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PHYSICIAN LAW BLOG

Department of Health and Human Services Declares Liability Immunity for Activities Related to COVID-19

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On March 10, 2020 the Secretary of Health and Human Services issued a declaration of liability protection under the Public Health Service Act pursuant to a seldom used section of the Act titled the "Targeted Liability Protections for Pandemic and Epidemic Products and Security Countermeasures." 42 U.S.C. 247d-6d.

The Declaration, effective February 4, 2020, immunizes licensed health professionals, manufacturers, distributors, program planners, and those that prescribe, administer, or dispense drugs, biological products, or devices, used to diagnose, mitigate, prevent, or treat COVID-19.

The Declaration protects the aforementioned from any liability under federal and state law for "any type of loss," ranging from property damage (including business interruption) to death, caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. 42 U.S. Code § 247d–6d(a)(1). In this instance, covered countermeasures include drugs, biological products, or devices, designed or used to diagnose, mitigate, prevent, treat, or cure COVID-19 or limit the harm COVID-19 might otherwise cause. *Id*. at (i)(7)(A)(I-II). For immunity to apply, the Act requires the covered countermeasure be administered or used for COVID-19 from February 4, 2020 to October 1, 2024. *Id*. at (a)(3)(A-C); *see also* Declaration Sections VIII, X, and XII.

As with many legislatively endorsed immunities, there is an exception for willful misconduct, which the Act defines as an act or omission taken: intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is "so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S. Code § 247d–6d (d)(1).

Some guidance can be found in the Declaration:

[W]hen a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.

However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use.

Declaration, Section IX, Administration of Covered Countermeasures.

As described above, the Declaration does not contemplate immunity for actions not *directly* related or connected to the COVID-19 countermeasures. For more information on liability issues arguably not "directly" related to COVID-19 countermeasures, see Dennis Harms' recent post, "COVID-19 and the Standard of Care."

There is always, unfortunately, a risk of litigation. Whether immunity applies depends entirely on the facts and circumstances. The Act's definition of willful misconduct is, however, more stringent than others commonly seen in state laws and hopefully provides some relief for strained healthcare providers during this trying time.

Secretary of Health and Human Services Declaration (March 20, 2020)

42 U.S.C. 247d-6d