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[submitted electronically via: steven.schierholt@pharmacy.ohio.gov]

Steven W. Schierholt, Esq.
Executive Director
Ohio Board of Pharmacy
77 S High Street, 17th Floor
Columbus, OH 43215

Re: Immunization administration

Dear Director Schierholt,

The Ohio Pharmacists Association (OPA) and the American Pharmacists Association (APhA) appreciate the opportunity to submit comments on the recent rule the Ohio Board of Pharmacy (BOP) filed with the Joint Committee on Agency Rule Review (JCARR) regarding pharmacy technician-administered immunizations. We appreciate the opportunity to provide our support and recommendations of the proposed rule filed with JCARR, Ohio Administrative Code (OAC) 4729:3-3-06 "Immunization administration."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. In Ohio, with 23,267 licensed pharmacists and 43,783 pharmacy technicians, APhA represents pharmacists, students, and pharmacy technicians that practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

The Mission of OPA is to unite the profession of pharmacy and encourage interprofessional relations while promoting public health through education, discussion, and legislation. OPA is the largest association of pharmacists in the state, and our membership represents providers that practice across the healthcare continuum.

Ohio pharmacy technicians have been administering vaccines under the supervision of pharmacists since October 2020, when the U.S. Department of Health and Human Services (HHS) issued guidance related to the HHS Declaration under the PREP Act for Medical Countermeasures Against COVID-19. This guidance authorized pharmacy technicians, acting under the supervision of a pharmacist, to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard

immunization schedule.¹ In August 2021, this temporary authority was expanded to authorize pharmacy technicians to administer seasonal influenza vaccines, under the supervision of a pharmacist, to persons ages 19 and older consistent with ACIP recommendations.² As beneficial as this temporary federal authority has been in expanding access to care and relieving some of the burden on an overstressed healthcare system, it is set to expire in the near future without further federal or state clarification. OAC 4729:3-3-06 makes a portion of this temporary federal authority permanent under pharmacy technician state scope of practice to minimize interruptions to patient access to vaccines and ensure Ohio can meet its public health needs.

OAC 4729:3-3-06 will make notable steps to codify pharmacy technician authority to administer immunizations under the direct supervision of a pharmacist and align patient age requirements for receiving an immunization by a pharmacy technician with comparable requirements for pharmacists and pharmacy interns. However, with the eventual end of the federal liability protections for pharmacy personnel under the PREP Act Declarations, access to childhood vaccinations will decline. This will be the most significant for children aged three to six years old.

Throughout the COVID-19 pandemic, routine childhood vaccination rates have decreased. In January 2023, the Centers for Disease Prevention and Control (CDC), found that for the second year in a row, vaccination rates among kindergarten students declined for all state-required vaccines.³ During the 2020-2022 school years, national coverage declined by approximately 250,000 children that are not appropriately protected from vaccine-preventable diseases and can contribute to outbreaks that put both vaccinated and unvaccinated children at risk.

As vaccination rates continue to decline, it is essential to ensure maximum access for children to ACIP-recommended vaccines. Nearly 90% of the overall U.S. population lives within 5 miles of a community pharmacy.⁴ The pharmacy personnel workforce has the potential to continue to serve as an immunization access point. However, patients' access to childhood immunizations from pharmacy teams will be jeopardized without authorities that pharmacy personnel are currently operating under the federal PREP Act Declarations being codified in Ohio. In a study of childhood COVID-19 vaccination rates, the CDC found that "the presence of at least one active provider in a county was associated with higher vaccination coverage when compared with having no active provider in a county, irrespective of provider type".⁵ This study also identified that pharmacies were the most commonly available childhood vaccine provider in a majority of counties. With the high accessibility of community pharmacies due to geographic proximity and county coverage, these results can translate to the maximum amount of childhood immunization providers. However, this is only if pharmacists and pharmacy personnel remain authorized to order and administer ACIP-recommended childhood vaccines.

¹ Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing (October 20, 2020), <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>

² Eighth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (August 4, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-16681.pdf>

³ Centers for Disease Control and Prevention. Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2021–22 School Year. Published January 13, 2023. Available at: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7202a2.htm>.

⁴ Berenbrok LA, Tang S, Hernandez I. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *Journal of the American Pharmacists Association*. Published July 12, 2022. Available at: [https://www.japha.org/article/S1544-3191\(22\)00233-3/fulltext](https://www.japha.org/article/S1544-3191(22)00233-3/fulltext).

⁵ DeCuir J, Meng L, Pan Y, et al. COVID-19 Vaccine Provider Availability and Vaccination Coverage Among Children Aged 5–11 Years — United States, November 1, 2021–April 25, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:847–851. DOI: <http://dx.doi.org/10.15585/mmwr.mm7126a3>.

OPA and APhA are supportive of the steps the BOP has taken in OAC 4729:3-3-06 to better leverage the pharmacy personnel workforce in providing immunizations to patients aged seven and older. However, we are concerned for the continued decline of immunization rates of children aged three to six with the loss of access to vaccines provided by pharmacists, pharmacy interns, and pharmacy technicians. We urge the BOP to use its current statutory authority to align pharmacy personnel immunization authority with the authorities granted under the PREP Act Declarations. If current statutory authority does not allow the BOP to make these changes, we urge the BOP to support efforts to codify these authorities in the Ohio Revised Code. This is an appropriate position for the BOP to take as it is in the best interest of the public and public health to maximize vaccine access as immunization rates decline.

Our second recommendation is to remove the following lines from OAC 4729:3-3-06:

Delete the following stricken text from OAC 4729:3-3-06(C)(4)(b)

~~(viii) Patient populations;~~
~~(ix) Precautions and contraindications;~~

The pharmacist is more appropriately positioned to identify recommended immunizations for specific patient populations as well as immunization precautions and contraindications for patients. We recommend that the pharmacist's role in Pharmacy technicians may be aware of this information, but the responsibility for reviewing this information should be with the pharmacist. Thus, this is outside the scope of pharmacy technician when administering an immunization and is not necessary to be a required component of pharmacy technician immunization programs. Due to this knowledge not being necessary for pharmacy technician administered immunizations, current pharmacy technician immunization training programs may not adequately include this information. The mandated inclusion of this information would require updates to current training programs which would further delay pharmacy technicians in serving as an additional immunization access point within their communities under the supervision of a pharmacist.

Our final recommendation is regarding the mention of the 8/5/2022 immunization schedule in OAC 4729:3-3-06(C)(4)(b). There is potential for the CDC immunization schedule to regularly be changed and updated. In order to ensure that the most up-to-date iteration of the immunization schedule is being taught and adhered to by pharmacy technicians immunizing under the direct supervision of a pharmacist, we recommend that the following change be made:

Add the following underlined text and remove the following stricken text from OAC 4729:3-3-06(C)(4)(b), "A review of each immunization currently 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 ~~(8/5/2022)~~."

Thank you again for the opportunity to submit comments on ensuring optimized access to immunizations for Ohioans. If you have any questions or require additional information, please don't hesitate to contact Don Bennett, RPh, MBA, OPA Interim Executive Director by email at dlbennett@ohiopharmacists.org and E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,

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CC: Cameron McNamee, State of Ohio BOP Director of Policy and Communications