

Fourth Amendment to the PREP Act Expands Protection and Adopts Guidance

Associates

Kaitlyn M. Wright

Related Practices

Product Liability & Mass Tort

By Kaitlyn M. Wright on December 22, 2020

On March 10, 2020, in response to the outbreak of COVID-19, the Secretary of the United States Department of Health and Human Services (HHS), Alex Azar (“Secretary”), issued a Declaration invoking broad liability protections under the Public Readiness and Emergency Preparedness Act (the PREP Act) for certain individuals and entities engaged in the design, manufacture, testing, and administration of countermeasures to the emerging public health emergency. Public Readiness and Emergency Preparedness Act, codified at 42 U.S.C. §§247d-6d; Medical Countermeasures Against COVID-19 Declaration, 85 Fed. Reg.15,198 (Mar. 17, 2020)) (“Declaration”). We explored the nature and extent of the immunity conferred under the PREP Act as a result of the March 10 Declaration in an earlier [article](#).

Recently, the Secretary issued a “Fourth Amendment” to the Declaration. The Amendment confers the most substantive changes to the Declaration to date, expanding the already broad liability protections previously afforded under the initial Declaration and expressly adopting guidance issued by the HHS Office of the General Counsel. [Fourth Amendment to the Declaration](#), 85 Fed. Reg. 79,190 (Dec. 9, 2020). Most significantly, the Fourth Amendment expands the application of the term “covered persons” to include certain telehealth personnel, explicitly extends liability protection to a third channel of covered countermeasure distribution, adopts previously issued guidance and advisory opinions, and clarifies liability immunity for a failure to administer a “covered countermeasure.”

Expansion of the application of “covered person”

The Fourth Amendment extends the application of the term “covered persons” (Declaration, *supra*, at § V; Fourth Amendment) to include healthcare personnel permitted to order or administer a covered countermeasure through telehealth. The telehealth personnel expansion includes those administering countermeasures to patients in another state, provided that the healthcare personnel is permitted to order and administer the covered countermeasure by means of telehealth in the state where they located when they are “virtually practicing.” The amendment serves as recognition of the importance of remote access to healthcare services, particularly for those who are “medically or socially vulnerable” during the pandemic. The delineated uses of telehealth services include screening patients who may have COVID symptoms and referring patients as needed for further assessment; providing low-risk urgent care for non-COVID conditions; and performing primary care/specialist assessment for chronic health conditions, including mental and behavioral health concerns, and medication management of the same.

Additional covered “channel of distribution”

The Declaration originally provided that a covered activity must be related to a contract, arrangement, or agreement with the federal government or be authorized in accordance with the public health and medical response of an “authority having jurisdiction” to respond to the emergency. *Id.* at §§VII. An Advisory Opinion issued on April 17, 2020 suggested that this requirement should be interpreted broadly to include “1) activities that relate to any arrangement with the federal government, or 2) any activity

that is part of an authorized emergency response at the federal, regional or state level.” Advisory Op., *supra*, at 2. The Fourth Amendment both adopted this advisory guidance (*see infra* §(c)) and expressly added a third “channel of distribution” for covered persons that “manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, clearance, or authorization (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval.” By adding this third channel of distribution, the Fourth Amendment effectively extends PREP Act liability coverage to certain instances “when there is no federal agreement or authorization in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.” This change will extend PREP Act liability immunity to additional private-distribution channels, but notably is only applicable to conduct after December 3, 2020.

Express incorporation of advisory opinions

Previously, the Advisory Opinions relating to the initial Declaration were presented as representative of the views of the HHS Office of the General Counsel only and did not otherwise constitute a final agency action or final order, nor did they have the force or effect of law, and did not bind HHS or the federal courts. Accordingly, to the extent that the guidance denoted a broader application of the liability protections than the letter of the PREP Act and the Declaration provided, such application was vulnerable to challenges and opposing interpretations by the courts. The Fourth Amendment addressed this vulnerability, stating: “The Secretary now amends the Declaration to clarify that the Declaration must be construed in accordance with the Advisory Opinions. The Secretary expressly incorporates the Advisory Opinions for that purpose.” As the Advisory Opinions sought to clarify points in the Declaration that were open to differing interpretations, this explicit adoption helps to eliminate some gray areas within the original text of the Declaration and the PREP Act itself.

Failure to administer countermeasures as covered activity

The Fourth Amendment expressly extends PREP Act liability immunity to certain situations where a covered countermeasure is not administered due to limitations in supply of such countermeasure.

Prior to this Amendment, due to shortages of COVID-19 tests, personal protective equipment, therapeutics, and vaccines, healthcare workers and hospitals that were required to ration covered countermeasures remained vulnerable to claims that they negligently failed to administer such measures. This portion of the Amendment addresses some of the ambiguities that became evident in recent litigation arising under the PREP Act, where defendants, primarily nursing homes, sought to raise the PREP Act as a defense to allegations of negligent failure to administer covered countermeasures. Many of these claims were found by courts to fall outside of the scope of federal jurisdiction and PREP Act liability protections because the suits were focused on the absence of a countermeasure, rather than protected use of a covered countermeasure; the Fourth Amendment squarely rejects this interpretation of the PREP Act and clarifies the preemption of potential state law negligence claims in this realm. *See Maglioli v. Andover Subacute Rehabilitation Center*, Civ. No. 20-6605 (KM)(ESK) (D.N.J. Aug. 12, 2020); *Gunter v. CCRC OPCO-Freedom Square, LLC*, No. 8:20-cv-1546-T-36-TGW (M.D. Fla. October 29, 2020); *Sherod v. Comprehensive Healthcare Mgmt. Servs. LLC*, 20cv1198 (W.D. Pa. October 16, 2020); and *Block et al. v. Big Blue Healthcare*, Case No. 2:20-cv-2262-HLT-JPO (D. Kansas August 19, 2020).

Other noteworthy changes

The following modifications conferred by the Fourth Amendment were described with much less detail, as they present more straightforward clarifications and changes regarding the practical application of the Declaration's liability immunity provisions:

- Section VI of the Declaration regarding covered countermeasures was clarified to explicitly include all qualified pandemic and epidemic products under the PREP Act;
- Section XI of the Declaration, concerning the geographic area for the immunity from suit; the Secretary clarified that the only exception to the immunity from suit and liability insulation of covered persons is an "exclusive federal cause of action against a Covered Person for death or serious physical injury proximately caused by willful misconduct by such Covered Person." An exclusive federal cause of action is appropriate because of the substantial federal legal and policy interest in "a uniform interpretation of the PREP Act."
- Section XII of the Declaration, concerned the relevant time period of the liability protections, has been amended with respect to covered countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction lasts through *either* the final day the Declaration of Emergency is in effect or October 1, 2024, *whichever comes first*.

We encourage interested parties to keep abreast of amendments and advisory opinions regarding the Declaration, particularly in light of the evolving vaccination development efforts and subsequent distribution plans.