



ASPR

Expanding Access to COVID-19 Therapeutics

HHS PREP Act Declaration: 9th Amendment

September 2021

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Public Readiness and Emergency Preparedness (PREP) Act

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March 2020 PREP Act Declaration

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The Public Readiness and Emergency Preparedness (PREP) Act

The PREP Act

- The **Public Readiness and Emergency Preparedness Act** (PREP Act) authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act declaration.
- A declaration provides immunity from liability (except for willful misconduct) for claims:
 - of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
 - determined by the Secretary to constitute a present, or credible risk of a future public health emergency
 - to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures
- A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.



The March 2020 PREP Act Declaration

Public Readiness and Emergency Preparedness (PREP) Act Declaration



In March 2020, the Secretary of HHS issued a PREP Act declaration **providing liability protections to manufacturers, distributors, states, localities, territories, tribes, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer covered countermeasures, including COVID-19 therapeutics** authorized under an EUA by the U.S. Food and Drug Administration (FDA).

[Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19](https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures)

(<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>)

COVID-19 PREP Act Declaration



What is the PREP Act Declaration?

- Covers 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
- The Declaration has been amended several times to expand liability protections, including prior amendments to cover licensed healthcare professionals who cross state borders and federal response teams



Who is Covered?

- Licensed or certified health professionals or other individuals authorized by the state to administer COVID-19 countermeasures
- Health professionals and other individuals identified as qualified persons under the PREP Act Declaration amendments are also covered



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 vaccines.
- 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.

[PHE.gov | Public Readiness and Emergency Preparedness Act](https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx) (<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>)



Ninth Amendment to the March 2020 PREP Act Declaration

Ninth Amendment: Adding Covered Qualified Persons

WHY:

Provide 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

WHAT:

*Expanded pool of providers to **administer covered COVID-19 therapeutics** authorized under an EUA by the U.S. Food and Drug Administration (FDA)*

*The PREP Act Declaration should be used by SLTTs to **complement other efforts** to increase access to COVID-19 therapeutics, such as health education. **States are encouraged to further expand the categories of persons authorized** to administer COVID-19 therapeutics in their states and territories, as authorized under the PREP Act, to respond to the local needs and availability.*

Expanded Coverage of Qualified Persons

The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity and authorizes **licensed pharmacists** to order and administer select COVID-19 therapeutics authorized by the FDA and for **pharmacy technicians**, and **pharmacy interns** to **administer COVID-19 therapeutics** 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.

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Expanded Coverage of Qualified Persons

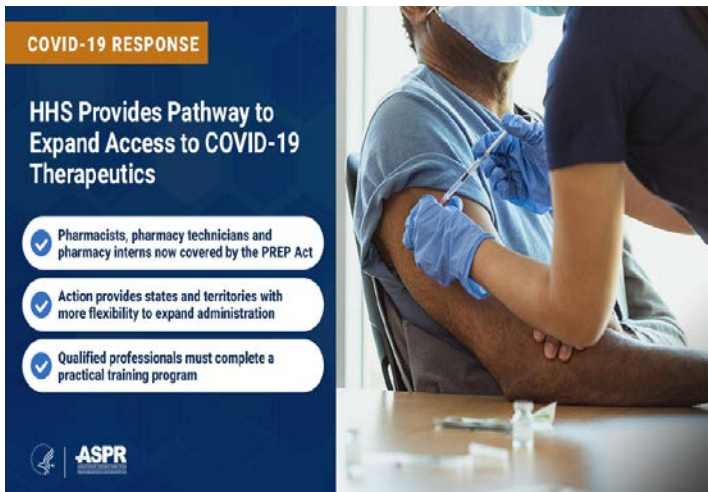
The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity and authorizes **licensed pharmacists** to order and administer select COVID-19 therapeutics authorized by the FDA and for **pharmacy technicians**, and **pharmacy interns** to **administer COVID-19 therapeutics** authorized by the FDA when the following criteria are met (*continued*):

- 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.

Communication: Amplification of Update

Share information about the March 2020 PREP Act Declaration Ninth Amendment with your stakeholders

Social Media



COVID-19 RESPONSE

HHS Provides Pathway to Expand Access to COVID-19 Therapeutics

- Pharmacists, pharmacy technicians and pharmacy interns now covered by the PREP Act
- Action provides states and territories with more flexibility to expand administration
- Qualified professionals must complete a practical training program

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Slide Presentation

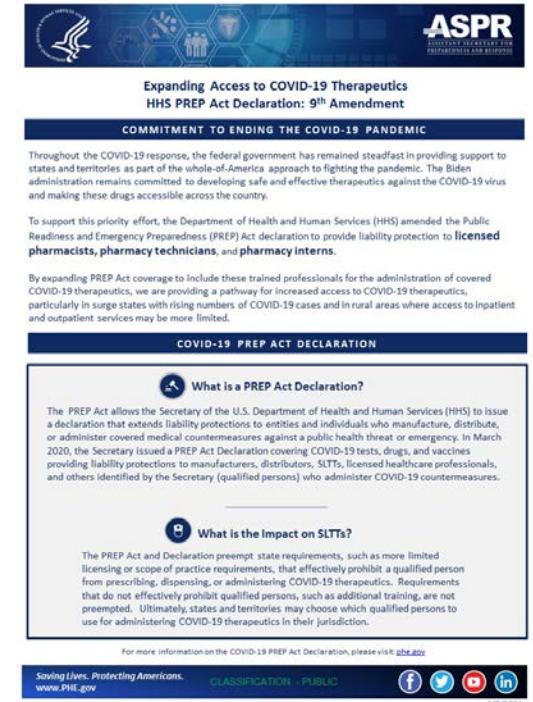
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Fact Sheet



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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: [gbt.gov](https://www.gbt.gov)

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9/8/2021



More Information

For more information on the [March 2020 PREP Act](https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx) and its [amendments](https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx), visit:
<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>
and
www.PHE.gov/COVIDvaccinators

If you have any questions, please [email ASPRStakeholder@hhs.gov](mailto:ASPRStakeholder@hhs.gov)