Expanding Access to COVID-19 Therapeutics
HHS PREP Act Declaration: 9th Amendment

COMMITMENT TO ENDING THE COVID-19 PANDEMIC

Throughout the COVID-19 response, the federal government has remained steadfast in providing support to states and territories as part of the whole-of-America approach to fighting the pandemic. The Biden administration remains committed to developing safe and effective therapeutics against the COVID-19 virus and making these drugs accessible across the country.

To support this priority effort, 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, we are 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.

COVID-19 PREP ACT DECLARATION

What is a PREP Act Declaration?

The PREP Act allows the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that extends liability protections to entities and individuals who manufacture, distribute, or administer covered medical countermeasures against a public health threat or emergency. In March 2020, the Secretary issued a PREP Act Declaration covering COVID-19 tests, drugs, and vaccines providing liability protections to manufacturers, distributors, SLTTs, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures.

What is the Impact on SLTTs?

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.

For more information on the COVID-19 PREP Act Declaration, please visit: phe.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 and pharmacy interns** to administer COVID-19 therapeutics to populations authorized by the FDA when the following criteria are meet:

- 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 he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events.
- 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.

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