

HHS Broadens Scope of PREP Act Immunity for Individuals and Entities Fighting COVID-19

On December 3, 2020, the Secretary of the Department of Health and Human Services issued a fourth amended PREP Act declaration expanding the scope of immunity for covered entities engaged in the provision of goods and services designed to aid in the fight against COVID-19. This amended declaration follows three earlier declarations, dating back to March 10, 2020, which we previously discussed [here](#) and [here](#).

The fourth amended declaration expressly incorporates several prior guidance documents clarifying the scope of PREP Act immunity, and specifically expands that immunity to a number of new categories of persons and entities including, among others, healthcare professionals using telehealth to prescribe "Covered Countermeasures" to patients across state lines, certain pharmacy employees who administer "Covered Countermeasures," and accredited CPR providers. Previously, there was no provision for telehealth, and only licensed pharmacists and nurses were covered pursuant to the COVID-19 declaration.

In addition, the fourth amended declaration expands the definition of "Covered Countermeasures" to include "all qualified pandemic and epidemic products under the PREP Act," including any products or technologies that "diagnose, mitigate, prevent, treat, or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom" or that "limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom might otherwise cause," as well as all products/technologies "used in the administration of any such product, and all components and constituent materials to any such product." Previously, "Covered Countermeasures" were limited to those products/technologies that were expressly approved by FDA for combating COVID-19; this new definition is broader.

The fourth amended declaration also extends immunity to those assisting persons/entities engaged in the distribution of otherwise-covered products/services even if there is no federal contract giving rise to that activity, provided certain conditions are met. Previously, an existing federal contract was a prerequisite for distributor immunity.

Finally, the fourth amended declaration extends the time limits for this immunity to "(a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first."

The full text of the fourth amended declaration, which has not yet been published in the federal register and may be further modified, is available [here](#).

This most recent declaration represents the broadest immunity yet conferred by HHS, which is certain to be welcomed by manufacturers, distributors, and healthcare professionals engaged in different aspects of the pandemic response. However, it remains to be seen whether this immunity expansion via rulemaking will be challenged in the courts or walked back by the Biden administration in January. For several months, Congress has been unable to agree on additional statutory grants of immunity, and the topic remains controversial.

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