



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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PREP Act Authorization for Hospital Distribution of COVID-19 Antivirals

BACKGROUND/RATIONALE:

Antivirals authorized for emergency use by the U.S. Food and Drug Administration (FDA) for the treatment of COVID-19 are an important new tool to combat the COVID-19 pandemic. The purpose of this authorization is to remove regulatory barriers to the distribution of COVID-19 antivirals by hospitals so that patients may promptly and securely obtain treatment and minimize their contacts with others while infected with COVID-19.

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.

Antivirals for which the U.S. Food and Drug Administration has issued an Emergency Use Authorization or other approval for the treatment of COVID-19 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 hospitals licensed by the Washington State Department of Health are authorized in accordance with the public health and medical emergency response of the Washington State Department of Health to distribute to patients any antiviral for which the U.S. Food and Drug Administration has issued an Emergency Use Authorization or other approval for the treatment of COVID-19.

Pursuant to 42 U.S.C. § 247d-6d(b)(8), the PREP Act preempts any Washington State provision of law or legal requirement that is different from or is in conflict with the PREP Act, the HHS Secretary's declaration, or this authorization. Accordingly, any provision of Washington State law that would prohibit a hospital licensed by the Washington State Department of Health from distributing COVID-19 antivirals to patients as authorized herein is preempted.

This authorization shall take effect upon signing and remain in effect until amended, rescinded, or overridden.

Signed this 4th day of January, 2022.



Umair A. Shah, MD, MPH
Secretary of Health