

Emailed from Neil Twitchell on August 27, 2009

Ref: Specifically Tort Claims for Vaccine Issues

The Secretary has already declared a public health emergency due to H1N1, but that declaration does not affect liability of healthcare providers. However, the Secretary has also issued a declaration issued under the PREP Act that provides liability immunity to healthcare providers and others for activities related to administration and use of the vaccine.

Specifically, on June 15, 2009, Secretary Sebelius signed a declaration under the PREP Act to extend liability immunity against tort claims (except for willful misconduct) to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. Liability immunity means that there is no legal tort claim that can be pursued in state or federal court. Individuals and entities that receive liability immunity under the declaration include manufacturers, distributors, States, locals, Tribes, and other entities that supervise or administer a vaccination program, and healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines, when they are carrying out activities in accordance with the conditions stated in the declaration. The declaration covers all vaccination activities related to present or future federal contracts, grants, cooperative agreements, interagency agreements, or memoranda of understanding, including all activities using vaccine procured by the Department.

The PREP Act also authorizes the Department to establish a compensation program when a declaration is issued under the Act. Funds for a compensation program were provided under the June 24 Supplemental Appropriations Act. The Department is currently working on developing a compensation program for eligible individuals who sustain covered injuries following vaccination.

Please note that the PREP Act liability protections under the declaration pertain to anything causally related to administration and use of the vaccine, but do not extend to general medical care rendered in emergencies.

A copy of the PREP Act declaration for H1N1 vaccines may be found at <http://edocket.access.gpo.gov/2009/E9-14948.htm>

More information about the PREP Act generally may be found at <http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html>

Please do not hesitate to contact me if you have any additional questions.
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