

4th Amendment to the Declaration Under the PREP Act – Medical Countermeasures Against COVID-19

On December 3, 2020, the US Department of Health and Human Services (HHS) issued a fourth amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19. In the amendment was the inclusion of a telehealth provider under the “covered person” designation. The amendment further noted that if a telehealth provider was delivering a “covered countermeasure” via telehealth to a patient in a state the telehealth provider was not licensed in, state laws, including state licensure requirements, that prohibited such actions would be pre-empted.

WHAT SITUATION ALLOWS FOR THE LICENSURE EXEMPTION?

As noted above, a telehealth provider who is not licensed in the state the patient is located in, will be able to provide a select set of services without having to be licensed. However, there are certain qualifications and parameters that must be met.

You need to be a covered person

The amendment does not say “all telehealth providers.” A covered person must be “healthcare personnel who are permitted to order and administer a covered countermeasure through telehealth in a state.” This person must comply with legal requirements of the state in which the healthcare personnel is permitted to use telehealth to administer a covered countermeasure. This means that if the state you are licensed in does not allow your particular profession to utilize telehealth **OR** you are not permitted by your license or scope to administer a covered countermeasure, you are not a “covered person.”

It only applies to the administration of covered countermeasures

The exception to the licensing laws in the state the patient is located will only apply to administration of services that are “covered countermeasures.” Covered countermeasures are:

- A qualified pandemic or epidemic product;
- A security countermeasure;
- A drug, biological product, or device that is authorized for emergency use; or
- A respiratory protected device that is approved by the National Institute for Occupational Safety and Health

Not every service delivered via telehealth will apply. For example, if you are treating a patient located in another state for a skin condition due to an allergic reaction to a food, the licensure exception will not apply.

PREP ACT ALSO IS ABOUT LIABILITY COVERAGE, DOES THAT INCLUDE TELEHEALTH PROVIDERS?

If you are a provider who meets the definition of a “covered person,” you do get liability coverage for the covered countermeasures used in dealing with the public health emergency (PHE). It is not blanket liability coverage. Therefore, if you are a covered person, but you are performing a service that is not under covered countermeasures, you do not have liability coverage for that service.

HOW CAN THIS PRE-EMPT STATE LAW?

The PREP Act is federal law that allows the Secretary of Health and Human Services to issue a declaration to provide liability protection to certain individuals and entities against claims resulting from the manufacture, distribution, administration or use of certain medical countermeasures. Actions that are “willful misconduct” are not protected. When COVID-19 hit, the Secretary used his powers under PREP to issue a declaration for medical countermeasures. In [Advisory Opinion 20-02](#) from HHS’ Office of the General Counsel, they note that:

“Under the PREP Act, state and local authorities may not prohibit or effectively prohibit “qualified persons” from ordering and administering covered countermeasures for three reasons:

First, through his PREP Act declaration, the Secretary can designate a “qualified person” to use and administer a covered countermeasure even when that person is not authorized to do so under state law...

Second, the PREP Act expressly preempts any state or local legal requirement that prohibits or effectively prohibits a qualified person from ordering and administering a covered countermeasure pursuant to the Secretary’s declaration.

Third, states and localities cannot challenge in court the Secretary’s designation of persons authorized to order and administer covered countermeasures. Under the PREP Act, “No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary” pursuant to his declaration under § 247d-6d(b).”

HOW LONG WILL THIS LAST?

The exception will last as long as the PHE is in effect or until October 1, 2024, whichever comes first.