

## South Carolina Department of Labor, Licensing and Regulation



**Board of Pharmacy** 

110 Centerview Drive Post Office Box 11927 Columbia, SC 29211-1927 Phone: (803) 896-4700 FAX: (803) 896-4596 Henry D. McMaster Governor

> Emily H. Farr Director

## DHHS EXTENDS AUTHORITY FOR QUALIFIED PHARMACY TECHNICIANS UNDER THE SUPERVISION OF A QUALIFIED 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

The Board previously issued its Overview Of Expansion Of Certain Pharmacists' and Pharmacy Interns' Ability to Order and/or Administer Certain Vaccines Under the Prep Act (Board's Overview).<sup>1</sup> The Board's Overview provided a brief outline of the Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (Third Amendment to Declaration) issued by The Department of Health and Human Services Office of the Secretary (Secretary).<sup>2</sup> As stated in the Board's Overview, 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.

On October 20, 2020, the Secretary issued *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing* (Secretary's Technician Guidance).<sup>3</sup> The Secretary's Technician Guidance authorizes qualified pharmacy technicians "acting under the supervision of a qualified 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."<sup>4</sup>

The Secretary's Technician Guidance defines a "qualified pharmacy technician" for purposes of administering the vaccines described above as a pharmacy technician who meets the following requirements:

- The vaccination must be ordered by the supervising qualified pharmacist.
- The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians.
- The vaccine must be FDA-authorized or FDA-licensed.

<sup>&</sup>lt;sup>1</sup> https://llr.sc.gov/bop/pforms/US%20DHHS%20Vaccination%20Overview%20(002).pdf

<sup>&</sup>lt;sup>2</sup> https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf.

<sup>&</sup>lt;sup>3</sup> <u>https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf</u>. This Guidance also relates to pharmacy interns who are not licensed or registered by their home states. Since interns are registered by certificate in South Carolina, they are covered by the Third Amendment to Declaration. Therefore, reference to interns is omitted in this document for the sake of clarity.

• In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).

• In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule.

• The qualified pharmacy technician or State-authorized pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.

• The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

• The qualified pharmacy technician must complete a minimum of two hours of ACPEapproved, immunization-related continuing pharmacy education during the relevant State licensing period(s).

• The supervising qualified 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 and submitting the required immunization information to the state or local immunization information system (vaccine registry).

• The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events.

• The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or State-authorized pharmacy intern.

• The qualified pharmacy technician and State-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

• The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

The Secretary's Technician Guidance further provides, and the Board does not disagree, that the authorization provided to pharmacy technicians "preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 or routine childhood vaccines as set forth above."<sup>5</sup> As the Board observed in its Overview of the Third Amendment to Declaration, the Board recognizes that the authority granted to pharmacy technicians under the Secretary's Technician Guidance would otherwise conflict with certain provisions of the Pharmacy Practice Act including, but not limited to, the requirements of S.C. Code Ann. § 40-43-190 and general scope of practice requirements for pharmacy technicians.

Because the Secretary's Technician Guidance preempts state law, however, the provisions contained in the Secretary's Technician Guidance apply, notwithstanding anything to the contrary contained in the Pharmacy Practice Act. To that end, the Board generally does not have the authority to interpret the provisions of the Secretary's Technician Guidance. These requirements are established by the Secretary and, as such, the Board is unable to determine if any particular fact-pattern would satisfy the Secretary's requirements.

For example, the Board has already received inquiries as to what constitutes an "approved" training program. The Secretary's Technician Guidance provides that to be considered a "qualified technician," a technician must "complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines." The Board does not have the authority to add to these requirements by imposing a requirement that the course must be a certain length or any similar requirement. Again, it is ultimately up to the Secretary as to whether the program meets the requirements contained in his Guidance.

Finally, as stated in the Board's Overview of the Third Amendment to Declaration, the Board recognizes that the Secretary's actions taken pursuant to the PREP Act present many opportunities for pharmacists, and now pharmacy technicians, to provide needed medical care throughout South Carolina. The Board also realizes that there are many practical considerations involved when vaccinating individuals in the three-through-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. Further, pharmacists now have the requirement to ensure that pharmacy technicians are administering vaccinations safely and otherwise complying with the requirements of the Third Amendment to Declaration. Every pharmacist and pharmacy technician has a responsibility for the safety and wellbeing of his/her patients.