



Expanding Access to COVID-19 Therapeutics

Updated 1/21/2022

To promote access to therapeutics to treat COVID-19, the Department of Health and Human Services (HHS) amended the [Public Readiness and Emergency Preparedness \(PREP\) Act declaration](#) to provide liability protection to **licensed pharmacists, pharmacy technicians*, and pharmacy interns.**

By expanding PREP Act coverage to include these trained professionals for the administration of covered COVID-19 therapeutics, HHS is providing a pathway for increased access to COVID-19 therapeutics, particularly in surge states with rising numbers of COVID-19 cases and in rural areas where access to inpatient and outpatient services may be more limited.

The PREP Act and Declaration preempt state requirements, such as more limited licensing or scope of practice requirements, that effectively prohibit a qualified person from prescribing, dispensing, or administering COVID-19 therapeutics. Requirements that do not effectively prohibit qualified persons, such as additional training, are not preempted. Ultimately, states and territories may choose which qualified persons to use for administering COVID-19 therapeutics in their jurisdiction.

IMPORTANT UPDATE 1/21/22: The FDA issued prescribing requirements for new COVID-19 therapeutics (such as EVUSHELD™) under emergency use authorization. Therefore, pharmacists are not permitted to order certain COVID-19 therapeutics using the PREP Act Authorization. For more information, pharmacists should consult each therapeutic's Emergency Use Authorization.

For specific questions regarding the distribution of COVID-19 therapeutics in Ohio, please email the Ohio Department of Health: therapeutics@odh.ohio.gov



PREP Act Declaration 9th Amendment Who's Covered?

Qualified Persons

The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID-19 therapeutics to populations authorized by the FDA **and** for **pharmacy technicians (registered or certified)* and pharmacy interns** to administer COVID-19 therapeutics to populations authorized by the FDA when the following criteria are met:

- The COVID-19 therapeutic must be authorized, approved, licensed, or cleared by the FDA.
- In the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be:
 - Ordered for subcutaneous, intramuscular, or oral administration; and
 - In accordance with the [FDA approval, authorization, clearance, or licensing](#).
- In the case of licensed pharmacists, qualified pharmacy technicians*, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be: administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, clearance, or licensing.+
- In the case of qualified pharmacy technicians*, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician.
- In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician* 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 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.
- The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician* must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which they administer COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events. For more information on COVID-19 therapeutics, visit: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx>
- The licensed pharmacist, the licensed or registered pharmacy intern, and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.

*As the HHS guidance contemplates a level of formal training to be deemed a pharmacy technician, an individual holding a registration as a pharmacy technician trainee does not qualify as a qualified pharmacy technician under this amendment.

+A pharmacist, pharmacy intern, or pharmacy technician (registered or certified) may also administer a COVID-19 therapeutic pursuant to a prescription from a licensed prescriber in accordance with this amendment.

Frequently Asked Questions

1. Can pharmacists order the administration of COVID-19 therapeutics by registered nurses?

Yes. Registered nurses are authorized under ORC 4723.01(B) to administer medications “authorized by an individual who is authorized to practice in this state and is acting within the course of the individual's professional practice.”