UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING PHARMACISTS TO ORDER AND ADMINISTER, AND QUALIFIED PHARMACY TECHNICIANS TO ADMINISTER, CERTAIN COVID-19 THERAPEUTICS

On September 9, 2021 the U.S. Department of Health and Human Services ("US DHHS") issued a declaration under the PREP Act authorizing pharmacists "to order and administer," and qualified pharmacy technicians and interns "to administer" select COVID-19 therapeutics to patient populations authorized by the FDA. The declaration is found here: https://www.phe.gov/Preparedness/legal/prepact/Pages/PREPact-NinethAmendment.aspx

COVID Therapeutic. A "COVID-19 therapeutic" must be one authorized, approved, licensed, or cleared by the FDA. A pharmacist may order and administer, and a qualified pharmacy technician or intern may administer, a COVID-19 therapeutic if by subcutaneous, intramuscular, or oral route. And the therapeutic must be administered in accordance with the FDA approval or authorization conditions.

Application to Monoclonal Antibody Therapy. The most immediate application of this authorization is the ordering and administration of REGEN-COV, a monoclonal antibody combination. The FDA has issued an emergency use authorization (EUA) for REGEN-COV to be administered subcutaneously to certain patients age 12 or older, and who weigh at least 40 kg, to treat COVID-19 or to provide post-exposure prophylaxis. Complete details on patient selection, dosing, administration, adverse event reporting, and other information are contained in the EUA Fact Sheet for Health Providers -- https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf. Note particularly the patient conditions that must be adhered to when ordering and administering REGEN-COV, found on pages 6-7 of the EUA Fact Sheet for Health Providers.

The FDA's emergency use authorization of REGEN-COV for post-exposure prophylaxis is found here: https://www.fda.gov/media/145610/download Note that the EUA specifies (p. 12) that any facility where healthcare providers administer REGEN-COV must:

- Provide authorized Fact Sheets to patients and caregivers prior to administration -- https://www.fda.gov/media/145612/download
- Track serious adverse events and medication errors considered attributable to REGEN-COV and report them within seven (7) days to FDA in accordance with the EUA Fact Sheet for Health Providers (pp. 16-17 here: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf)
- Ensure that appropriate storage and cold chain is maintained until the product is administered.
- Maintain records regarding dispensed REGEN-COV (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered, other drugs administered)

- Maintain records until notified by Regeneron of FDA, and must be made available to Regeneron, US DHHS, and FDA upon request.

- Report therapeutics information and utilization data as directed by US DHHS.

The FDA's FAQ on REGEN-COV for COVID-19 is found here:
https://www.fda.gov/media/143894/download

Regeneron provides Information and tools for patients and providers here:
https://www.regencov.com/

Training/Administration Requirements.

A pharmacist, qualified technician, or intern who administers a COVID-19 therapeutic intramuscularly or subcutaneously must:

- Complete an ACPE-approved practical training program that must include:

  hands-on injection technique

  clinical evaluation of indications and contraindications of COVID-19 therapeutics

  the recognition and treatment of emergency reactions to COVID-19 therapeutics, and

  any additional training required in the FDA approval, authorization, clearance, or licensing.

  NOTE: This COVID-19 therapeutic-specific aspect of the training requirement is new. A pharmacist, technician, or intern who has already completed ACPE-approved hands-on injection technique does not need to repeat that aspect of the required training. CE providers are encouraged to notify the Board of COVID-19 therapeutics course offerings.

- Have a current certificate in basic cardiopulmonary resuscitation. This is not a new requirement.

- Comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics (see above)

A qualified technician who administers a COVID-19 therapeutic must have a supervising pharmacist readily and immediately available.

A pharmacist who administers a COVID-19 therapeutic must comply with all applicable recordkeeping and reporting requirements, including informing the patient's primary care provider when available and complying with requirements with respect to reporting adverse events.

State Standing Order. Although the PREP Act declaration is an independent grant of authority to pharmacists, on September 2, Governor Cooper issued Executive Order 232, which directs State Health Director Betsey Tilson to issue a statewide standing order to expand access to monoclonal antibody

treatment for COVID-19: https://governor.nc.gov/media/2723/open When Director Tilson issues that standing order, Board of Pharmacy staff will update this guidance document.

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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) COVID-19 therapeutic 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.