

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING QUALIFIED PHARMACY TECHNICIANS TO ADMINISTER ACIPRECOMMENDED VACCINES TO PEDIATRIC PATIENTS AND FDA-APPROVED COVID-19 VACCINES TO PATIENTS AGED THREE YEARS AND OLDER DURING THE PUBLIC HEALTH EMERGENCY.

On August 19, 2020 the U.S. Department of Health and Human Services ("USDHHS") issued a declaration under the PREP Act authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer" certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. The purpose of this declaration was to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies." Board of Pharmacy guidance on that declaration is found here: <http://www.ncbop.org/PDF/COVID19PREPActVaccinationAug2020.pdf>

On September 9, 2020 USDHHS issued a declaration authorizing pharmacists "to order and administer," and a "supervised pharmacy intern acting under the supervision of [a] qualified pharmacist" "to administer" FDA-approved COVID-19 vaccines, when available, to patients ages three (3) years or older during the federally-declared public health emergency. Board guidance on that declaration is found here: <http://www.ncbop.org/PDF/PREPActCOVIDVaccination090920.pdf>

On October 21, 2020, USDHHS issued another declaration under the PREP Act authorizing "qualified pharmacy technicians" to administer ACIP-recommended vaccines to patients ages three (3) to eighteen (18) and FDA-approved COVID-19 vaccines to patients ages three (3) years or older under the supervision of a qualified pharmacist. (<https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>) Note: This declaration also clarified the ability of qualified pharmacy interns to administer such vaccines. The two Board guidance documents linked above discuss pharmacy intern authority.

USDHHS defines a "qualified pharmacy technician" as a technician "licensed and/or registered in accordance with state requirements." Under North Carolina law, registered pharmacy technicians do not have a statutory authority to administer vaccines (or any other drug). The USDHHS authorization, however, "preempts any state and local law that prohibits or effectively prohibits [qualified pharmacy technicians] from administering COVID-19 or routine childhood vaccines" as outlined in the declaration.

In addition to being registered, the pharmacy technician must comply with the following requirements to be eligible to administer vaccines pursuant to this declaration:

- The vaccination must be ordered by the supervising qualified pharmacist. See prior Board guidance noted above.
- The supervising qualified pharmacist must be readily and immediately available to the qualified pharmacy technicians administering vaccines. Note: This requirement is substantively identical to Board Rule .2507's description of pharmacist supervision of interns who administer vaccines.
- The vaccine must be FDA-authorized or FDA-licensed. Note: Administration of a vaccine that is not FDA-authorized or approved would lead to a host of problems, technician administration likely being the least of them.

- 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. Note: Because pharmacy technicians in North Carolina had no prior authority to administer vaccines, few, if any, are likely to have completed this type of training program. This training must be completed and documented prior to a technician administering any vaccine. Pharmacist-managers are responsible for ensuring that any pharmacy technician administering vaccines have received the training and documenting that training.
- The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. Note: This training must be completed and documented prior to a technician administering any vaccine. Pharmacist-managers are responsible for ensuring that any pharmacy technician administering vaccines has obtained basic CPR certification and documenting that training.
- The qualified pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the relevant State licensing period(s). Note: North Carolina law does not require pharmacy technicians to obtain continuing education. Certified technicians are required by their certifying entity -- PTCB or NHA – to obtain continuing education to renew their certification with those entities. Pharmacist-managers are responsible for ensuring that any pharmacy technician administering vaccines under this declaration obtains the required immunization-related CE during the 2021 registration year and documenting it.
- 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). See prior Board guidance noted above.
- The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events. See prior Board guidance noted above.
- 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. See prior Board guidance noted above.
- 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. See prior Board guidance noted above.

- 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). See prior Board guidance noted above.

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A North Carolina immunizing pharmacist, pharmacy intern, or qualified pharmacy technician who orders (immunizing pharmacist only) or administers (immunizing pharmacist, pharmacy intern, or qualified technician) vaccines in compliance with DHHS' declarations during the federally-declared COVID-19 public health emergency shall not be deemed by the Board of Pharmacy to be in violation of the North Carolina Pharmacy Practice Act.