
The PREP Act: Expanding Immunity Against COVID-19 Liabilities

Health-care providers, frontline responders, manufacturers, distributors, and others involved in the fight against COVID-19 should be comforted by the legal protections afforded by the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. §247d-6d. A review of the PREP Act and related Amendments illustrates the expanding shield the PREP Act can provide against COVID-19 related litigation. While the U.S. Department of Health and Human Services (HHS) continues to expand coverage of the PREP Act's broad-based, retroactive immunity, the case law is in its infancy and is at times inconsistent, highlighting the importance for "covered persons" to keep abreast of future developments.

The PREP Act and COVID-19

Enacted on Dec. 30, 2005, the PREP Act empowers the Secretary of HHS to issue a PREP Act Declaration that "a disease or other health condition ... constitutes a public health emergency." The PREP Act provides certain individuals and entities ("covered persons") broad immunity for specific recommended activities, namely, "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." This immunity encompasses claims under both federal and state law for actions based in doctrines ranging from tort to contract losses.

There is one exception. The PREP Act enables actions for "willful misconduct." Litigants pursuing this limited avenue must file claims in the United States District Court for the District of Columbia before a special three-judge panel, which determines whether there is "clear and convincing evidence" that the willful misconduct proximately caused death or serious physical injury. For injuries not involving willful misconduct, the PREP Act establishes a Covered Countermeasure Process Fund, which provides "compensation to eligible individuals for covered injuries directly cause by the administration or use of a covered countermeasure pursuant to such declaration." 42 U.S.C. §247d-6e(a).

On Jan. 31, 2020, in response to the burgeoning COVID-19 pandemic, then HHS Secretary Alex M. Azar II declared a public health emergency.



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Thereafter, on March 17, 2020, Secretary Azar published a Declaration, 85 Fed. Reg. 15198 (Mar. 17, 2020) (“the Declaration”), activating the PREP Act’s protections to apply retroactively as of Feb. 4, 2020, through Oct. 1, 2024. The Declaration provides immunity to covered persons against “all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use” of “covered countermeasures.”

The Declaration has since evolved to define the following key terms:

1. *Covered persons* include those who manufacture, distribute, administer, prescribe or use covered countermeasures, as well as program planners, and qualified persons, and their officials, agents, and employees. The Declaration also defines each of the aforementioned terms in detail, for example, “qualified persons” are licensed health professionals (like nurses, doctors, pharmacists, technicians, etc.) or other individuals authorized to prescribe, administer, or dispense covered countermeasures.
2. *Covered countermeasures* are products, more specifically, drugs and devices, as well as biological products, and their components and constituent materials, that are manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure COVID-19 or limit the harm of COVID-19. Covered countermeasures also include various products and technologies “intended to enhance the use or effect of such a drug, biological product, or device,” or protect against the underlying drug, device, or product’s adverse effects. Respiratory protective devices used to treat, diagnose, prevent, cure, or mitigate COVID-19 are expressly included within the definition. Generally, only products approved, licensed, or authorized by the U.S. Food and Drug Administration (FDA) may qualify; however, products authorized for emergency use under federal law or cleared by the FDA for investigational use may qualify as well.

Amendments

As of March 11, 2021, HHS has amended the Declaration seven times, each time expanding immunity coverage.

- On April 15, 2020, the First Amendment added respiratory protective devices approved by the National Institute for Occupational Health and Safety (like the N95 facemask) to the list of covered countermeasures. 85 Fed. Reg. 21012 (Apr. 15, 2020).
- On June 8, 2020, the Second Amendment named qualified products that “limit the harm” the pandemic might cause as covered countermeasures. 85 Fed. Reg. 35100 (June 8, 2020).
- On Aug. 24, 2020, the Third Amendment enlarged the definition of “qualified persons” to include certain pharmacists and pharmacy interns, based upon the need to expand the health-care workforce available to administer vaccines to children. The Amendment further expanded the category of disease, health condition, or threat that requires a covered countermeasure response from COVID-19 to include other diseases, health conditions, and threats, specifically, noting the risk that fewer childhood vaccinations could increase the rate of other infectious diseases. 85 Fed. Reg. 52136 (Aug. 24, 2020).
- On Dec. 9, 2020, the Fourth Amendment added significant changes on multiple fronts:
 - The Declaration originally limited immunity to covered countermeasures “related to” (a) federal contracts, or (b) activities authorized by state authorities’ (state, federal, local, tribal, etc.) public health response. The Fourth Amendment established (c) immunity for private-distribution channels of covered counter measures, meaning immunity is extended to covered persons whose product is “licensed, approved, cleared, or

authorized by the FDA ... to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19 ... or a virus mutating therefrom,” as well as to covered persons for recommended activities related to respiratory protective devices.

- o Significantly, the Amendment established that immunity could apply to situations where a covered person does not give a particular individual a covered countermeasure.
- o The Amendment added health-care personnel who practice telehealth medicine across state lines to the definition of “qualified persons.” The Amendment also expressly preempted state laws that might otherwise prohibit administering covered countermeasures through telehealth.
- o Importantly, the Amendment states, “that there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), necessitating “a uniform interpretation of the PREP Act.”
- o Last, the Amendment provides that the original Declaration should be construed in accordance with the HHS Office of the General Counsel (“OGC”) Advisory Opinions and amends the Declaration to incorporate the HHS Office of the Assistant Secretary for Health (“OASH”) guidance documents.
 - » Further analysis of OGC Advisory Opinions and OASH Guidance documents is essential to appreciate the PREP Act’s scope of immunity. For example, under the April 17, 2020, Advisory Opinion, immunity can apply to a product that is not a covered countermeasure or to an individual who is not a covered person provided the PREP Act’s other requirements are satisfied and there was a reasonable belief that the product was a covered countermeasure/the person was a covered person.

85 Fed. Reg. 79190 (Dec. 9, 2020).

- In February and March of 2021, the Fifth, Sixth, and Seventh Amendments expanded the definition of “qualified persons” to increase the number and availability of health-care workers available to administer COVID-19 vaccines. The Amendments afforded health-care workers from wide ranging practices (doctors, nurses, midwives, dentists, veterinarians, etc.) protections if they: (1) administer vaccines in states where they are not licensed; (2) administered vaccines yet had expired licenses (within five years); or (3) were a federal employee, contractor, volunteer, etc., involved in the administration of covered countermeasures. 86 Fed. Reg. 7872 (Feb. 2, 2021); 86 Fed. Reg. 9516 (Feb. 2, 2021); 86 Fed. Reg. 14462 (Mar. 11, 2021).

Application of the PREP Act in New Jersey

Estate of Maglioli v. Andover SubAcute Rehab. Ctr. I, 478 F. Supp. 3d 518 (D.N.J. 2020), is the only published case in New Jersey addressing the PREP Act. Plaintiffs in *Estate of Maglioli* were representatives of former residents who allegedly died from the defendant nursing home’s failure to take precautions against COVID-19. Plaintiffs asserted negligence, wrongful death, and malpractice claims. Defendants removed the case to federal court under PREP Act preemption. In granting the plaintiffs’ motion to remand, the court declined to find that the PREP Act preempted plaintiffs’ claims. The court determined the PREP Act “does not ‘occupy the field’ of negligence or malpractice claims, even if that negligence or malpractice happens to relate to the COVID-19 illness[;]” rather, the PREP Act applies “to the administration of certain countermeasures, and requires a case by

case analysis.” *Id.* at 531. The court held the PREP Act “leaves room for ordinary claims of negligence or substandard care,” and since plaintiffs allege that defendant failed to administer or use countermeasures, the court found the record lies outside the scope of PREP Act coverage. *Id.* at 532.

By contrast, in a factually similar case decided in February 2021, the court in *Garcia v. Welltower OpCo Grp.*, No. SACV-20-02250-JVS-KESx, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021), applied PREP Act immunity in favor of the defendant nursing home. The *Garcia* court held that not only does the PREP Act provide a basis for removal, but it also provides immunity from state-law tort claims as the “PREP Act provides for complete preemption.” *Id.* at *7. The *Garcia* court relied heavily on recent Amendments and advisory opinions to support its conclusion.

Estate of Maglioli was decided before publication of the Fourth Amendment, but whether or not a different decision would have been reached had the case been heard in 2021 is far from clear. In March 2021, a district court in New Mexico that had the benefit of the Fourth Amendment’s sweeping immunity protections reached a similar conclusion to *Estate of Maglioli*. See *Lopez v. Life Care Ctrs. of Am.*, No. 20-0958-JCH-LF, 2021 WL 1121034 at *12 (D.N.M. Mar. 24, 2021) (finding that the defendant nursing homes’ inaction was “not closely connected enough to the administration of a countermeasure plan to fall within the scope of the PREP Act’s remedies”).

Conclusion

The inconsistent case law reflects divergent interpretations of PREP Act immunity. The *Estate of Maglioli* matter is currently on appeal. Hopefully the Third Circuit will provide guidance for interpretation of this important statute.