

The Public Readiness and Preparedness Act (PREP): What you need to know

Overview

Private or public organizations can play a key role in a large-scale public health emergency by assisting public health in the distribution and/or dispensing of medical countermeasures, such as antibiotics to any or all of the following:

- Employees
- Contract Staff
- General Public
- Employee Families
- Clients

These medical countermeasures would be provided to organizations by public health agencies at no cost.

Employers benefit by protecting the health and safety of their employees while helping to ensure their own continuity of operations. Employers would also be helping limit any negative impact on the economy and society.

Liability issues are a common concern of individuals and organizations when asked to participate in distributing or dispensing medical countermeasures on behalf of public health. Liability protection is provided by the federal Public Readiness Emergency Preparedness (PREP) Act.

What does the PREP act do?

The PREP Act was enacted in 2005 by Congress. The PREP Act authorizes the

Secretary of the U.S. Department of Health and Human Services to issue a PREP Act declaration in response to a public health emergency. A PREP Act declaration provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures.

PREP Act declarations have been issued many times in the past, including for the H1N1 pandemic in 2009.

What is a declaration?

A declaration includes the determination of a threat or credible risk, recommendation for action, and the category of diseases, health conditions or health threats. It also includes the effective time period, the covered population, the geographic area of administration, and any limitations.

What is covered countermeasure?

A covered countermeasure may include vaccines, antidotes, medications, medical devices or other FDA regulated assets used to respond to pandemics, epidemics, or any biological, chemical, radiological, or nuclear threat.

What is “immunity from tort liability”?

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Immunity from tort liability means there is no legal tort claim that can be pursued in state or federal courts. Tort claims include all claims (except for willful misconduct), under federal or state law for any type of loss including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss, with any causal relationship to any stage of development, distribution, administration, dispensing, or use of the covered countermeasure recommended in the PREP Act declaration.

Who may be provided immunity?

Immunity from tort liability may, at the secretary's discretion, include:

- *Manufacturers* of countermeasures;
- *Distributors* of countermeasures;
- *Program planners* of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
- *Qualified persons* who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers); and
- Officials, agents, and employees of any of these entities or persons are also covered persons.

This immunity protection extends to individuals, partnerships, corporations, associations, or other private entities; or public corporations, including federal, state, or local government agencies and their departments.

What are the limitations on immunity from liability?

- Death or serious physical injury caused by willful misconduct.
- Claims based on activities that fall outside the scope of the declaration.
- Claims of loss that do not allege a causal relationship to the administration or use of a covered countermeasure and are not in fact based on such a causal relationship.
- Claims filed under foreign law in courts outside the United States.
- Lawsuits other than tort claims. For example, violations of civil rights laws, the Americans with Disabilities Act, labor laws, or other such claims that have no connection to a tort claim.

Where can I go for more information on the PREP Act?

The federal Department of Health and Human Services (HHS) has a website where you can get more detailed information on the PREP Act:

<https://aspr.hhs.gov/legal/PREPact/pages/default.aspx>

This document is for informational purposes only and does not constitute legal advice. You should consult your attorney for such guidance.

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