

Nothing herein is legal advice.



COVID-19 Vaccine Liability Protection Under the PREP Act

The Texas Hospital Association offers this guidance as THA members begin to receive COVID-19 vaccines and therapeutics, to increase awareness of liability protections currently available under the Public Readiness and Emergency Preparedness Act. The following provides basic information on the PREP Act and potential implications for certain actions hospitals might undertake in response to the COVID-19 pandemic.

1. What is the PREP Act?

The PREP Act was established by the U.S. Congress in 2005 to deter litigation and instead quickly compensate individuals for serious injuries resulting from certain medical interventions in response to serious public health threats, such as pandemics. Among other things, the Act allows the U.S. Health and Human Services Secretary to provide immunity to “covered persons” against any liability related to the manufacture, distribution, administration or use of “covered countermeasures.”

2. How are the PREP Act’s provisions triggered?

The HHS Secretary must issue a formal declaration to trigger the PREP Act’s provisions, including immunity from liability. A declaration includes the determination of a threat or credible risk, recommendation for action, category of diseases, health conditions or health threats, effective time period, covered population, geographic area of administration, and any limitations. It must delineate the activities covered by the Act’s immunity provisions and indicate those liability protections are in effect.

3. Is there a COVID-19-related declaration?

Yes. The HHS Secretary issued a [declaration, effective Feb. 4](#), in response to COVID-19. The declaration is separate and apart from the Secretary’s Jan. 31 public health emergency declaration but includes many of the same findings.

The Secretary [amended this declaration on Dec. 3](#) to expand and clarify its scope.

4. Does this provide liability protection?

Yes, subject to the declaration, covered persons receive immunity from tort liability related to covered countermeasures.

Under the Act, declaration, and amendment, liability protection for covered countermeasures began Feb. 4, 2020 and currently extend through Oct. 1, 2024. Specific to vaccine countermeasures, liability protection began Aug. 24, 2020 and extend through the final day of the Declaration of Emergency or Oct. 1, 2024, whichever occurs first.

The declaration and amendment limit liability protection to covered persons undertaking recommended activities related to:

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- Covered countermeasures related to any present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda or understanding, or other federal agreements;
- Covered countermeasures properly authorized with the public health and medical response of an appropriate public health authority;
- Covered countermeasures that received licensure or emergency use authorization from the Food and Drug Administration; or are permitted for use under an investigational new drug application or Investigational Device Exemption; and
- Respiratory protective devices approved by the National Institute for Occupational Safety and Health.

5. Are there limitations to the PREP Act's liability protection?

The PREP Act's immunity is broad, but not absolute and limited to claims for personal injury or damage to property. The Act addresses certain claims with a no-fault compensation program and contains a broad preemption provision, which prohibits any law or requirement in conflict with the Act's requirements. States may not impose any requirement that would prohibit or effectively prohibit activities authorized by the Secretary in a PREP Act declaration.

Specific examples of some claims not protected by the PREP Act include:

- Claims based on activities outside the declaration's scope;
- Federal enforcement actions;
- Claims with no causal relationship to the administration or use of a covered countermeasure;
- Death or serious physical injury caused by willful misconduct;
- Claims filed under foreign law in courts outside of the U.S.; and
- Claims other than tort claims (e.g., violations of civil rights laws, the ADA, labor laws, etc.).

6. What is a Covered Countermeasure?

Under the Act, declaration, and amendment, a "covered countermeasure" includes:

- Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:
 - To diagnose, mitigate, prevent, treat or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
 - To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause;
- A product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;
- A product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or,
- Any device used in the administration of any such product, and all components and constituent materials of any such product.

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7. Am I or my facility a “covered person” for purposes of immunity?

The definition of covered person should be sufficiently broad to cover hospitals and health care entities involved in designated countermeasures.

Under the Act, declaration and amendment, both “qualified persons” – broadly defined as those who prescribe, administer or dispense covered countermeasures (e.g., health care providers) – and “program planners” – broadly defined as individuals or entities involved in planning, administering or supervising programs for distribution of a countermeasure and which may be private sector employers – are “covered persons” and afforded liability protection.

Additionally, the amendment adds the following to the definition of covered person:

- State-licensed pharmacists, pharmacist interns, and pharmacy technicians, operating under proper licensure and supervision, who administer COVID-19 vaccines pursuant to the Act and declarations provisions; and,
- Health care personnel using telehealth to order or administer covered countermeasures in a state other than a state where the healthcare personnel is licensed or otherwise permitted to practice, if the healthcare personnel complies with all requirements for ordering and administering covered countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice.

8. How can I be certain the PREP Act’s immunity provisions apply in my situation?

HHS believes Congress did not intend to impose strict liability on covered persons for determining whether a product is a covered countermeasure. HHS indicates a person or entity that otherwise meets PREP Act immunity requirements if that person or entity reasonably could have believed they were a covered person, reasonably could have believed that the product was a covered countermeasure (even if the product is not, in fact, a covered countermeasure), and did not engage in willful misconduct that proximately caused serious injury or death. The test should be whether reasonable steps or reliance were undertaken in connection with the product or activity.

Note: the declaration and amendment make explicit that there may be situations where *not* administering a covered countermeasure to a particular individual can fall within the Act’s liability protections. This provision may be in response to a judicial holding from 2014, indicating that failure to provide a vaccine may be outside the Act’s scope; this explicit provision should eliminate any such gap in coverage.

9. How can I be sure a specific individual is considered a covered person under the PREP Act?

“Covered person” is broadly defined and individuals may be added to the definition if they are authorized to respond to the public health and medical emergency response by the public agency with legal responsibility and authority for such response.

As above, an entity or person that otherwise meets requirements will maintain immunity if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person – even if not actually a covered person.

10. Is there anything else to consider regarding the PREP Act’s immunity protection?

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The Act's immunity is broad, but willful misconduct is not protected – meaning this is generally the standard of proof for claims covered by the Act. Moreover, the Act exempts from the definition of “willful misconduct” acts consistent with applicable directions, guidelines or recommendations by the Secretary regarding the administration or use of a covered countermeasure, provided either the Secretary or a state or local health authority was provided with information regarding serious physical injury or death from the administration or use of a covered countermeasure within seven days of the actual discovery of such information.

Actual and potential covered persons should document all reasonable activities and precautions undertaken with regards to any actual and potential covered countermeasures.

11. Must I provide any informed consent to the recipient of the COVID-19 vaccine?

No, as of the date this document was updated. State and federal officials indicate that no formal consent or signature is required from the recipient. However, some THA members prepared short forms for recipients to indicate that the vaccine is provided subject to an EUA, with any effect not yet fully known, and referencing the need for Texas hospitals to report the administration of the vaccine via the state tracking program.

12. Must I provide the vaccine recipient with any documentation?

Yes. Each vaccine should arrive with an information or fact sheet and must be provided to the recipient at the time of vaccination. Please reference and share the Pfizer vaccine [Fact Sheet for Recipients and Caregivers](#) and Moderna vaccine [Fact Sheet for Recipients and Caregivers](#). THA will forward any other information or fact sheets, as received.

Contact:

Please forward any questions to THA's associate general counsel, [Cesar J. Lopez](#).