



FLORIDA PHARMACY ASSOCIATION

Unifying and strengthening the voice of pharmacy while advancing pharmacy practice through education, advocacy collaboration, and relationships

September 15, 2020

Florida Department of Health
Attn: Surgeon General Rivkees
4052 Bald Cypress Way
Tallahassee, Florida 32399

Re: HHS Declaration on Childhood Immunizations by Pharmacists

Dear General Rivkees:

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. (FPA), a not-for-profit corporation which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession. The purpose of this letter is to request the issuance of an emergency order clarifying that Florida licensed pharmacists can order and administer vaccines to persons ages three through 18.

As you know, on January 31, 2020, the Secretary of the United States Department of Health and Human Services (the Secretary) declared a public health emergency to aid in response to the COVID-19 outbreak. On March 10, 2020, the Secretary issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act to provide immunity to Covered Persons against any claim of loss relating to the administration of Covered Countermeasures (the Declaration).

On August 19, 2020, the Secretary issued an amendment to the Declaration to include as Covered Persons certain licensed pharmacists when ordering and administering, and certain registered pharmacy interns when administering, any ACIP-recommended vaccine to persons ages three through 18 (the Amendment).¹ The Amendment notes that childhood-vaccination rates have declined since the beginning of the pandemic due to decreases in access to healthcare and COVID-19 mitigation strategies, and that such reduction in childhood vaccinations is a public health threat. To respond to this threat, the Amendment authorizes licensed pharmacists to order and administer, and registered pharmacy interns to administer, vaccines to persons ages three through 18 under the following circumstances:

1. The vaccine must be FDA-authorized or FDA-licensed.
2. The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
3. The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
4. The registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
5. The licensed pharmacist and registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
6. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.

¹ Available at <https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf>.

7. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
8. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

Importantly, the Amendment does not require that pharmacists or pharmacy interns be authorized to administer such vaccines under state law in order to do so under the Amendment. The Amendment itself "authorizes" pharmacists and pharmacy interns to order and administer vaccines in accordance with the requirements of the Amendment.² It is our belief that the Amendment preempts Florida law and authorizes Florida licensed pharmacists and registered pharmacy interns to immediately order and administer vaccines to persons ages three through 18, provided the requirements of the Amendment are met. This interpretation is consistent with a May 19, 2020, advisory opinion from the Department of Health and Human Services indicating that a Declaration under the PREP Act preempts any state law that would prohibit a Covered Person from providing the services authorized by the Declaration.³

While it is our belief that an emergency order is not necessary to authorize Florida licensed pharmacists and Florida registered pharmacy interns to provide vaccinations in accordance with the Amendment, we feel an emergency order is important to clarify which vaccination courses approved under rule 64B16-26.1031, Florida Administrative Code, qualify under the Amendment and the applicable recordkeeping and reporting requirements. For example training

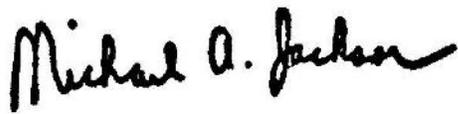
² See Page 3 of the Amendment.

³ See Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (May 19, 2020), <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.

programs offered by the Florida Pharmacy Association have been in collaboration with the American Pharmacists Association (APhA). That program was created using the very best resources of the Center for Disease Control and Prevention as well as cross walking all elements of Florida laws and rules. Pharmacists who completed that training program not only will qualify as vaccine providers for Florida but also could meet requirements as an immunizing pharmacist for all patients in other states the pharmacist may be licensed in. Many of these states have broader authority than Florida. An emergency order addressing these issues will provide clarity to the health care community and will allow Florida pharmacists to assist in remedying the public health threat caused by decreasing childhood-vaccination rates.

On behalf of the FPA, I would like to thank you for your time and consideration of this important matter. Please feel free to contact me should you have any questions or need any additional information.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, BPharm, CPh
Executive Vice President and CEO

Cc: The Honorable Governor Ron DeSantis
Florida Board of Pharmacy
FPA Board of Directors