

Exhibit F



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201**ADVISORY OPINION 20-04 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT
AND THE SECRETARY'S DECLARATION UNDER THE ACT
OCTOBER 22, 2020, AS MODIFIED ON OCTOBER 23, 2020**

The Office of the General Counsel (OGC) has received questions concerning the scope and meaning of “program planner” and “Authority Having Jurisdiction” under the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, and its implementing secretarial Declarations. This Advisory Opinion addresses:

1. Who is a program planner under the PREP Act and the Secretary’s March 10, 2020 Declaration, as amended (Declaration)?¹
2. What is the scope of the proviso in the Declaration limiting PREP Act coverage to, *inter alia*, activities authorized by an “Authority Having Jurisdiction”?

In this Advisory Opinion, OGC re-emphasizes the breadth of PREP Act immunity. It covers a broad range of entities when such entities take reasonable steps to follow public-health guidelines and directives in using covered medical products. Such entities are not limited to healthcare professionals and healthcare companies that are part of a government response to the COVID-19 pandemic. Such entities may also include businesses, schools, and places of worship.

I. ANALYSIS**A. BACKGROUND**

COVID-19 is an unprecedented global challenge. As we learn more about the highly contagious pathogen that causes COVID-19, public-health guidance and directives tend to change to reflect the new knowledge. Those changes do not always occur uniformly or simultaneously among scientists and across America’s federal, state, territorial, tribal, local, and other public-health authorities—leading to uncertainty.

Those uncertainties present potential legal risk for public and private individuals and organizations as they combat the pandemic, restore and strengthen America’s economy, ensure that transportation remains available, and provide safe environments for education and worship. Unfortunately, such perceived risks may hinder those essential efforts.

They should not. The PREP Act exists, in part, to remove legal uncertainty and risk. When an individual or organization satisfies the requirements of the PREP Act and the Declaration, that “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.”²

¹ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020) (Declaration); 85 Fed. Reg. 21,012 (Apr. 15, 2020) (First Amendment); 85 Fed. Reg. 35,100 (June 8, 2020) (Second Amendment); 85 Fed. Reg. 52,136 (Aug. 24, 2020) (Third Amendment).

² 42 U.S.C. § 247d-6d(a)(1).

Under the PREP Act, the term “covered person” includes a broad range of individuals and organizations. The term includes, among other things, anyone who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including anyone who provides a facility to administer or use a covered countermeasure in accordance with the Declaration.

The term “covered countermeasure” generally includes products (1) that the Food and Drug Administration (FDA) has approved, cleared, licensed, or authorized for emergency or investigational use; and (2) that are used to address COVID-19 or associated health threats, including harms that COVID-19 might otherwise cause.

The Declaration broadly extends PREP Act immunity to, among other things, a covered person’s conduct relating to the administration or use of covered countermeasures according to applicable public-health guidance and directives during this declared emergency.³

As we have previously explained, when a person complies with all other requirements in the PREP Act and Declaration, PREP Act immunity applies if

- the person reasonably could have believed that the person was a covered person,
- the person reasonably could have believed that the product was a covered countermeasure, and
- the person did not engage in willful misconduct that proximately caused serious physical injury or death.⁴

This Advisory Opinion discusses the broad availability of that immunity in more detail. Specifically, we focus on (1) the definition of a “program planner” and (2) the activities authorized by an “Authority Having Jurisdiction.” This Advisory Opinion also provides examples of PREP Act coverage when a “program planner” follows the public-health guidance or directives of an applicable “Authority Having Jurisdiction”—even as guidance or directives change or they conflict with other guidance or directives.

B. PROGRAM PLANNERS

Under the PREP Act, the term “covered person” includes the United States or “manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees.”⁵

³ See 85 Fed. Reg. at 15,200 (affording liability immunity to “covered persons” for “recommended activities” related to activities authorized in accordance with the public-health and medical response of the Authority Having Jurisdiction).

⁴ See Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act (May 19, 2020), <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Oct. 23, 2020) (PREP Act Advisory Opinion); see also 42 U.S.C. § 247d-6d(a)(4)(B).

⁵ 85 Fed. Reg. at 151,199; 42 U.S.C. § 247d-6d(i)(2).

The PREP Act broadly defines a “program planner” using three elements: identity, function, and compliance.

Identity: A program planner is a state or local government, including an Indian tribe, a person employed by the State or local government, or other “person” who carries out the functions described immediately below. Under the PREP Act, a “person” includes “an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, state, or local government agency or department.”⁶

Function: A program planner performs certain functions, including “supervis[ing] or administer[ing] a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product.”⁷ The statute explains that those functions broadly include “establish[ing] requirements, provid[ing] policy guidance, or suppl[y]ing technical or scientific advice or assistance or provid[ing] a facility to administer or use a covered countermeasure.”⁸

Compliance: Finally, to qualify as a program planner, the entity must perform those functions “in accordance with” the Declaration.⁹

The Declaration incorporates these definitions.¹⁰ The Declaration’s preamble further explains that a program planner can be a “private sector employer or community group” that “carries out the described activities.”¹¹ Nothing in the preamble or text of the Declaration limits the statutory definitions.

In short, any individual or organization can potentially be a program planner and receive PREP Act coverage. So for example, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration. It is important to remember, however, that the PREP Act does not provide immunity against federal enforcement actions.¹² And PREP Act immunity (but not preemption) is limited to claims for death, physical, mental or emotional injury, illness, disability or condition, fear of such harm or need for medical monitoring, and damage to property, including business interruption loss.¹³

⁶ 42 U.S.C. § 247d-6d(i)(5).

⁷ *Id.* at § 247d-6d(i)(6).

⁸ *Id.*

⁹ We use the term “entity” to include persons (*see* 1 U.S.C. § 1) and governmental units, whether state, tribal, local, or federal.

¹⁰ *See* 85 Fed. Reg. at 15,201.

¹¹ *Id.* at 15,199.

¹² *See* PREP Act Advisory Opinion at 2.

¹³ *See* 42 U.S.C. § 247d-6d; PREP Act Advisory Opinion.

C. AUTHORITY HAVING JURISDICTION

In order for there to be PREP Act coverage, there must be a PREP Act declaration.¹⁴ Among other things, such a declaration may specify whether PREP Act immunity “is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.”¹⁵

For the COVID-19 public-health emergency, section VII of the Declaration specifies that “liability immunity is afforded to Covered Persons *only* for Recommended Activities involving Covered Countermeasures that are related to” (1) federal agreements or (2) “[a]ctivities 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.”¹⁶ An Authority Having Jurisdiction may authorize such activities through, among other things, guidance, requests for assistance, agreements, directives, or other arrangements (collectively guidance).¹⁷

Public-health guidance from an applicable Authority Having Jurisdiction that recommends or requires using covered countermeasures in certain circumstances may qualify as authorizations under the PREP Act and the Declaration. But to obtain such authorization, a covered person must follow that public-health guidance. The Declaration explains that the 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.”¹⁸ Therefore, 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.

If there are conflicts, PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with *any* of the guidance. 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. 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

¹⁴ See 42 U.S.C. § 247d-6d(a)(1).

¹⁵ 42 U.S.C. § 247d-6d(b)(2)(E).

¹⁶ See 85 Fed. Reg. at 15,202.

¹⁷ PREP Act Advisory Opinion at 2.

¹⁸ 85 Fed. Reg. at 15,202.

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