

Sixth Amendment to HHS Declaration on COVID-19 Vaccine Efforts Adds Flexibility

Category: Policy Blog

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On February 16, the HHS issued its latest amendment to its Declaration that provides immunity from liability for COVID-19 vaccine administration and other countermeasures during this Public Health Emergency (PHE). Since the pandemic emergency started back in late January 2020, HHS has issued the declaration and six amendments to it.

The Public Emergency and Emergency Preparedness Act (PREP Act) authorizes HHS Secretary to issue such a declaration to insulate from liability, except for willful misconduct. The flexibility inherent in the PREP Act and in the HHS agency actions, has afforded expanded protections for UIOs, as well as increase the number of interventions and categories of people able to administer vaccines.

On April 10, 2020, the former Secretary Alex M. Azar II, amended the Declaration under the PREP Act to extend liability immunity to countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary further amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm "COVID-19 might otherwise cause" securing further liability from tort claims. (85 FR 35100, June 8, 2020). On August 19, the next amendment approved additional categories of Qualified Persons authorized to prescribe and dispense the covered countermeasures.

The last amendment posted February 10, 2021, authorizes any health care provider authorized or licensed in any state to administer vaccines in any other state or territory (physician, registered nurse, practical nurse whose license expired in last 5 years and was in good standing to administer in any state or territory). The health care provider is required to complete CDC vaccine training.

In another turn of great advocacy by NCUIH staff in Congressional Relations, all the difficulties experienced by IOUs wanting to test for COVID-19, and interaction with the various federal agencies during the course of the COVID-19 emergency, served to lay the ground work and arguments for introducing the Congressional bill that for the first time extended protections in the Federal Torts Claim Act to urban Indian health providers, becoming Public Law 116-313 on January 5, 2021! See our FTCA bill, H.R. 6535, 116th Congress (2019-2020), deeming an urban Indian organization and its employees to be part of the Public Health Service for purposes of certain claims of personal injury.