

The PREP Act And How It Affects Your Long-Term Care Community

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Even though the PREP Act has been federal law since 2005, many senior living and care community leaders are just hearing about it for the first time. This article will review the Public Readiness and Emergency Preparedness Act and explain why its significance is more notable today than when it was enacted 15 years ago.

What is the PREP Act?

The PREP Act was enacted by Congress and signed into law by President George W. Bush in 2005 in the wake of an avian influenza outbreak. Specifically, the PREP act authorizes the secretary of the Department of Health and Human Services to issue a declaration to provide liability immunity to certain individuals and entities regarded as “covered persons” against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of certain medical “covered countermeasures.”

In 2020, the PREP Act now raises questions regarding broad liability protections for healthcare providers who administer vaccines as a countermeasure to COVID-19.

What authority does the PREP Act provide to the HHS secretary?

Specifically, the PREP Act provides that: “Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an

individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.” 42 U.S.C.A. § 247d-6d (a).

The PREP Act specifically and clearly delegates to the secretary of the HHS the authority to issue a declaration that provides for immunity from liability for administering disease countermeasures in the event of a public health emergency.

Has HHS issued a declaration under the PREP Act?

On March 10, 2020, HHS Secretary Alex Azar issued a declaration under the PREP Act, setting Feb. 4, 2020, as the effective date for certain medical countermeasures used against COVID-19. He declared a public health emergency and specifically declared liability immunity for medical countermeasures against COVID-19 under the PREP Act. To address several questions and clarify the PREP Act’s scope, HSS amended the declaration on April 10 and published an advisory opinion on April 14.

What is a covered countermeasure?

Generally, a covered countermeasure includes any medical product used for COVID-19 that is:

- Approved, cleared or licensed by the U.S. Food and Drug Administration under an investigational new drug application or an investigational device exemption and
 - Authorized under an emergency use authorization issued by the FDA and as authorized by the Centers for Disease Control and Prevention.
- The Pfizer-BioNTech vaccine that recently received emergency use authorization is one example of a covered countermeasure. Other vaccines being manufactured by Moderna, Johnson & Johnson and AstraZeneca soon also may be authorized covered countermeasures.

Is the immunity provided under the PREP Act unlimited?

The PREP Act does not provide immunity that is unlimited in scope related to the COVID-19 vaccine. Most importantly, the PREP Act specifically provides an exception to liability immunity in the event of serious physical injury as a result of willful misconduct. Additionally, although there is limited case law on the subject, the cases that have been decided on the PREP Act have indicated that although the

PREP Act protects from liability for actively administering a countermeasure such as a vaccine, it does not generally prevent or preempt liability for negligence or malpractice claims for failure to administer a vaccine or for failure to take other countermeasures to protect a patient from COVID-19. See *Estate of Maglioli v. Andover SubAcute Rehab Ctr. I*, 2020 WL 4671091 (D.N.J. Aug. 12, 2020).

HHS also recently issued a Dec. 3, 2020, amendment to the PREP Act that discusses prioritization and provides immunity for such situations involving decisions made regarding the allocation of scarce resources including the COVID-19 vaccine, particularly when such decisions are made according to public health authority guidelines.

Clearly, the legal applications of this law are still in the process of developing and being amended, so these developments will need to be closely monitored moving forward.

Regarding immunity, which individuals or entities are covered?

The PREP Act provides that a “qualified person who prescribed, administered or dispensed such countermeasure is entitled to immunity. Under the statute, a “qualified person” is (when used with respect to the administration or use of a covered countermeasure) either a licensed health professional or other individual who is authorized to prescribe, administer or dispense such countermeasures under the law of the state in which the countermeasure was prescribed, administered or dispensed; or a person within a category of persons so identified in a declaration by the secretary.

In addition to the individuals specified in the statute, the PREP Act provides the secretary with authority to declare additional covered persons for whom the liability immunity will apply. In the declaration by Azar, he further expanded the definition of covered persons to include:

(a) any person authorized in accordance with the public health and medical emergency response, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency;

(b) any person authorized to prescribe, administer or dispense the covered countermeasures or who is otherwise authorized to perform an activity under an emergency use authorization in accordance with Section 564 of the FD&C Act; and

(c) any person authorized to prescribe, administer or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.

What is recommended to ensure immunity?

Consistent with the guidance from the HHS, all covered persons using or administering covered countermeasures should document the reasonable precautions they have taken to safely use the covered countermeasures. Those administering the vaccination should do so in strict compliance with the manufacturer and CDC guidance. It is important to make certain that chain of custody of the covered countermeasure is properly documented, that those administering it are properly trained and licensed, and that management remains up-to-date with the constant changes.

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