

H1N1 Influenza and Immunity under Public Readiness and Emergency Preparedness Act
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Texas Department of State Health Services (DSHS)
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ISSUE: What immunity exists under the PREP Act concerning H1N1 influenza?

ANSWER: The federal Public Readiness and Emergency Preparedness (PREP) Act, 42 United States Code sec. 247d-6d, and declarations issued by the secretary of the US Department of Health and Human Services (HHS) create immunity from tort liability for “covered persons” who are involved in the administration and use of H1N1 influenza vaccine; H1N1 pandemic antivirals (Tamiflu and Relenza); and pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices (covered countermeasures).

DISCUSSION: See one page summary concerning immunity under the PREP Act for a general discussion of the Act and emergency use authorizations (EUA). As of August 2009 the HHS secretary has issued the following declarations for H1N1 influenza covered countermeasures. (Declarations are found at www.hhs.gov/disasters/discussion/planners/prepact/ and should be reviewed for details.)

Vaccine: Countermeasures are 2009 H1N1 influenza vaccine and associated adjuvants; time period extends through March 31, 2013 during pre-pandemic and pandemic times; immunity for the covered persons below; covers injury to persons who use vaccine or to whom vaccine is administered; and no geographic limitations.

Influenza antivirals: Countermeasure is H1N1 influenza antiviral drugs (Tamiflu and Relenza); time period is through December 31, 2015 for antivirals administered or used in accordance with federal requirements and through the time of an emergency declaration; immunity for the covered persons below; covers injury to persons who receive an antiviral during a declared emergency or under an EUA; and no geographic limitations. Additional covered persons are ones who prescribe, administer, deliver, distribute, or dispense antivirals during declared emergency and persons authorized to prescribe, administer, or dispense antivirals under law or an EUA.

Devices: Countermeasures are pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices; time period is through December 31, 2015 for devices administered or used in accordance with federal requirements and through the time of an emergency declaration; immunity for the covered persons below; covers injury to persons who receive a device during a declared emergency or under an EUA; and no geographic limitations. Additional covered persons are ones who prescribe, administer, deliver, distribute, or dispense devices during declared emergency and persons authorized to prescribe, administer, or dispense devices under law or an EUA.

A covered person is a: 1) manufacturer of a countermeasure; 2) distributor of a countermeasure; 3) public or private program planner (including state or local government) who supervises or administers a program using a countermeasure; 4) qualified person authorized under state law to prescribe, administer, or dispense a countermeasure; or 5) official, agent, or employee of a person or entity described in 1-4.