



Public Readiness and Emergency Preparedness Act (PREP Act) Overview

The federal Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the federal Department of Health and Human Services (HHS) to issue a declaration related to threats to the public health from diseases or other health conditions.¹ Such a declaration triggers immunity from tort liability for certain persons (covered persons) “arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]”²

Effective Feb. 4, 2020, the HHS Secretary issued a declaration under the PREP Act due to COVID-19 and has since issued several amendments to the declaration. For additional information about the declaration and amendments go to: <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

If you have specific legal questions about whether the PREP Act provides immunity for you or your business or organization, you should contact an attorney. However, below is some general information about PREP Act liability protection that may be helpful.

Liability protection

The PREP Act provides legal immunity from tort liability for covered persons engaged in activities related to covered countermeasures:

- **Covered persons:** The PREP Act covers specific classes of individuals and entities, and the PREP Act declaration and amendments further elaborate on those classes. Covered persons may include manufacturers, distributors, program planners and qualified persons who prescribe, administer or dispense countermeasures, such as health care and other providers. For purposes of COVID-19, qualified persons administering a COVID-19 vaccine or performing a COVID-19 test would be covered persons.

¹ 42 USC § 247d-6d(b)

² 42 USC § 247d-6d(a)(1). A tort is an act or omission that causes harm or injury for which an individual can seek compensation.

- **Activities covered:** Immunity applies to the development, manufacture, testing, distribution, administration and use of covered countermeasures. The administration or use of a COVID-19 vaccine would be a covered activity.
- **Covered countermeasures:** Countermeasures can include but are not limited to vaccines, drugs or medical devices to be used to mitigate, prevent or limit harm from pandemics. For purposes of COVID-19, personal protective equipment (PPE), masks, tests, drugs or vaccines approved by the Federal Drug Administration (FDA) under an Emergency Use Authorization (EUA) are covered countermeasures. For more information about EUAs go to: <https://www.phe.gov/Preparedness/planning/authority/Pages/eua.aspx>; and <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices>.
- **Claims covered:** The PREP Act provides immunity from tort liability, including but not limited to claims related to death and physical, mental or emotional injury, illness or disability, and the fear of these conditions. The PREP Act DOES NOT cover actions or failures to act that are the result of willful misconduct. For additional information about what kinds of claims are covered, go to: <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>.

Compensation fund

The PREP Act has an emergency fund that provides compensation for injuries caused by administration or use of a countermeasure covered by an HHS Secretary's declaration. The fund is administered through the Countermeasures Injury Compensation Program (CICP). For more information about the fund go to: <https://www.hrsa.gov/cicp/about>.

What the PREP Act does not do

A PREP Act declaration only provides immunity from liability for the persons, activities and countermeasures specified in the declaration; it does not automatically protect everyone involved in any kind of medical response to an emergency. As stated above, the PREP Act does not apply where the liability arose from willful misconduct.

Additionally, there is no immunity for claims related to civil rights violations, such as discriminatory treatment based on race or disability, or related to violations of the Americans with Disabilities Act (ADA), as these are not connected to tort claims.

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