

Nothing herein is legal advice.



Liability Protections Available Under the PREP Act

As the health care community's response to COVID-19 evolves, the Texas Hospital Association continues to advocate for increased liability protection for Texas hospitals at the state and federal levels. THA offers this frequently asked questions document 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 influenza 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.

4. Does this provide liability protection?

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

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

The PREP Act's immunity is broad (as set forth below), but not absolute and limited to claims for personal injury or damage to property. The Act also 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.

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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 casual 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?

Covered countermeasures may include emergency use of certain products in emergency situations, products held for emergency use, products or technologies intended to enhance the use or effect of a drug, biological product, or device used in response to a pandemic or epidemic, and qualified pandemic and epidemic products, and use may be afforded immunity under the PREP Act.

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

As determined by the Secretary and for purposes of immunity, covered persons may include “qualified persons” who prescribe, administer or dispense covered countermeasures (e.g., health care providers) and “program planners,” defined as individuals or entities involved in planning, administering or supervising programs for distribution of a countermeasure and which may be private sector employers. This definition should be sufficiently broad to cover hospitals and health care entities involved in designated countermeasures.

8. What is covered by this declaration?

Under this declaration, a covered countermeasure is:

any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

In addition, covered countermeasure includes:

1. any drug, device, or biological product approved, cleared, or licensed by the Food and Drug Administration and used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19;
2. respirators, which may not be medical devices, so long as they are approved by the National Institute for Occupational Safety and Health and subject to an emergency use authorization;
3. any drug, device, or biological product authorized for emergency use with respect to COVID-19 under an EUA, described in emergency use instructions issued by the Centers for Disease Control and Prevention, or being researched under certain investigational provisions to treat COVID-19;
4. a qualified pandemic or epidemic product, which is a product that
 - a. must be used for COVID-19; and must be
 - i. approved, licensed, or cleared by FDA;
 - ii. authorized under an EUA;

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- iii. described in an EUI; or,
- iv. used under either an investigational new drug application or an investigational device exemption.

9. 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 will maintain that immunity if that person or entity reasonably could have believed that the product was a covered countermeasure (even if the product is not, in fact, a covered countermeasure). The test should be whether reasonable steps or reliance were undertaken in connection with the product or activity.

10. 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. For example, HHS issued guidance for licensed pharmacists to order and administer FDA-approved COVID-19 tests. Because the tests are covered countermeasures, the applicable pharmacists are covered persons, even if they may not be licensed or authorized by the state to prescribe the tests.

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.

11. Is there anything else to consider regarding the PREP Act's immunity protection?

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 7 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.