

The PREP Act and its Application to Health Care Providers and Entities

Many healthcare providers and their insurers are asking how the PREP Act applies to the care provided during this unprecedented global pandemic. The PREP Act is federal legislation that will preempt any state law regarding the same subject matter as to certain actions taken by certain authorized individuals in response to the Covid-19 pandemic. As authorized by the PREP Act, Secretary Azar has issued a Declaration providing for civil immunity for any state or federal claim of loss arising out of certain covered countermeasures taken by a covered individual or entity. Who is covered under the PREP Act immunity is broad. However, the definition of “covered countermeasures” within the Declaration is not as broad and therefore limits the applicability of civil immunity. Secretary Azar’s Declaration pursuant to the PREP Act is backdated to provide this immunity from February 4, 2020 until the final date the emergency declaration is in effect or October 1, 2024, whichever comes first.

Who civil immunity is provided to:

- Manufacturers, distributors, program planners, qualified persons and their officials, agents, employees (as defined by the PREP Act) and the United States;
- Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction (i.e. as authorized by a state or local emergency order, etc.) to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures including their officials, agents, employees, contractors and volunteers following a Declaration of an emergency;
- Any person authorized to prescribe, administer, or dispense the covered countermeasures or who is otherwise licensed to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;
- Any persons authorized to prescribe, administer or dispense covered countermeasures in accordance with Section 564A of the FD&C act.

What are “covered countermeasures”:

- Any antiviral, drug, biologic, diagnostic or other device or any vaccine, used to treat, diagnose, cure prevent or mitigate COVID-19 or the transmission of SARS or any device used in the administration of any such product;
- Covered countermeasures must be qualified pandemic or epidemic products or security countermeasures or drugs, biological products or devices authorized for investigational or emergency use.

What activities are specifically provided civil immunity:

- Present or future federal contracts, cooperative agreements, grants other transactions, interagency agreements, memoranda of understating or other federal agreements;
- 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 an emergency.

What actions are not provided civil immunity:

- Any willful misconduct;
- Actions not directly related to the treatment, diagnosis, cure, prevention or mitigation of COVID-19.

For health care providers and insurers, this means that insureds (if authorized by the state or local emergency declaration or order in place regarding covid-19) who are participating in the effort to treat COVID-19 patients, including all mitigation efforts, may have civil liability immunity if those efforts involve administering medication, vaccine administration or development, or use of a ventilator or other

device related to treatment of COVID-19, for example. The passing of this Act also means that health care facilities may have civil liability in operational measures such as patient intake, treatment and mitigation of COVID-19 such as treatment tents, parking lot and/or crowd control measures, etc. This immunity covers a variety of different claims, including medical negligence claims, agency claims against facilities, premises liability claims, manufacturing and products liability claims.

Regarding medical negligence claims, however, not all care and treatment directly related to COVID-19 is covered. Because of the limited definition of “covered countermeasures,” only care involving those products, drugs, or devices as defined in the Declaration are protected with civil liability immunity. However, the good news for health care providers and their insurers is that a substantial amount of health care provided in the diagnosis, care, treatment and cure of COVID-19 patients will be covered with civil immunity, as it very likely that their care involves administering medication and/or using medical devices as defined in the Declaration.

A handwritten signature in black ink, appearing to read 'Zoe Butts', written in a cursive style.

Zoe Butts

Fareshteh Hamidi