

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

PO Box 47890 • *Olympia, Washington 98504-7890 Tel: 360-236-4030* • *711 Washington Relay Service*

PREP Act Authorization for CDC COVID-19 Vaccination Program Participants

The Washington State Department of Health (Department) and its partners are working diligently to implement the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program to swiftly and safely administer vaccines to Washingtonians and bring an end to the COVID-19 epidemic in our state. To encourage participation and remove legal uncertainty and risk, the federal Public Readiness and Emergency Preparedness Act (PREP Act) provides broad immunity from suit and liability under federal and state law to those engaged in this vital and challenging work.

The purpose of this authorization is to assure the Department's partners, including hospitals, clinics, health care providers, and their staff and volunteers will benefit from the PREP Act's protections. This authorization includes, but is not limited to, those who organize, operate, and participate in COVID-19 vaccination clinics.

To trigger PREP Act immunity, the Secretary of Health and Human Services (HHS Secretary) issued a declaration under the PREP Act, effective February 4, 2020, determining that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency. *See* 85 Fed. Reg. 15,198 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e. The current version of the HHS Secretary's declaration was published at <u>85 Fed. Reg. 79,190</u> on December 9, 2020.

The HHS Secretary's declaration establishes numerous pathways to qualify for the PREP Act's liability protections. Relevant here, the declaration provides that the protections are in effect for Covered Persons for 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 Emergency.

COVID-19 vaccines that have received emergency use authorization by the Food & Drug Administration are Covered Countermeasures.

Governor Jay Inslee's *Proclamation by the Governor 20-05*, issued on February 29, 2020 and subsequently amended, is a Declaration of Emergency.

Covered Persons include, among others, any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, program planners, and their officials, agents, employees, contractors and volunteers, following a Declaration of Emergency.

PREP Act Authorization for CDC COVID-19 Vaccination Program Participants Page 2

The Washington State Department of Health is an Authority Having Jurisdiction within the meaning of the HHS Secretary's declaration because it is a public agency that has legal responsibility and authority for responding to the COVID-19 emergency in the state of Washington as the Coordinating and Primary Agency for Emergency Support Function 8 – Public Health, Medical, and Mortuary Services, of the state of Washington's Comprehensive Emergency Management Plan adopted under Chapter 38.52 RCW. The Washington State Department of Health also has legal responsibility and authority in the state of Washington for investigating disease epidemics, enforcing the state's public health laws, controlling and preventing the spread of disease in an emergency, and generally protecting the public health, under Chapter 43.70 RCW.

As Secretary of Health, the executive head and appointing authority of the Washington State Department of Health, under RCW 43.70.030, I hereby exercise the Washington State Department of Health's authority as an Authority Having Jurisdiction under the PREP Act and the HHS Secretary's declaration issued thereunder to declare that all facilities, organizations, agencies, health care providers, program planners, and persons, as defined in the PREP Act, that participate in the CDC COVID-19 Vaccination Program, and all officials, agents, employees, contractors, and volunteers thereof, are authorized in accordance with the public health and medical emergency response of the Washington State Department of Health to prescribe, administer, deliver, distribute, and dispense COVID-19 vaccines that qualify as Covered Countermeasures. Such vaccinations are not required to be recorded in a Covered Person's electronic medical record if they are reported to the State via the Washington Immunization Information System (IIS) pursuant to the CDC COVID-19 vaccination program provider agreement. This authorization includes, but is not limited to, those who organize, operate, and participate in COVID-19 vaccination clinics, whether or not they maintain an electronic health record of the vaccinations provided.

By virtue of this authorization, those included within its scope are Covered Persons as defined in the HHS Secretary's declaration, meet the requirements of subsection (b) of section VII of said declaration, and qualify as vaccination providers as defined in the letters of authorization issued by the FDA for the Pfizer-BioNTech and Moderna COVID-19 vaccines.

This authorization shall take effect upon signing and remain in effect until amended, rescinded, or overridden.

Signed this <u>13th</u> day of January, 2021.

Umair A. Shah, MD, MPH Secretary of Health