

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy



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OVERVIEW OF EXPANSION OF CERTAIN PHARMACISTS' AND PHARMACY INTERNS' ABILITY TO ORDER AND/OR ADMINISTER CERTAIN VACCINES UNDER THE PREP ACT

The Department of Health and Human Services Office of the Secretary recently issued its Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 (Third Amendment to Declaration). The Third Amendment to Declaration temporarily expands certain pharmacists' and pharmacy interns' ability to order and/or administer certain vaccines, provided they comply with the requirements set forth in the Third Amendment to Declaration. The South Carolina Board of Pharmacy issues the following overview of the key elements of the Third Amendment to Declaration.¹

The Board recognizes that the Third Amendment to Declaration presents many opportunities for pharmacists throughout SC to provide needed medical care. The Board also realizes that that there are many practical considerations involved when vaccinating individuals in the 3-18-year-old population. The Board encourages any vaccinating pharmacist to consider these differences and become educated on the best practices for vaccinating children and adolescents. Every pharmacist has a responsibility for the safety and wellbeing of his/her patients.

Additionally, the Board notes that the Third Amendment to Declaration conflicts with certain provisions of the protocol established by the Joint Pharmacist Administered Vaccines Committee and approved by the South Carolina Board of Medical Examiners. It also conflicts with certain provisions of S.C. Code Ann. § 40-43-190, including, most notably, the minimum age of patients who may receive certain vaccines. Notwithstanding these provisions of state law, the Board concludes that the Third Amendment to Declaration, as authorized by the Public Readiness and Emergency Preparedness (PREP) Act, preempts state law to the extent state law would prohibit the ordering and administration of vaccines in accordance with the Third Amendment to Declaration.

Finally, this guidance is intended to serve as an overview of the Third Amendment to Declaration, only. It is <u>not</u> intended to provide a comprehensive overview of all requirements for vaccinations under state and federal law. Compliance with the requirements set forth in this document, alone, does not ensure compliance with all federal and/or state requirements/standards regarding vaccinations.

WHO MAY ORDER AND ADMINISTER VACCINATIONS PURSUANT TO THE THIRD AMENDMENT TO DECLARATION?

Licensed pharmacists may order and administer, and pharmacy interns (who are licensed or registered by the Board and acting under the supervision of a licensed pharmacist) may administer, vaccines authorized by the Third Amendment to Declaration.

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¹The full Third Amendment to Declaration is available at: https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf. Licensees should read the Amendment in its entirety. To the extent any information contained herein conflicts with the Third Amendment to Declaration, the Third Amendment to Declaration shall control. Likewise, to the extent the information contained herein conflicts with any future Amendment, that Amendment shall control.

WHAT VACCINES MAY BE ORDERED AND ADMINISTERED PURSUANT TO THE THIRD AMENDMENT TO DECLARATION?

The Third Amendment to Declaration allows for the ordering and administration of any vaccine the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule.

The only vaccines that ACIP has recommended are authorized or licensed by the Food and Drug Administration (FDA). The Third Amendment to Declaration is limited to the ordering and administering of FDA-authorized or FDA-licensed vaccines.

The vaccines must be ordered and administered according to ACIP's standard immunization schedule.²

WHAT TRAINING IS REQUIRED PRIOR TO ORDERING AND/OR ADMINISTERING VACCINES?

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 handson injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

The licensed or 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.

The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.

WHAT ARE THE PHARMACIST'S RECORD KEEPING AND REPORTING OBLIGATIONS?

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.

WHAT INFORMATION MUST BE PROVIDED TO PATIENTS?

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.

²See Immunization Schedules: For Health Care Providers, CDC, https://www.cdc.gov/vaccines/sched-ules/hcp/index.html The immunization schedule recommends that certain vaccines be administered only to children of a certain age. For example, the second dose of both the measles, mumps, and rubella vaccine, as well as the varicella vaccine, should not be administered until a child is between four and six years old. See Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020, CDC (Jan. 29, 2020), https://www.cdc.gov/vaccines/sched-ules/downloads/child/0-18yrs-child-combined-schedule.pdf