

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

PREP Act Authorization for Participants in Learn to Return COVID-19 Testing Program

BACKGROUND/RATIONALE:

The Washington State Department of Health (Department), in partnership with Health Commons Project, has established the Learn to Return program to enable schools to conduct diagnostic and screening testing of students and staff for COVID-19. This project will help schools catch cases quickly, prevent spread, protect students and staff, and limit disruption to students' learning. The success of the Learn to Return program depends on active and widespread participation. The purpose of this authorization is to facilitate and encourage such participation by removing regulatory barriers and legal uncertainty and risk.

This authorization grants participants the legal authority to undertake the activities of the Learn to Return COVID-19 testing program, including individuals who do not hold health care profession licenses, provided they meet certain training requirements and other program requirements. This authorization also ensures that participants in the program are eligible for the broad immunity protections from suit and liability available under the federal Public Readiness and Emergency Preparedness Act (PREP Act).

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 HHS Secretary's declaration has been amended numerous times, and those amendments may be found at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

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 tests that have received emergency use authorization or other approval 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.

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.

ACTION:

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, and all officials, agents, employees, contractors, and volunteers thereof, who participate in and comply with any training requirements, protocols, and other requirements of the Washington State Department of Health's Learn to Return COVID-19 testing program are authorized in accordance with the public health and medical emergency response of the Washington State Department of Health to purchase, donate, dispense, deliver, distribute, administer, and use any COVID-19 tests authorized for use in the Learn to Return COVID-19 testing program by the Washington State Department of Health, and any devices used in the administration of such tests and any component and constituent materials of such tests.

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

Signed this 27th day of August, 2021.

Umair A. Shah, MD, MPH

Secretary of Health