Automatic Exemptions to Rule 4729-16-10 and Expanded Definitions of Drug Shortages

Updated 3/16/2020

To promote patient access to needed medications during the COVID-19 outbreak, the State of Ohio Board of Pharmacy has adopted the following guidance regarding the compounding of drugs in shortage as authorized under rule 4729-16-10 of the Administrative Code.

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

A pharmacy intending to compound drugs in shortage pursuant to rule 4729-16-10 of the Administrative Code may do so without first obtaining an exemption from the Board’s Executive Director, if the pharmacy complies with the following:

1. The in-state compounding pharmacy maintains documentation of a request for the compounding of drugs in shortage by a medical director of an in-state health care facility, as defined in rule 4729-16-01, or Ohio licensed pharmacist who is authorized by the in-state health care facility to act on behalf of the medical director. The documentation of a request is not required if the in-state health care facility owns and operates the compounding pharmacy.

2. The in-state compounding pharmacy maintains documentation of a drug shortage for three years in a readily retrievable manner (i.e. must be produced for review no later than three business days to an agent, officer or inspector of the Board), which as defined as either:

   a. 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.

   b. A drug on the American Society of Health-System Pharmacists 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.

This guidance is in effect until rescinded by the Board.

For questions regarding this guidance, please e-mail the Board office by visiting:
http://www.pharmacy.ohio.gov/contact.aspx.