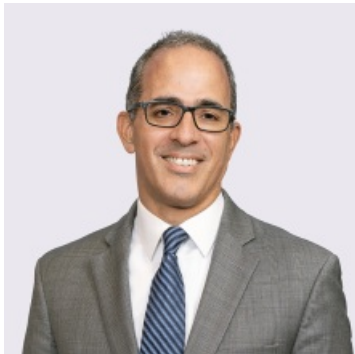


PREP Act and COVID-19 Vaccinations: Health and Human Services Department Clears Way to Assist

By Joseph J. Lazzarotti &

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Individuals and organizations that want to play a role in administering countermeasures to combat a disease or combat a public health emergency, such as COVID-19, worry about the potential legal exposure. The choice to cooperate with a local public health department, for example, to establish closed “point of dispensary” or “POD” to administer COVID-19 vaccines is not an easy one, particularly if there is unlimited liability.

Fortunately, the [Public Readiness and Emergency Preparedness \(PREP\) Act](#) (42 U.S.C. § 247d-6d) authorizes the Secretary of the Department of Health and Human Services to issue PREP Act declarations that provide immunity from liability (except for willful misconduct) for certain claims. For COVID-19, the Secretary initially issued a declaration on [March 17, 2020](#), that provides for immunity from liability for “covered persons” that can extend to employers.

The declaration provides immunity from liability for claims:

of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.

PREP Act Liability Shield

With respect to the COVID-19 vaccine, the declaration provides a liability shield for “covered persons” involved in the administration of the vaccine (except in cases of willful misconduct) when acting in accordance with applicable directions, guidelines, or recommendations issued by the Secretary regarding administration and use of a countermeasure.

“Covered persons” under the PREP Act include categories such as “program planners” and “qualified persons,” which, according to [PREP Act guidance](#), are defined as follows:

- A program planner means a state or local government, including an Indian Tribe; a person employed by the state or local government; or other person (such as a private sector employer or community group) who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a countermeasure. This includes persons who establish requirements or provide policy guidance, or who supply technical or scientific advice or assistance or who provide a facility to administer or use a “covered countermeasure” in accordance with a declaration.
- A qualified person means:
 - A licensed health professional or other individual who is authorized to

prescribe, administer, or dispense covered countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or

- A person within a category identified as “qualified” in a declaration, such as volunteers.

The initial declaration has been amended six times to date, and the Secretary has continued to expand coverage through various amendments, including broadening the definition of who is a “qualified person” who can prescribe, dispense, and administer authorized COVID-19 vaccines.

Effective February 2, 2021, the Secretary issued a [‘Fifth Amendment to the Declaration’](#) that allows providers to cross state lines and permits certain providers with inactive licenses to step in to help. This amendment to the declaration allows:

- A provider licensed or certified in any single state to prescribe, dispense, or administer vaccines is authorized to do so in any state.
- A physician, registered nurse, or practical nurse whose license expired within the last five years can engage in prescribing, dispensing, or administering vaccines as permitted under their active license if the provider’s license was in good standing when it became inactive.

However, these healthcare professionals must complete Centers for Disease Control and Prevention [COVID-19 Vaccine Training](#). If the provider is not practicing, there is also an on-site observation period to complete with a currently practicing healthcare professional.

This expansion was designed “[t]o respond to the nationwide public health emergency caused by COVID-19,” [Department of Health and Human Services Acting Secretary Norris Cochran](#) said. He continued, “[T]he Biden Administration is broadening use of the PREP Act to expand the vaccination workforce quickly with additional qualified healthcare professionals.” He also said, “As vaccine supply is made more widely available over the coming months, having additional vaccinators at the ready will help providers and state health departments meet the demand for vaccine and protect their communities more quickly.”

Effective February 16, 2021, a [‘Sixth Amendment to the Declaration’](#) added as “qualified persons” all “Federal employees, contractors and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities.”

Implications

Although these expansions may help speed vaccine distribution, they pose another layer of analysis for organizations that want to engage these providers on a limited basis and maintain the immunity from liability afforded under the PREP Act. For example, organizations that establish closed PODs to administer a COVID-19 vaccination to their employees and possibly employees’ family members will need to consider whether the providers engaged to administer vaccinations have satisfied the requirements.

If you have any questions regarding the PREP Act, please reach out to the Jackson

Lewis attorney with whom you regularly work. We will continue to monitor the PREP Act for any developments.

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