Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: June 27, 2019

RE: **CSI Review – Pharmacy Compounding (OAC 4729:7-2-01, 4729:7-2-02, 4729:7-2-03, 4729:7-2-04, 4729:7-2-05, 4729:5-8-04, 4729-16-01, 4729-16-03, 4729-16-05, 4729-16-06, 4729-16-08, and 4729-16-12)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of six new rules and six rescinded rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on April 9, 2019 and the public comment period closed on April 26, 2019. Eight comments were received during this time. Responses to those comments were provided on June 7, 2019.

The new rules replace the rescinded rules, and do not change the majority of the content aside from adding two exemptions and two new requirements. Non-hazardous, non-sterile, conventionally manufactured products are exempt from compounding requirements if a final check is conducted by a pharmacist using positive identification. The Board is also providing exemptions for certain sterile compounded drugs based on national sterile compounding standards. New provisions require adherence to national compounding standards, and require all nonresident pharmacies that are selling compounded drugs into Ohio to have a responsible person who is an Ohio-licensed pharmacist. The proposed rules do not implement a federal requirement; the Board states that the regulation of the practice of pharmacy has traditionally been done at the state level. ORC 4729.26 and 3719.28 give the Board authority to adopt rules governing the practice of pharmacy, as well as

the form and content of records to be kept by those authorized to deal with controlled substances.

As part of early stakeholder outreach, the Board had the rules reviewed by a special ad-hoc committee composed of compounding pharmacists throughout the state. Prior to filing with CSI the rule was reviewed and approved by the Board. The ad-hoc committee made several recommendations that were included in the rule package as submitted to CSI: to limit the application of USP 800 to anti-neoplastic drugs and provide that clarity throughout the rule; to add exemptions in proposed versions of USP 797 and 795; to clarify that registered technicians may conduct non-sterile compounding; to permit the national drug code in lieu of product name and manufacturer in the required recordkeeping section; and, to require nonresident pharmacies to have an Ohio-licensed pharmacist as the responsible person on the license.

Eight comments were received during the CSI public comment period. The majority of the comments asked for clarifications on various provisions in the rules, which the Board provided in its response. Commenters also pointed out where the rules diverged from national compounding standards, and the Board made revisions so that its requirements mirrored national guidelines. Two commenters requested that the Board allow pharmacies licensed as of a certain date to be exempted from the new requirement that nonresident pharmacies have a responsible person who is an Ohio-licensed pharmacist. The Board declined to make this change, noting that because compounding is high-risk it is appropriate to require Ohio licensure. It did state that the requirement will not take effect until April 2021.

The rules impact compounding pharmacies licensed as terminal distributors of dangerous drugs. Pharmacists preparing non-hazardous, non-sterile, conventionally manufactured products are exempt from final check when they are using positing identification. This can range from providing a paper record with a hard copy signature to providing a biometric scan. Pharmacists are already required to adhere to national compounding standards USP 800, USP 795, and USP 797. The costs for new pharmacies to comply with USP 797 is variable, ranging from minimal cost for immediate-use exemption to thousands of dollars for simple low-risk compounding (e.g., laminar flow hood in a segregated area) and to more than $100,000 for medium-risk compounding (e.g., biological safety cabinet in a clean room).

Pharmacies engaged in compounding anti-neoplastic drugs will have to comply with USP 800. Facility improvements should be achievable with an investment of $50,000 or less. Additional costs include approximately $5,000 for personal protective equipment. If facility and engineering changes are needed, it may require twelve to eighteen months to complete. The rule also requires the reporting of adverse events or product recalls potentially associated with the quality of a compounded sterile preparation, and any warning letters, injunctions, or decrees issued in relation to the pharmacy by

the United States Food and Drug Administration. All nonresident pharmacies that are selling compounded drugs into Ohio must have a responsible person who is an Ohio licensed pharmacist. Pharmacists licensed in Ohio may apply to the Board for reciprocity. The cost of an initial license by reciprocity is $337.50. The Board justifies any adverse impact by noting that the regulations protect and promote public safety by ensuring uniform standards for the preparation of compounded drug preparations.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.