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LIABILITY IMMUNITY

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Liability Immunity Laws for Healthcare Providers

To determine what immunity, if any, applies during a government declared emergency, healthcare professionals and institutions must work through a patchwork of federal and state laws, as supplemented by government declarations or executive orders.

Links to individual State summaries of COVID-19 related actions

The following provides an overview of the federal immunity laws.

Federal Laws

The Volunteer Protection Act[1] provides immunity in emergency situations to healthcare professionals, but they must be unpaid volunteers (no compensation except expense reimbursements) and they may only perform services on behalf of a nonprofit organization or a governmental entity. To qualify for immunity, the volunteer must be properly licensed, certified, or authorized to practice in the state in which the services were rendered and the services must be within the scope of the volunteer's responsibilities. The immunity only applies to volunteers, not to the entities that deploy them. The immunity does not apply to claims involving willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual. No immunity is provided in cases where the nonprofit or governmental body brings a claim against the volunteer. The federal law preempts state law except where state law expands immunity protections.

The federal Department of Health & Human Services published a Notice of Declaration on March 17, 2020[2], providing qualified immunity to licensed health care professionals and entities against any claim of loss arising out of the manufacturing, distribution, administration or use of medical countermeasures for COVID-19 patients. Medical countermeasures include the administration of any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, including those not otherwise approved by the FDA, but designated by the FDA as emergency use authorizations. The immunity does not apply to claims involving willful and wanton misconduct.

During this emergency, a healthcare professional or entity should be afforded immunity if he or she acts in accordance with applicable directions, guidelines or recommendations issued by HHS regarding the countermeasure and so long as he or she notifies HHS or the applicable state or local health authority about a resulting serious injury or death within seven days of its discovery.

The Coronavirus Aid, Relief, and Economic Security Act or the ''CARES Act'' signed into law by the President on March 27, 2020 includes immunity from liability for volunteer health care professionals from harm or injury to another during the COVID-19 emergency response. To be afforded immunity under the CARES Act, the health care professional must be an unpaid volunteer providing health care services that relate to the diagnosis, prevention, or treatment of COVID-19 or the assessment or care of

1 42 U.S.C. § 14501

2 Available at https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

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the health of a person that may be an actual or suspected case of COVID-19.[3] Additionally, the act or omission occurs in the course of providing health care services within the scope of the license, registration, or certification of the treating provider and in good faith that the individual being treated is in need of health care services.[4] Protections do not apply if harm was caused by an act or omission of willful or criminal misconduct, gross, negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed, or if rendered under the influence of alcohol or an intoxicating drug.[5] The immunity takes effect upon the enactment of the Act (March 27, 2020) and is in effect for the length of the COVID-19 public health emergency.[6]

On June 8th, the Department of Health and Human Services issues a Second Amendment to the Public Readiness and Emergency Preparedness Act ("PREP Act") for medical countermeasures against COVID-19. A copy of the announcement can be found HERE.

The PREP Act authorizes the Secretary to issue a Declaration to provide covered persons against any claim of loss caused by, or arising out of, relating to or otherwise resulting from, the manufacture, distribution, administration, or use of a medical countermeasure, with the exception of claim involving willful misconduct.

The amendment clarifies the March 10th amendment the improperly defined Medical Covered Countermeasures. Per the June 8th amendment, said medical covered countermeasures should be defined as:

(1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used

a. to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID– 19, or the transmission of SARS–CoV– 2 or a virus mutating therefrom, or

b. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause; or

(2) any device used in the administration of any such product, and all components and constituent materials 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, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

[3] § 3215(d)(3)
[4] § 3215(a)(2)(C) and (D)
[5] § 3215(b)
[6] § 3215(e) and (f)