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# The PREP Act Revisited: Limitations of Immunity and Federal Court Jurisdiction for Nursing Homes

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Nursing homes have faced numerous lawsuits alleging their negligence caused deaths from COVID-19. Many thought they would be able to access federal courts and receive the immunity protections of the Public Readiness and Emergency Preparedness Act, commonly known as the "PREP Act." The PREP Act protects certain covered persons who engage in certain activities during a public health crisis like the COVID-19 pandemic. 42 U.S.C. §247d-6d.

A recent decision by the U.S. Court of Appeals for the Ninth Circuit held that the PREP Act does not provide federal courts jurisdiction over nursing home wrongful death claims. See *Saldana v. Glenhaven Healthcare*, 27 F.4th 679 (9th Cir. 2022).

Despite setbacks in federal courts, many states, including New York, have afforded nursing homes some protections that mirrored the immunities granted by the PREP Act. In 2021, however, New York repealed those protections, leaving nursing home defendants to defend these claims by establishing that the care and treatment provided was not a departure from good and accepted care, and that the care was not negligently provided, unreasonable or intended to cause harm.

## Background

In 2005, Congress passed the PREP Act in order to provide protection from lawsuits during public health emergencies for certain covered persons or entities. 42 U.S.C. §247d-6d(a)(1). Perhaps the most significant protection the PREP Act granted was immunity to persons who administered or used certain covered "countermeasures." 42 U.S.C. §247d-6d(a)(3-4).

The PREP Act creates an exception to such immunity for willful misconduct, and provides the U.S. District Court for the District of Columbia exclusive jurisdiction to hear and decide such claims. 42 U.S.C. §247d-6d(d). Significantly, the PREP Act preempts "any provision of law or legal requirement that … is different from, or is in conflict with, any requirement applicable under this section." 42 U.S.C. §247d-6d(a)(8).

In accordance with the PREP Act, the COVID-19 pandemic was deemed a covered emergency by virtue of the Declaration of the U.S. Secretary of Health and Human Services (HHS or Secretary). See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. 85 Fed. Reg. 15198-01 (March 17, 2020).

In subsequent statements by HHS during the COVID-19 pandemic, particularly through an advisory opinion of its Office of General Counsel (see U.S. Dept. Health & Hum. Servs., Gen. Couns. Advisory Op.

21-01 (Jan. 8, 2021), the preemption set forth in the PREP Act was deemed "complete preemption."

Complete preemption is a jurisdictional rule providing federal courts jurisdiction over claims arising under federal statutes whose "pre-emptive force of a statute is so 'extraordinary' that it 'converts an ordinary state common-law complaint into one stating a federal claim.'" *Caterpillar v. Williams*, 482 U.S. 386, 393 (1987) (citation omitted).

Accordingly, if the PREP Act completely preempted state law claims asserting wrongful death from COVID-19, then typical state law causes of action that might traditionally be asserted against nursing homes, such as negligence or wrongful death claims, could not be sustained.

The authority of the advisory opinions was reinforced by the Secretary's Fourth and Fifth Amendments to the Declaration. In the Fourth Amendment, the "advisory" opinions were expressly made part of the Secretary's Declaration: "The Secretary now amends the Declaration to clarify that the Declaration must be construed in accordance with the Advisory Opinions. The Secretary expressly incorporates the Advisory Opinions for that purpose." 85 Fed. Reg. 79190-01, 79192 (Dec. 9, 2020).

In the Fifth Amendment, the HHS Secretary confirmed his counsel's opinion that the PREP Act constituted complete preemption: "[t]he plain language of the PREP Act makes clear that there is complete preemption of state law as described." See Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021).

Most federal courts reviewing the issue disagreed with the HHS Secretary.

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### Federal Courts' View of PREP Act Preemption

Despite the clear position of HHS, most federal courts have declined to give deference to the agency's view of PREP Act complete preemption. Instead, those courts engaged in their own analysis, most concluding that preemption of the PREP Act is not "complete," and that for claims for personal injury and wrongful death arising from nursing home care of COVID-19 patients, removal to federal court is not appropriate.

The reasons for declining to apply PREP Act preemption fall into two broad categories. One looks at whether the complaint alleges conduct related to the administration or use of "countermeasures." In cases where defendants argue the complaint alleges injury due to a nursing home's *failure* to take such countermeasures, PREP Act application has been denied. See, e.g., *Jackson v. Big Blue Healthcare*, No. 20-CV-2259, 2020 WL 4815099, at *6 (D. Kan. Aug. 19, 2020).

The other reason for declining federal jurisdiction focuses on the application of complete preemption. Despite the statements by the HHS Secretary and his counsel to the contrary, most courts have determined that complete preemption is a jurisdictional question that is solely within the purview of the courts. Undertaking an independent analysis, most courts determined that the statutory scheme did not intend to establish complete preemption.

As the PREP Act only creates a very narrow cause of action for willful misconduct, and provides exclusive jurisdiction in the District Court for the District of Columbia, such a limited federal right, these courts held, does not create complete preemption. This meant that the courts did not have jurisdiction and, therefore, these cases were remanded to state court. See, e.g., *Dupervil v. Alliance Health Operations*, 516 F. Supp. 3d 238 (E.D.N.Y. 2021).

Only one case, *Garcia v. Welltower*, 522 F. Supp. 3d 734 (C.D. Cal. 2021), agreed with the defendant nursing home, holding that the determination of the HHS Advisory Opinion deserved deference in accordance with the standard set out by the U.S.

Supreme Court in *Chevron, USA v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). Since the decision in *Garcia*, the Court of Appeals for the Ninth Circuit, which includes the Central District of California, held in *Saldana* that the PREP Act is not a "complete preemption" statute and ruled that remand was appropriate. 27 F.4th at 686-88.

### New York Giveth and New York Taketh Away

Despite setbacks in federal courts, nursing homes were still protected by various state laws enacted to confer immunity, even when the PREP Act protections were not available. Debra Cassens Weiss, **At Least 15 States Grant Lawsuit Protection to Long-Term Care Facilities During Pandemic**, ABA Journal (May 4, 2020).

In New York state, nursing homes had temporarily enjoyed immunity under Public Health Law §§3080-3082 (repealed 2021). These provisions, which arguably went further than the immunity provisions of the PREP Act, granted broad immunity to nursing homes and other health care facilities and professionals who provided health care services in the context of the COVID-19 pandemic. Public Health Law §3082 (repealed 2021).

Backlash to this law followed the multitude of deaths in nursing homes attributed to COVID-19. This was particularly noted in New York Attorney General Letitia James's report, Nursing Homes Response to COVID-19 Pandemic, which found, among other issues:

- A lack of compliance with infection control protocols;
- Insufficient personal protective equipment (PPE) for nursing home staff; and
- Insufficient COVID-19 testing for residents and staff in the early stages of the pandemic.

Attorney General James's report recommended that New York's immunity provisions be "eliminate[d]." **Nursing Home Response to COVID-19 Pandemic**, N.Y. State Office of the Att'y Gen., 50 (last revised Jan. 30, 2021). The state Legislature and ultimately the governor followed that recommendation, and the immunity provision of the state's public health law was repealed on April 6, 2021. **2021 N.Y. Senate Bill S5177** (last visited March 28, 2022).

### Where Do Nursing Homes Go From Here?

Nursing home negligence and wrongful death cases, whether related to COVID-19 or not, are usually fact-intensive: whether the facility or its employees departed from accepted standards of care. See, e.g., *Noga v. Brothers of Mercy Nursing & Rehabilitation Center,* 198 A.D.3d 1277 (4th Dept. 2021), rearg. denied, 200 A.D.3d 1746 (4th Dept. 2021); *Domoroski v. Smithtown Center for Rehabilitation and Nursing Care*, 95 A.D.3d 1165 (2d Dept. 2012).

In any cases where the claim centers on care and treatment that was administered rather than claims that care was not provided, the protections of the PREP Act may yet apply. Even in such cases—where a nursing home defendant may have an affirmative defense based on compliance with the PREP Act—the weight of the federal decisions on the issue indicates no basis for federal removal jurisdiction, i.e., the court where the action was filed would decide whether an affirmative defense provides immunity.

The unique crisis presented by the COVID-19 pandemic, and the lack of clear information, resources, treatment options and guidance from public health authorities that was available at the time, may provide some help to nursing homes defending their care and treatment of residents in their charge.

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