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## **Federal Government Protects Local and State Governments from COVID-19 Liability Exposures**

### **By Kirk Mylander, CIS General Counsel**

CIS members provide crucial COVID-19 testing but worry about liability exposures for staff, doctors, nurses and even volunteers. Because liability concerns should not get in the way of providing necessary services to battle the pandemic, the federal government is providing immunity from state and federal lawsuits to local, government-organized COVID-19 testing and treatment.

The [Public Readiness and Emergency Preparedness Act](#) ("PREP Act"), codified at 42 U.S.C. § 247d-6d, provides liability immunity under federal and state law. In March the Secretary of the U.S. Department of Health and Human Services [issued a declaration](#) pursuant to the PREP Act specifically adding COVID-19 countermeasures to the list of covered epidemics.

This immunity from suit applies to counties, cities, their employees, volunteers, and any doctors, nurses, pharmacists or other licensed health-care professionals who are working or volunteering at such a site.

Importantly, the immunity provided by the PREP Act is not just a legal defense, but immunity from suit; far better to be immune from suit than to have to prove a defense applies or go through a loss and get repaid through insurance.

### **What is this and Why Haven't I Heard of It Before?**

Congress originally passed and President George Bush signed the PREP Act in 2005 in response to the avian flu. Going forward from that time, the Act authorized the Secretary of Health and Human Services (HHS) to provide immunity to both private and public actors who develop, distribute, or administer "covered countermeasures" during a declared public health emergency.

Current Health and Human Services Secretary Alex Azar declared COVID-19 to be a public health emergency on Jan. 31, 2020, and then issued a Declaration effective Feb. 4, 2020, making PREP Act protections apply to COVID-19.

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Due to concerns about who and what will be currently shielded from COVID-19 related liability claims, on April 16, 2020 HHS Director Azar issued an advisory opinion clarifying the broad applicability of the PREP Act, specifically including local governments and the administration of COVID-19 diagnostic tests. In the future, if local governments distribute a COVID-19 vaccine, PREP Act immunity would apply to that as well.

### **Who is Covered?**

The PREP Act liability shield provides immunity from lawsuits to a “covered person” for the manufacture, distribution, use, or administering of any “covered countermeasure” as defined in the PREP Act Declaration.

In addition to manufacturers and distributors, the Act defines a covered “person” to include an individual or entity that is “authorized ... to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures...” as well as a “program planner” for countermeasures, and their officials, employees and agents. “A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.”

<https://www.federalregister.gov/d/2020-05484/p-23>. The Act covers physicians, licensed health professionals, and even volunteers who are administering “covered countermeasures”. <https://www.federalregister.gov/d/2020-05484/p-22>.

Importantly, the PREP Act further defines “Program Planner” to include local government and its officers, employees, and agents.

<https://www.federalregister.gov/d/2020-05484/p-21>

The term “program planners” refers to a State or local government, a person employed by the State or local government, or other persons “who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product. March 10, 2020 Declaration at 1520.

As a result, any local government in Oregon that is planning or coordinating COVID-19 testing, treatment, or vaccinations site would be immune from liability under the PREP Act. Individual officers, employees and agents simply need to be acting in “accordance with the public health and medical emergency response” of a local, state, or federal agency with “legal responsibility and authority for responding to an incident.” March 10, 2020 Declaration at 15201.

### **What is a Covered Countermeasure?**

A “covered countermeasure” include “Qualified pandemic or epidemic products” that are used “to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic.”

Further, the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended the PREP Act to define respirators as covered countermeasures if they are approved by the National Institute for Occupational Safety and Health (NIOSH). Diagnostic tests, vaccines and ventilators are all clearly covered.

To minimize any uncertainty, HHS issued two lists of covered products and processes as appendices to its April 14 Advisory Opinion, which includes therapeutics, diagnostic tests, medical devices, and personal protective equipment (PPE). You can download the lists from the FDA website: [Appendix A](#) and [Appendix B](#).

### **Limits of PREP Act Immunity**

There is a limit to the immunity the PREP Act provides. First, the Act does not cover “willful misconduct” which result in death or serious injury. Simply alleging “willful misconduct” will not allow a person to file a lawsuit. Instead, the claimant will have to file in the U.S. District Court in Washington D.C. and prove to a three-judge panel that the defendant’s willful misconduct “proximately caused” death or serious injury. And even in cases of serious injury or death, proving that there was not “willful misconduct” can be established before a lawsuit even starts. If a covered person was following directions regarding the administration or use of a covered countermeasure and notifies the Secretary, or a State or local health authority, with the particulars of a serious physical injury or death within 7 days of the incident, the covered person will be declared to have not engaged in “willful misconduct” as a matter of law. (HHS Advisory Opinion at 7; See also 42 U.S.C. § 247d-6d(c)(4)).

Immunity is further limited to personal injury and property damage liability. The PREP Act does not protect covered persons from liability from any federal enforcement action, or claims under federal law for equitable relief.

### **Good Faith Safe Harbor**

Despite the “willful misconduct” limitation, the PREP Act’s liability shield is meant to be broadly applied and even includes a “good faith” safe harbor. For example, if a county procured tests and took steps to check that the tests kits or PPE were covered, but some or all of the tests or PPE turned out to be counterfeit, the person would still be immune against a claim arising out of the use of a counterfeit test or respirator. The Advisory Opinion states that “a person or entity that otherwise meets the requirements for PREP Act immunity *will not lose that immunity* — even if the product is not a covered countermeasure — if that person or entity *reasonably could have believed* that the product was a covered countermeasure.”

### **How Can I be Certain We Will Be Covered?**

To start, ensure that your entity qualifies as a “Program Coordinator” be sure to be acting according to a written program plan to provide covered treatments or diagnostic tests to the public.

Be sure to have your county counsel or city attorney review the Secretary's [Advisory Opinion](#) and the list of covered countermeasures in the two appendices. ([Appendix A](#) and [Appendix B](#)).

Finally, to ensure that “good faith” can always be shown, HHS “encourages all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.”