
Coverage under the Public Readiness and Emergency Preparedness (PREP) Act for H1N1 Vaccination

Q1: What is the PREP Act?

A1: The Public Readiness and Emergency Preparedness Act or PREP Act is a federal law that authorizes the Secretary of Health and Human Services to issue a declaration to provide tort liability immunity (except for willful misconduct) to individuals and organizations involved in the development, manufacture, distribution, administration and use of countermeasures against pandemics, epidemics and diseases and health threats caused by chemical, biological, radiological, or nuclear agents of terrorism.

Q2: How does the PREP Act work?

A2: On June 15, 2009, Secretary of Health and Human Services Kathleen Sebelius extended the PREP Act declaration for pandemic vaccines to H1N1 vaccines, and amended the declaration on (date) to add provisions that can help H1N1 vaccination campaigns.

Q3: What is tort liability immunity?

A3: Tort liability immunity means that no legal tort claim related to activities described in the declaration that can be pursued in State or U.S. Federal court. The declaration provides legal liability protections for individuals or entities that are involved in the distribution and administration of H1N1 vaccine.

Q4: Who is immune from tort liability under H1N1 vaccine declaration?

A4: The H1N1 vaccine declaration provides tort liability immunity to a group named “program planners.” Program planners include State and local governments, Tribes, other entities that supervise or administer a vaccination program, establish requirements, provide policy guidance, supply technical or scientific advice or assistance, or provide a facility to administer the vaccine. Program planners can include private sector individuals and organizations, community groups, schools, or businesses.

Government program planners only have tort liability immunity when the vaccines are provided to them voluntarily, such as when Federal Government provides vaccines from Federal stockpiles, or when the vaccines are donated or sold.

The H1N1 vaccine declaration also provides tort liability immunity to a group named “qualified persons.” Qualified persons include healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines.

The declaration also provides tort liability immunity to individuals or organizations that assist public officials with vaccination programs, even if they are not licensed healthcare professionals. Qualified persons also include individuals or organizations (including their officials, agents, employees, contractors and volunteers) that are part of the public health and medical emergency response of the “Authority Having Jurisdiction” for prescribing, administering, delivering, distributing, or dispensing the vaccine following a declaration of emergency issued by a federal, regional, State, or local official. The “Authority Having Jurisdiction” is the public agency or entity or its delegate with legal responsibility and authority to respond to the incident. These qualified persons can include any public or private person, entity, or organization – such as local businesses, community groups and volunteer groups -- and their officials, agents, employees, contractors and volunteers, assisting in carrying out vaccine programs under agreements, plans, protocols, procedures, policies or other arrangements with any State, local or other public agency or its delegate that has legal responsibility and authority for public health and medical response. The Acting HHS Secretary’s April 26 declaration of nationwide public health emergency caused by

H1N1, which was renewed by the HHS Secretary on July 24, can be used by “Authorities Having Jurisdiction” to begin their public health and medical response.

The H1N1 vaccine declaration also provides tort liability immunity to the United States, to vaccine manufacturers, and vaccine distributors.

Officials, agents, and employees of program planners, qualified persons, the United States, manufacturers, and distributors are also immune from tort liability.

Q5: Which vaccines are covered under the H1N1 vaccine declaration?

A5: All of the H1N1 vaccine procured by the Department of Health and Human Services and distributed to the states is covered by the declaration.

Vaccines are covered only when they are administered and used as 1) licensed or approved by the Food and Drug Administration (FDA); 2) authorized for investigational use by the FDA; or 3) authorized under an Emergency Use Authorization (EUA) by the FDA. On September 15, 2008, the FDA approved four vaccines against H1N1 that are covered by the declaration.

Q6: What tort claims are prevented by the H1N1 vaccine declaration?

A6: The declaration prevents tort liability claims under U.S. Federal law and State law (except for willful misconduct) for losses caused by, arising out of, relating to, or resulting from administration or use by any individual of the vaccine, including any claim with a causal relationship to any stage of development, distribution, dispensing, prescribing, administration or use of the vaccine.

Types of loss include death; physical, mental, or emotional injury, illness, disability or condition; fear of physical, mental, or emotional injury illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption. In addition, by defining “administration” to include “delivery, distribution, and dispensing activities... and management and operation of distribution and dispensing locations” the H1N1 vaccine declaration clarifies that “slip and fall” types of claims are also covered, not just injuries and illnesses arising from actually receiving the vaccine.

Q7: What types of claims are not prevented by the H1N1 vaccine declaration?

A7 The declaration does not prevent claims for willful misconduct. Willful misconduct is a term used in the PREP Act, and is beyond any standard of negligence or recklessness. Willful misconduct does not include acts or omissions by program planners and qualified persons who act consistently with the declarations, as long as they notify HHS or a State or local health authority within seven days of discovering any serious physical injury or death from the administration or use of the countermeasure.

The declaration also does not prevent other types of claims, such as claims for negligence in providing medical care unrelated to vaccine administration and use, claims brought under foreign law, or claims for civil rights or labor law violations.

Q8: What compensation is available for vaccine injuries?

A8: The U.S. Department of Health and Human Services is establishing a Countermeasures Injury Compensation Program for H1N1 vaccines. Under this program, compensation may be available to eligible individuals who suffer serious physical injuries or death from administration of the

vaccine under the declarations. Eligibility, and the types of injuries for which compensation may be available, will be defined by regulations. Compensation can include medical benefits, lost wages and death benefits.

Q9: Where can I go for more information?

A9: For a copy of the PREP Act declaration for H1N1 vaccines, please go to:
<http://edocket.access.gpo.gov/2009/E9-14948.htm>.

For more information about PREP Act liability protections, please go to
<http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-ga.html>.

For more information about PREP Act Countermeasure Injury Compensation Program, please go to
<http://www.hrsa.gov/countermeasurescomp/default.htm>.

For more information about the H1N1 vaccines approved by FDA, please go to
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>