Dear Colleague:

Due in large part to the hard work of public health partners and colleagues across the country, the United States has been able to significantly decrease the number and scale of COVID-19 outbreaks. Since January 2021, large-scale vaccination administrations, effective testing strategies, and non-pharmaceutical interventions have resulted in lower rates of COVID-19 and its complications.

During this phase of the response, we are aware of changes in the status of emergency declarations at state, tribal, local, or territorial levels. As we monitor potential public health impacts of these changes, we want to provide a reminder that the federal public health emergency (PHE) declaration and the Declaration, as amended, authorized by the Public Readiness and Emergency Preparedness (PREP) Act are still in effect.

Public Readiness and Emergency Preparedness Act (PREP Act)

The PREP Act allows the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that extends liability protections to entities and individuals who manufacture, distribute, or administer covered medical countermeasures against a public health threat or emergency. In March 2020, the Secretary issued a PREP Act Declaration covering COVID-19 tests, drugs, and vaccines providing liability protections to manufacturers, distributors, States, Local, Tribes, and Territories (SLTT), licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures. This declaration will be in place through 2024.

As a reminder, for jurisdictions that have ended or are considering ending public health state of emergencies, under the PREP Act Declaration, as amended, state and local authorities may not prohibit or effectively prohibit "qualified persons" (such as pharmacy interns and technicians) from ordering and administering covered countermeasures. The PREP Act contains an express preemption provision the PREP Act and the Declaration, as amended, are still applicable regardless of state laws and regulations. Qualified persons identified/covered by PREP Act to administer vaccines will still be covered regardless of whether a state has an emergency declaration in place.

A current fact sheet on the PREP Act can be reviewed by clicking on the link below: PREP Act Fact Sheet: Expanding the COVID-19 Vaccination Workforce (phe.gov).

See also: <u>Use of PREP Act to Administer COVID-19 Vaccines and ACIP Recommended Childhood Vaccinations</u>

HHS Public Health Emergency Declaration

The Secretary of Health and Human Services (HHS) has declared a public health emergency (PHE) for COVID-19, under section 319 of the Public Health Service Act (42 U.S.C. §247d). The PHE for COVID-19 was originally declared on January 31, 2020 and has been renewed every 90 days since. The current PHE was renewed effective April 15, 2021 and will be in effect for 90 days. Correspondence from the Acting Secretary to Governors earlier this year, indicated that the PHE will likely remain in place for the entirety of 2021, and when a decision is made to terminate the PHE or let it expire, HHS will provide states with 60 days' notice prior to termination.

Among other things, the PHE determination provides for the ability to streamline and increase the accessibility of healthcare, such as the practice of telemedicine. It allows under section 1135 of the

Social Security Act, in conjunction with a Presidential Declaration under the National Emergencies Act or Stafford Act, the Secretary to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements. The goal is to ensure to the maximum extent feasible that, in an emergency area during an emergency period, sufficient health care items and services are available to meet the needs of individuals receiving Medicare, Medicaid, and CHIP and that providers that furnish such items and services can be reimbursed for them and exempt from sanctions, absent fraud or abuse. Required reporting of SARS-CoV-2 test results to the HHS Secretary, as provided under section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, is also dependent upon an active PHE.

State, Tribal, Local, and Territorial Emergency Declarations

As of July 2, 2021, we are aware that 17 states have ended COVID-19 emergency declarations, however it is challenging to understand the full impact ending emergency declarations can have on a jurisdiction's response.

The legal impact of emergency declarations varies across jurisdictions. Emergency declarations can expressly authorize or direct specific response activities and may also trigger statutes, regulations, and policies/plans (e.g., procurement rules, emergency response plans, etc.) that rely on the presence of a declared emergency. For example, state COVID-19 emergency declarations may have implications for regulatory requirements for laboratory testing, depending on state laws and regulations. Our partners, including ASTHO, NEMA and NGA, are tracking the status of state emergency declarations nationwide. Additionally, the Congressional Research Service (CRS) has also published a helpful tool, "Expiring State COVID-19 Emergency Declarations: Effects on Federal Aid (congress.gov)" that outlines the interplay between state and federal emergency declarations. Regardless of jurisdictions' decisions, the federal declarations of a public health emergency (both the PREP Act and Declaration, as amended, and the PHE declaration) remain in place.

Within CDC, we are working across the response and with our Office of the General Counsel and Public Health Law Program to provide information to our programs on potential impacts.

Thank you for your ongoing efforts to support the nation's response to COVID-19.

Margaret (Peggy) Honein, PhD, MPH

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COVID-19 Emergency Response

U.S. Centers for Disease Control and Prevention

