

## Overview of PREP Act

The Public Readiness and Emergency Preparedness Act (“Prep Act”) authorizes the Secretary of Health and Human Services (“HHS”) to issue a declaration to provide liability protections to certain individuals and entities (“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 countermeasures (“Covered Countermeasures”), except for claims involving “willful misconduct,” as defined in the PREP Act. Such declarations are subject to amendment as circumstances warrant.

On January 31, the Secretary of HHS declared a public health emergency, effective January 27, for the entire U.S. to aid in the response to the Coronavirus Disease 2019 (COVID–19) outbreak. This public health emergency declaration was renewed on April 21, July 23, and October 2.

On March 17, the HHS Secretary issued a declaration under the PREP Act for medical countermeasures against COVID–19 (“PREP Act COVID Declaration”) and has subsequently amended it, as follows:

- Amended to extend liability protections to Covered Countermeasures authorized under the CARES Act (“1<sup>st</sup> Amendment”) (April 15)
- Amended to clarify that Covered Countermeasures under the Declaration include qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause (“2<sup>nd</sup> Amendment”) (June 8)
- Amended to add additional categories of Qualified Persons and to amend the category of disease, health condition, or threat for which he recommends the administration or use of Covered Countermeasures (3<sup>rd</sup> Amendment”) (August 24)
- Amended the Declaration to, among other things, expand and clarify the PREP Act’s liability protections (“4<sup>th</sup> Amendment”) (December 9)

Additionally, HHS has issued several advisory opinions explaining and clarifying the scope of the PREP Act as follows:

### Advisory Opinions of the General Counsel

- First Advisory Opinion on the PREP Act Declaration (May 19)
- Second Advisory Opinion on the PREP Act Declaration (May 19)
- Third Advisory Opinion on the PREP Act Declaration (October 23)

- Fourth Advisory Opinion on the PREP Act Declaration (October 23)

### **HHS Guidance**

- Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act (September 3)
- Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act (April 8)

Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (August 31)

### **Liability Immunity under the PREP Act**

A PREP Act declaration provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures.

Among other things, such a declaration may specify whether PREP Act immunity is effective only to a particular means of distribution.

The current PREP Act COVID Declaration specifies that liability immunity is afforded to Covered Persons:

1. Only for Recommended Activities<sup>1</sup> involving Covered Countermeasures that are related to:
  - a. Federal agreements, or
  - b. Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction<sup>2</sup> to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.
2. For Recommended Activities that are related to any Covered Countermeasure that is:

---

<sup>1</sup> Recommended Activities means “the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.” PREP Act COVID Declaration.

<sup>2</sup> An Authority Having Jurisdiction means the “public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.” PREP Act COVID Declaration.

- a. licensed, approved, cleared, or authorized by the Food and Drug Administration (FDA) (or that is permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the Federal Food, Drug, and Cosmetic (FD&C) Act or Public Health Service (PHS) Act to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.
- b. a respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from, COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

As stated above, in order for there to be PREP Act coverage, there must first be a PREP Act declaration -- which there currently is (i.e., the PREP Act COVID Declaration). Next, a Covered Person seeking PREP Act immunity must be engaged in the countermeasure distribution measure covered under the declaration.

Under the current PREP Act COVID Declaration one distribution method that is granted immunity is to being engaged in “Recommended Activities involving Covered Countermeasures” that are “related to activities authorized 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.”<sup>3</sup>

An Authority Having Jurisdiction may authorize activities entitled to immunity protection through, among other things, guidance, requests for assistance, agreements, directives, or other arrangements (collectively “Guidance”).<sup>4</sup>

Public-health guidance from an applicable Authority Having Jurisdiction that recommends or requires using covered countermeasures in certain circumstances may qualify as authorizations, but to obtain such authorization, a Covered Person must follow that public-health guidance. In other words, a covered person must comply with the public-health guidance issued by an Authority Having Jurisdiction over the person’s activity or location in order to qualify for PREP Act immunity.<sup>5</sup>

If there are conflicts among the public-health guidance, PREP Act coverage will apply to a Covered Person using a covered countermeasure in accordance with any of the guidance.<sup>6</sup>

---

<sup>3</sup> Advisory Opinion 20-04.

<sup>4</sup> Id.

<sup>5</sup> Id.

<sup>6</sup> Id.

A conflict exists when (1) one guidance includes a recommendation or mandate that another guidance does not, and (2) there is no order of precedence under applicable law or in the guidance itself.<sup>7</sup>

If the applicable law or the guidance explains which authority takes precedence, a covered person must follow the guidance of the Authority Having Jurisdiction that takes precedence in order to obtain PREP Act coverage. To illustrate, if a governor's order on using face masks preempts or otherwise takes precedence over a mayor's order under that state's law, then the former must be the basis for PREP Act coverage.

If one guidance says that it does not replace another guidance, the latter must be the basis for PREP Act coverage. For example, the Centers for Disease Control and Prevention's (CDC) guidance for "Preparing for a Safe Return to School" specifies that "[t]his guidance is meant to supplement—not replace—any state, local, territorial, or tribal health and safety laws, rules, and regulations with which schools must comply." So if there were a conflict between that CDC guidance and "any state, local, territorial, or tribal health and safety laws, rules, and regulations with which schools must comply," a covered person must rely on guidance of the latter jurisdiction, and not CDC's guidance, as the basis for PREP Act coverage.<sup>8</sup>

If a guidance changes, the guidance in effect during the activity at issue will determine whether there is PREP Act coverage.<sup>9</sup>

### **PREP Act Liability Immunity for Use of Additional Doses**

With respect to PREP Act liability immunity with respect to the use of potential additional doses of the Pfizer vaccine, it appears that, so long as the Covered Person meets all of the other requirements of the PREP Act and the PREP Act COVID Declaration that PREP Act immunity could apply.

Specifically, since the FDA tweeted that "*[a]t this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending resolution of the issue*" this could constitute the necessary guidance from an Authority Having Jurisdiction to invoke the PREP Act immunity.

In this case, the FDA tweet appears to supersede prior guidance it issued. Additionally, even though this guidance may conflict with other guidance previously issued by the FDA, according to the conflict rules set forth in Advisory Opinion 20-04, if there is a conflict in guidance, then PREP Act coverage will apply to a Covered Person using a covered countermeasure in accordance with any of the guidance.

Thus, theoretically, if a Covered Person follows the FDA's tweeted guidance, the PREP Act coverage should still apply.

---

<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> Id.