

Public Readiness and Emergency Preparedness Act Fact Sheet

Overview

The [Public Readiness and Emergency Preparedness Act of 2005](#) (PREP Act)¹ authorizes the secretary of the Department of Health and Human Services (HHS) to issue a declaration that provides immunity from tort liability for claims of loss caused by countermeasures (e.g., vaccines, drugs, products) against diseases or other threats of public health emergencies. The PREP Act added new authorities under the Public Health Service Act to address concerns about potential liability associated with the development and administration of countermeasures.

What the Law Does

Liability Protection

The PREP Act confers immunity from liability on specified persons for certain activities related to covered countermeasures:

- **Persons Covered**—The PREP Act covers individual persons and entities. Covered persons may, at the secretary's discretion, include manufacturers, distributors, program planners (i.e., individuals and entities involved in planning and administering programs for the distribution of countermeasures), and qualified persons who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers). The U.S. officials, agents, and employees of any of these entities or persons are also covered persons.
- **Activities Covered**—Immunity applies to the development, manufacture, testing, distribution, administration, and use of countermeasures.
- **Countermeasures Covered**—Countermeasures can include vaccines, drugs, or medical devices to be used against chemical, biological, radiological, and nuclear (CBRN) agents of terrorism, epidemics, and pandemics.
- **Claims Covered**—The act provides immunity from tort liability except for willful misconduct. PREP Act immunity covers claims for death and physical, mental, or emotional injury, illness, or disability and the fear of these conditions. Liability protections also extend to claims made for medical monitoring as well as loss or damage to property, including business interruption. Claims that have a causal relationship to the development, distribution, administration, or use of the covered countermeasures are potentially included within the scope of PREP Act liability protections.³

Compensation Fund

The PREP Act authorizes an emergency fund in the U.S. Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the secretary's declaration. The [Countermeasures Injury Compensation Program \(CICP\)](#) is administered by the Health Resources and Services Administration (HRSA).

What the Law Does Not Do

A PREP Act declaration by the HHS secretary 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. The act's liability protections do not apply where the liability arose from willful misconduct. It also does not protect individuals who violate a person's civil rights or who violate the Americans with Disabilities Act, among other exceptions stated in the act. The PREP Act does not confer any other immunities or liability protections.

A PREP Act declaration is different from, and independent of, other federal emergency declarations. A separate public health emergency determination under [Public Health Service Act Section 319](#) or another statute is not required for PREP Act immunities to take effect.³

How the Law Works

Before issuing a PREP Act declaration, the secretary must determine that a disease, condition, or threat to health constitutes a public health emergency or a credible risk of future public health emergency and find that the development

of a countermeasure is desirable. The secretary then issues a PREP Act declaration that specifies the following, among other things:

- The countermeasures covered by the declaration.
- The category of diseases, health conditions, or health threats determined by the secretary to constitute a present or credible risk of a future public health emergency for which administration and use of the countermeasures is recommended.
- The effective time period of the declaration.
- The population of individuals receiving the countermeasure.
- Limitations, if any, on the geographic area for which immunity is in effect.
- Limitations, if any, on the means of distribution of the countermeasure.
- Any additional persons identified by the secretary as qualified to prescribe, dispense, or administer the countermeasures.²

PREP Act Declarations

As of December 2011, there have been seven PREP Act declarations since the act's passage, some which have been amended multiple times.⁵ The declarations have covered H5N1 and H1N1 pandemic influenza vaccine and antivirals and countermeasures for the following diseases: anthrax, botulism, pandemic influenza, smallpox, and acute radiation syndrome. A declaration for influenza antiviral Peramivir has expired.

Compensation Fund

An interim final rule (IFR) governing the submission and review of claims to the CICP was issued by HRSA in October 2010. The IFR allows the CICP to begin evaluating requests for benefits filed by individuals who sustained serious physical injuries as a direct result of the administration or use of covered countermeasures identified by the HHS secretary in declarations issued under the PREP Act.⁴ Claims must be filed within one year of administration or use of a covered countermeasure. Eligible countermeasures include certain influenza vaccines, antivirals, respiratory protection and support devices, and anything to identify, prevent, or treat smallpox, anthrax, botulinum toxin, and acute radiation syndrome.⁴ Claims for injuries from seasonal influenza vaccine are administered through the [National Vaccine Injury Compensation Program \(VICP\)](#).

How the Law Affects States

The PREP Act has a direct impact on states because it provides a source of potential liability protection for governmental and private sector persons developing and administering approved countermeasures during a public health emergency. During the H1N1 outbreak, PREP Act declarations were issued for H1N1 vaccines, antivirals, and personal protective equipment. PREP Act declarations have also been used in conjunction with [Emergency Use Authorizations \(EUA\)](#) under the Federal Food, Drug, and Cosmetic Act, which allow for the use of an unapproved medical product (drug, device, or diagnostic), or an unapproved use of an approved medical product, during a declared emergency. Covered countermeasures that are issued under an EUA may have supplementary requirements on their administration and use in addition to those imposed by the PREP Act declaration.

Sources

¹ Public Readiness and Emergency Preparedness Response Act of 2005, Pub. L. No. 109-148. Codified in the Public Health Service Act at 42 U.S.C. §§ 247d-6d, 247d-6e.

² Centers for Disease Control and Prevention, Public Health Law Program. "Selected Federal Legal Authorities Pertinent to Public Health Emergencies." September 2009. Available at <http://www2.cdc.gov/phlp/docs/Selected%20Fed%20Legal%20Authorities%20re%20PH%20Emergencies%20102709%20v2.pdf>. Accessed January 31, 2012.

³ Department of Health and Human Services. "Public Readiness and Emergency Preparedness Act Questions and Answers" webpage. Available at www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx. Accessed January 31, 2012.

⁴ Health Resources and Services Administration. "Countermeasures Injury Compensation Program" webpage. Available at www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/index.html. Accessed January 31, 2012.

⁵ Department of Health and Human Services. "Public Readiness and Emergency Preparedness Act" webpage. Available at www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx. Accessed January 31, 2012.

Practice Notes

- Questions and concerns about potential liabilities for agency staff, providers, and volunteers will arise in every public health emergency event. Plan on frequently discussing liability and immunity concerns with each new event.
- Before an event, educate state and local public health agency staff, private clinicians, and other potential volunteers about the scope of liability protections provided by the PREP Act and any other federal and state liability protections that may apply to those persons.
- Develop educational materials that describe and differentiate the various liability protections available to staff, medical providers, and other volunteers under state and federal law.
- During an event, carefully review the PREP Act declaration, if one is issued, to understand the scope of coverage. Brief staff, clinicians, and volunteers about their potential liabilities and immunities under the current PREP Act declaration(s).

This document was compiled from June-December 2011 and reflects the laws and programs current then. It reflects only portions of the laws relevant to public health emergencies and is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.