

HHS Issues Fourth Amendment to PREP Act COVID-19 Declaration

DECEMBER 11, 2020

On December 3, 2020, the Department of Health and Human Services (HHS) issued an expansive Fourth Amendment to its original Public Readiness and Emergency Preparedness Act (PREP Act) Declaration for Medical Countermeasures Against COVID-19. The following summarizes some of the potential impacts the Fourth Amendment may have on manufacturers and distributors of COVID-19 products:

- ***Incorporates Advisory Opinions.*** As discussed in our prior article [here](#), the General Counsel of HHS has published four Advisory Opinions that often expanded and clarified the scope of the PREP Act, with the goal of assisting businesses in making decisions related to COVID-19 products. The Fourth Amendment strengthens the authority of these Advisory Opinions by expressly providing that the PREP Act Declaration “must be construed in accordance with the Advisory Opinions” and the “Secretary expressly incorporates the Advisory Opinions for that purpose.” As a result, businesses can rely more authoritatively on the Advisory Opinions that provide broad interpretations of “covered persons” and “covered countermeasures” under the PREP Act (as discussed in previous alerts [here](#) and [here](#)).
- ***Increases Likelihood of Successful Removal of State Law Claims.*** In the limited PREP Act litigation that has occurred to date, some plaintiffs have successfully defended against the removal of state court actions based on the argument that the PREP Act does not preempt certain state law claims (as discussed in prior alerts [here](#)). Significantly, the Fourth Amendment states that “there are substantial federal legal and policy issues, and substantial federal legal and policy interests . . . in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.” Thus, even if a claim is ultimately premised on state law, the Fourth Amendment provides additional authority that express preemption justifies the removal of actions relating to the PREP Act or COVID-19 covered countermeasures to federal venues.
- ***Broadens PREP Act Immunity to Potentially Cover “Not Administering” a Countermeasure.*** Several recent decisions have held that a claim premised on the failure to use a covered countermeasure is not preempted by the PREP Act (as discussed [here](#)). In a potentially extensive expansion of PREP Act immunity, the Fourth Amendment now clarifies “that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration’s liability protection.” It, of course, remains to be seen how broadly courts will interpret the Fourth Amendment with respect to claims involving an alleged failure to act with due care, but this potentially eliminates an avenue for plaintiffs seeking to keep litigation in state courts.

- **Expands Liability Protections to Private Distribution Channels.** As discussed in a prior alert [here](#), PREP Act immunity extended to businesses, manufacturers, or healthcare providers that produced goods or provided services covered in the PREP Act pursuant to a contract with the federal government or related authorized agency. The Fourth Amendment broadens immunity to “extend PREP Act coverage to additional private-distribution channels.” As a result, covered countermeasures will be afforded PREP Act immunity even absent a contract with the federal government. Notably, this is only effective for conduct occurring on or after December 3, 2020.
- **Clarifies the Types of Covered Countermeasures.** The Fourth Amendment clarifies that Section VI of the Declaration outlining covered countermeasures “covers all qualified pandemic and epidemic products under the PREP Act.”
- **Defines the Evidence Required for Claims Under the Countermeasures Injury Compensation Program.** The Fourth Amendment states that a claim for benefits under the PREP Act’s Countermeasures Injury Compensation Fund (CICP) for individuals who sustained “serious physical injuries” “as the direct result of administration or use of the covered countermeasures” must be “supported by compelling, reliable, valid, medical and scientific evidence.” Notably, this required showing is distinct from the requirements for alleging that PREP Act immunity does not apply as the result of “willful misconduct,” which must be pled with particularity, including providing certified medical records, an affidavit from the plaintiff verifying the truth of the allegations, and an affidavit with the complaint from an independent physician verifying the injuries.
- **Extends Time Frame for PREP Act Immunity.** The Fourth Amendment extends PREP Act immunity for “an additional 12 months” until October 1, 2024.
- **Permits Providing Covered Countermeasures via Telehealth.** The Fourth Amendment extends PREP Act immunity to healthcare professionals already permitted to practice in a state to administer covered countermeasures such as diagnostic tests via telehealth.

If you have any questions about the effect of the Fourth Amendment, please contact Sandra Edwards, Rand Brothers, John Drosick, or your Winston relationship attorney. A link to the Fourth Amendment is [here](#).

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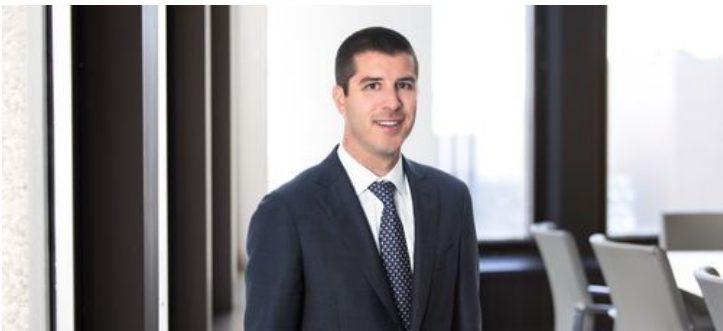
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