



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: March 11, 2019

RE: **CSI Review – Clinics and Prescriber Offices (OAC 4729:5-19-01, 4729:5-19-02, 4729:5-19-03, and 4729:5-19-04)**

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 four new rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on May 7, 2018 and the public comment period closed on May 25, 2018. Six comments were received during this time and responses to those comments were received on December 31, 2018.

The new rules establish guidelines for clinics and prescriber offices. This includes the requirements for a prescriber who personally furnishes dangerous drugs; the standards for security, control, and storage of dangerous drugs; and recordkeeping requirements. 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 and the legal distribution of prescription drugs, 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 posted the rule package to its website. Several commenters felt that the Board should not regulate prescriber offices, but the Board referred them

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to the authorizing statute which grants it permission to regulate the distribution of dangerous drugs in prescriber offices. The Ohio State Medical Association expressed general support for the rule package, and the Ohio Veterinary Medical Association requested that the definition section exempt veterinarians from the rules. The Board amended the definition of “clinic or prescriber office” to specifically exempt veterinarians.

Six comments were received during the CSI public comment period. Most of the commenters were physicians expressing concerns over the sign-off provision in the rules. Physicians must sign off on the personal furnishing of drugs under the physician’s license. They noted that requiring a physician to physically sign off on dispensed products, even when a licensed pharmacist has already done so, is redundant and counterproductive. The Board noted that the physical furnishing rules are required by law. It clarified that the rules do not require physicians to sign off on what pharmacists dispense from a pharmacy, including pharmacies within a clinic. It went on to note that physicians are only required to sign off on what is personally furnished from their office, and that except for free clinics it does not feel that it is appropriate for a pharmacist to dispense a drug under the license of a physician without a sign-off. The remaining comments dealt with clarification issues, which led the Board to remove a provision on positive identification requirements; clarify that pharmacists can have unsupervised access to controlled substances, and access to prescription blanks in certain instances; and further clarify that veterinarians are not considered prescribers under the rules.

The rules impact clinics licensed as terminal distributors of dangerous drugs, and prescribers. The impact is largely administrative, resulting from the costs necessary to perform monthly checks of refrigerated or frozen drugs, ensure compliance with recordkeeping and labeling requirements, and appropriately label and handle hazardous drugs. A clinic may also incur expenses related to the security, control, and storage requirements of the rule. They may need to purchase a lockable cabinet, or other secure storage area, in which to store dangerous drugs and hypodermics. The Board justifies any adverse impact by noting that the rules are necessary to protect and promote public safety. The Board notes that without these regulations, it would be unable to ensure the licensure and safe operation of clinics and prescriber offices.

Recommendations

For the reasons described above, the CSI Office has no recommendations on this rule package.

Conclusion

Based on the above comments, the CSI Office recommends that the State of Ohio Board of Pharmacy should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.