Authorizing Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products

Updated 3/30/2020

In order to reduce opportunities for the transmission of COVID-19 and mitigate possible shortages, the State of Ohio Board of Pharmacy has adopted the following guidance to permit the compounding and sale of certain alcohol-based hand sanitizer products by Ohio-licensed pharmacies and outsourcing facilities (referred to collectively in this guidance as compounders).

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020 and section 4729.25 of the Revised Code. This document serves as the formal notice required pursuant to section 4729.25 of the Revised Code.

Compounders must adhere to the requirements and recommendations set forth in the FDA’s Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.

UPDATED 3/30/2020 – Due to the public health emergency posed by COVID-19, the FDA has issued additional guidance permitting the use of alcohol (i.e., ethanol or ethyl alcohol) produced by alcohol production firms to be used as the Active Pharmaceutical Ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020. Therefore, compounding pharmacies may utilize ethanol or ethyl alcohol to compound hand sanitize products that is consistent with this guidance. Additionally, the pharmacy compounding guidance has been updated to include the use of denatured alcohol (see page 3 of guidance).

This guidance is in effect until rescinded by the Board or the United States Food and Drug Administration.

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