy.ohio.gov/prescriberTDDD to ensure compliance

(2) The preparation or reconstitution of non-hazardous*[1], 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**. (Example, Preparing Botox injections)**

(3) The compounding, preparation, dilution or reconstitution of non-hazardous*, nonsterile dangerous drug preparations. **(Example, amoxicillin oral suspension that requires reconstitution.)**

(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). (**Example, Diluting Kenalog, buffering Lidocaine)**

If physicians draw up or prepare in anticipation (i.e. batch compounding or anticipatory compounding for procedures throughout the day) that action would fall under OAC 4729:7-3-04.

I have a few patients in my office who require injections with substances like Bleomycin or Methotrexate. What do I have to do in order to comply with the pharmacy board's rules?

Ohio Administrative Code 4729:7-3-05 outlines the requirements when compounding hazardous drugs in a physician's office. When physicians are compounding hazardous drugs in the office, there are many additional requirements including gloving, gowning, airflow, workspace, documentation, and others. Physicians who compound hazardous drugs should refer to page 32 of the pharmacy board's guidance document for detailed information.

Keep in mind, if you are administering a hazardous drug from a single-use vial with no intervening steps, you are not compounding.

I only compound non-hazardous drugs that I use within 6 hours of compounding. Do the pharmacy board's compounding rules apply to me?

Yes. While many of the compounding tasks you perform may be exempted from the compounding rules, you need to be aware of Ohio Administrative Code 4729:7-3-04, the rule that outlines what physicians must do if compounding non-hazardous drugs for immediate use. "Immediate use" for most non-hazardous drugs is defined as six hours after preparation. However, for preparations of buffered lidocaine containing antimicrobial preservatives, the pharmacy board allows administration no later than

[1] Ohio rules define a hazardous drug as any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

twelve-hours following preparation of the drug. Refer to page 16 of the pharmacy board's guidance document for detailed information.