

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING PHARMACISTS TO ORDER AND ADMINISTER COVID-19 VACCINES TO PATIENTS AGED THREE YEARS AND OLDER DURING THE PUBLIC HEALTH EMERGENCY.**

On September 9, 2020 the U.S. Department of Health and Human Services issued a declaration (<https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>) 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.

This US DHHS authorization "preempts any State and local law that prohibits or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines . . . ." On May 4, 2020, the North Carolina General Assembly passed, and Governor Cooper signed into law, S.L. 2020-3 (<https://www.ncleg.gov/Sessions/2019/Bills/Senate/PDF/S704v6.pdf>) Among other things, that law provides a mechanism by which "any person" may petition the State Health Director to authorize immunizing pharmacists to administer a COVID-19 vaccine once such a vaccine is approved. That statute provides a process whereby such authority could be granted, including a process for creating written protocols and screening questionnaires. The US DHHS authorization preempts that state law process during the public health emergency.

This update describes the conditions under which pharmacists and pharmacy interns may exercise the authority granted in the US DHHS declaration, and how these conditions differ from existing North Carolina law (see G.S. § 90-85.15B, "Immunizing pharmacists").

- *Pharmacists may "order" FDA-approved COVID-19 vaccines for patients ages three (3) or older. This is a new authority. Under current North Carolina law, immunizing pharmacists' authority to "order" vaccines is limited to administering certain vaccines to patients age 18 and older by protocol, see G.S. § 90-85.15B(b)(1)-(7), and to administering influenza vaccine to patients age 10 and older by protocol, see G.S. § 90-85.15B(c).*

A prior US DHHS declaration under the PREP Act authorized pharmacists to order and administer certain vaccines to patients ages three (3) to eighteen (18) during the public health emergency. More information on that prior authorization is found here: <http://www.ncbop.org/PDF/COVID19PREPActVaccinationAug2020.pdf>

- *The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP's) COVID-19 vaccine recommendation. This is a "new" requirement. As of this writing, there is no FDA-approved COVID-19 vaccine on the market. When such vaccines are approved, ACIP will implement recommendations.*

- 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. This is not a new requirement under North Carolina law or the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. Under North Carolina law, immunizing pharmacists already must have completed “a certificate program in vaccine administration accredited by . . . the Accreditation Council for Pharmacy Education . . . .” G.S. § 90-85.3(i1)(3).*
- The 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. This is not a new requirement under North Carolina law or the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. Under North Carolina law, a pharmacy intern under the supervision of a registered pharmacist may perform all acts constituting the practice of pharmacy. 21 NCAC 46.1317(29). And that authority expressly extends to the administration of a vaccine. 21 NCAC 46.2507(b)(1)(A). Supervising pharmacists must, of course, ensure that the pharmacy intern has completed his/her immunization certification course.*
- The licensed pharmacist and pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. This is not a new requirement under North Carolina law or the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. Under North Carolina law, an immunizing pharmacist must hold a “current provider level cardiopulmonary resuscitation certification issued by the American Heart Association or the American Red Cross, or an equivalent certification.” G.S. § 90-85.3(i1)(1) (emphasis added). Provider-level CPR certification covers basic CPR and more. Supervising pharmacists must, of course, ensure that the pharmacy intern holds current CPR certification.*
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period. This is a (slightly) new requirement under North Carolina law. This is not a new requirement under the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. North Carolina law requires an immunizing pharmacist to maintain “documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration.” G.S. § 90-85.3(i1)(3). Any pharmacist exercising authority granted under the PREP Act must slightly increase his/her immunization-related CE and acquire two (2) hours in 2020 and two (2) hours in 2021 (assuming, as is likely, that the federally-declared COVID-19 public health emergency remains in effect into 2021).*

- 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. This is not a new requirement under North Carolina law or the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. North Carolina law already requires an immunizing pharmacist to notify a patient's identified primary care provider of the vaccine administration, access the North Carolina Immunization Registry prior to administering a vaccine, and record any vaccine (other than influenza) administered in the Registry. G.S. § 90-85.15B(d)(2)-(3). \*Note: Pharmacists are nonetheless encouraged to enter flu vaccine into the Registry, especially for pediatric populations, to help ensure a complete vaccine history is captured in the NCIR and visible to the patient's primary care provider*
- The licensed pharmacist 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. This is a (slightly) new requirement under North Carolina law. This is not a new requirement under the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines. North Carolina law requires an immunizing pharmacist administering a vaccine to conduct a screening questionnaire and, when a patient does not identify a primary care provider, to direct the patient to certain information describing the benefits of having a primary care physician. Slight modifications to this process will satisfy the DHHS requirement.*
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s). This is a "new" requirement. As of this writing, there is no FDA-approved COVID-19 vaccine on the market. When such vaccines are approved, CDC and FDA will set forth requirements concerning their administration.*
- The DHHS declaration does not condition a pharmacist's ability to order or administer a qualifying vaccine to a patient age three (3) or older. This differs from North Carolina law. This does not differ from the previous US DHHS declaration concerning pharmacist administration of pediatric vaccines North Carolina law requires that an immunizing pharmacist have in place a written protocol with a supervising physician. 21 NCAC 46.45.2507(b)(12). Pharmacists are reminded that, as detailed immediately above, the HHS declaration does require notification to the patient's primary care physician when available.*

A North Carolina immunizing pharmacist who orders and administers COVID-19 vaccines in compliance with DHHS' declaration 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.