



### **Determination of Coverage for H1N1-Related Activities Not Addressed by the Public Readiness and Emergency Preparedness Act ("PREP Act")**

The PREP Act authorizes DHHS to issue a declaration that provides immunity from tort liability for claims arising from administration and use of certain antiviral countermeasures in connection with certain public health and medical responses initiated by appropriate authorities. Generally, the PREP Act applies only in circumstances where the countermeasure was administered or used by a person in a population described in a PREP Act declaration and within the geographic area described in a PREP Act declaration. When applicable, the PREP Act is the exclusive federal remedy. On 2 separate occasions in 2009 (April 26 and June 15), DHHS issued PREP Act declarations for H1N1 antiviral countermeasures and the H1N1 vaccine, respectively. Thus, immunity from tort liability applies in connection with populations who receive the countermeasures in accordance with the terms of the declarations.

Given that the PREP Act is an exclusive remedy, FTCA will not apply to H1N1-related injuries covered by the PREP Act declarations. However, in the limited circumstances in which the PREP Act does not apply, the recently issued Determination of Coverage extends FTCA coverage, provided that the health center is deemed and that the site at which the H1N1 activities are furnished are determined to be "temporary sites" in accordance with PIN 2007-16 (which addresses the requirements for ensuring FTCA coverage for services provided at non-health center sites to non-health center patients during declared emergencies). The Determination of Coverage is based on the following provision from the FTCA statute, which extends coverage for services provided to non-health center patients based on a particularized determination that:

"the provision of the services to such individuals--

(i) benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;... "

See 42 USC 233(g)(1)(C). Thus, HRSA has issued a "blanket" particularized determination of coverage for H1N1 activities not covered by the PREP Act

rather than requiring each health center to request its own determination. HRSA has linked this coverage to its previously-issued policy for obtaining FTCA coverage in emergencies (PIN 2007-16), requiring each health center to add the non-health center site(s) at which the immunizations/services occur to its scope of project as "temporary sites." In accordance with PIN 2007-16, temporary locations will be considered part of a health center's scope of project if all of the following conditions are met:

1. Services are provided on a temporary basis.
2. The temporary locations are within the health center's service area or neighboring counties, parishes, or other political subdivisions adjacent to the health center's service area.
3. The services provided by the health center's staff (employees or FTCA-eligible contractors) are within the approved scope of project.
4. All activities of the health center's staff are conducted on behalf of the health center. Health center providers who volunteer in their individual capacity to respond will not be protected under the health center's FTCA coverage.

To obtain a change in scope for a temporary location, the health center is not required to go through the full change in scope process to add a site. Rather, it is required to provide, as soon as practicable but no later than 15 days after initiating emergency response activities, the following information to its HRSA Project Officer by phone, e-mail, or fax: (1) health center name; (2) the name of a health center representative and that person's contact information; and (3) a brief description of the emergency response activities. HRSA will determine on a case-by-case basis whether extraordinary circumstances justify an exception to this 15-day requirement. If the HRSA Project Officer is not available, the health center should contact the Bureau of Primary Health Care's main phone line or the FTCA Hotline at [1-866-FTCA-Help (382-2435)].

According to the Determination of Coverage, the temporary coverage is effective through December 31, 2009 and will be automatically renewed for calendar year 2010, provided that the health center continues to be deemed for FTCA coverage.

Insofar as it requires some affirmative action by the health center, the process to ensure FTCA coverage for H1N1 activities not covered by the PREP Act and described in the Determination of Coverage is not perfect. It does, however, streamline what could have been a lengthy process by eliminating the individual particularized determination process and in lieu thereof, allowing each health center to comply with the temporary change in scope process that merely requires minor communication with HRSA regarding the activities.

To access the document "Determination of Coverage" and related FAQs go to [www.bphc.hrsa.gov](http://www.bphc.hrsa.gov). For more information, or if you have any questions please contact Roger Schwartz at 202-296-3800 or [rschwartz@nachc.com](mailto:rschwartz@nachc.com).