



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO: Kylynn Johnson, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: December 22, 2022

RE: **CSI Review – Pharmacist and Intern Immunization Administration (OAC 4729:1-3-02 and 4729:2-3-03)**

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 Board as provided for in ORC 107.54.

Analysis

This rule package consists of two amended rules proposed by the State of Ohio Board of Pharmacy (Board). This rule package was submitted to the CSI Office on September 29, 2022, and the public comment period was held open through October 21, 2022. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on September 29, 2022.

Ohio Administrative Code (OAC) 4729:1-3-02 and 4729:2-3-03 provide for the administration of immunizations by pharmacists and pharmacy interns including training requirements, development of and adherence to a physician-established protocol, obtaining informed consent, record-keeping, vaccine information statement requirements of the National Vaccine Childhood Injury Act, notification of a primary care provider or a local board of health, and certification to perform basic life support. The rules are amended to specify that courses in the administration of immunizations must include a review of each immunization recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention in the United States Department of Health and Human Services, remove language regarding a requirement for pharmacists and pharmacy interns to conduct a review of clinical resources prior to administering an

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immunization, allow notification of an administered immunization to be done by reporting to the state's immunization registry, allow a pharmacist to administer epinephrine or diphenhydramine to individuals in emergency situations resulting from adverse reactions to immunizations administered by the pharmacist, clarify that a pharmacy intern is authorized to administer immunizations under the direct supervision of a pharmacist pursuant to provisions in statute and the OAC, and update language.

During early stakeholder outreach, the Board posted the rule on its website and solicited comments from stakeholders. The Board did not receive any comments from its public stakeholder posting. During the CSI public comment period, the Board received comments from the National Association of Chain Drug Stores (NACDS) and VillageMD. NACDS expressed its support of the proposed revisions to the rules while VillageMD proposed adding a requirement for a pharmacist that administers an immunization to provide a list of nearby primary care providers to individuals receiving the immunization if they do not have a primary care provider. The Board replied to VillageMD that the burden of maintaining such a list would be difficult and added that there are online resources that patients may utilize to locate a primary care provider themselves. As a result, the Board did not incorporate this suggestion into the rules.

The business community impacted by the rules includes pharmacists and pharmacy interns. The adverse impacts created by the rules include training requirements, developing and following a protocol, obtaining informed consent, obtaining and maintaining basic life support certification, and administrative licensure discipline for violation of the rules such as reprimand, license suspension or revocation, continuing education, and/or a monetary fine. The Board notes that a course for vaccine administration costs up to \$425. The Board states that the adverse impacts to business are justified to protect the health and safety of all Ohioans by providing uniform standards for immunization administration.

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.