Central Compounding for Compounded Sterile Products

Updated 3/20/2020

In order to mitigate reported shortages of personal protective equipment (PPE) and address staffing concerns, the State of Ohio Board of Pharmacy has adopted the following guidance to permit licensees to perform sterile compounding for another licensee, referred to as central compounding.

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020.

As used in this guidance “originating facility” means the facility where compounded medication administration occurs and “compounding facility” means the facility where drugs are compounded for the originating facility.

For a terminal distributor of distributor drugs (TDDD) to compound for another licensee, the TDDD must comply with all the following:

- The compounding facility is responsible for compliance with chapters USP 797 and 795 and rule 4729-16-04 of the Administrative Code.
- The compounding facility and the originating facility (i.e. where the medication administration occurs) are under common ownership.
- Only patient-specific compounded sterile products (CSPs) are permitted. No batch compounding of CSPs shall be provided to the originating facility.
- All CSPs must comply with appropriate labeling of CSPs in accordance to OAC 4729-17-10. In addition, the label must also include the name and address of the compounding facility. This may be achieved by affixing an auxiliary label on the CSP.
- All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Transportation and storage of the CSPs shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer’s or distributor’s labeling unless otherwise directed by the board.
- Unused, patient-specific CSPs may be returned to the compounding facility for appropriate disposal only. Returned CSPs to the compounding facility shall not be reused or redispensed.
- Unused, patient specific CSPs may be reused at the originating facility if stored under appropriate conditions.
- The compounding and originating facility must maintain appropriate recordkeeping for each licensee in accordance to OAC 4729-16-06, 4729-9-22, 4729-9-14, 4729-17-04.

This guidance shall remain in effect until rescinded by the Board.