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Medical Malpractice Claims During A Declared Health Emergency: Statutory Immunities and Defense Strategies

The Federal Public Readiness & Emergency Preparedness (PREP) Act

What is the PREP Act and How Is It Applicable?

In 2005, Congress passed the Public Readiness & Emergency Preparedness Act ("PREP Act"), which provides immunity from suit to certain covered parties during a declared public health emergency. In March 2020, the Secretary of the Department of Health & Human Services issued a declaration under the PREP Act that COVID-19 is a public health emergency and that those "covered persons" administering "covered countermeasures" be subject to the PREP Act's immunities. Those claims brought by plaintiffs that are subject to the PREP Act's immunities arising from negligence must be brought to the federal compensation fund; those stemming from "willful misconduct" have an exclusive federal cause of action.

As of the time this narrative is being prepared (March 15, 2022), there is no binding federal authority that has interpreted whether the PREP Act applies to claims against healthcare providers brought by patients who contracted COVID-19 allegedly due to the negligence or willful misconduct of said provider.

The defense bar has adamantly argued that that PREP Act should apply to healthcare providers responding to the COVID-19 pandemic. First, healthcare providers are "covered persons" under the PREP Act, in that they are considered part of the critical infrastructure of the country. Additionally, in administering countermeasures to combat COVID-19, healthcare providers meet the definition of "program planner" under the PREP Act ("a person who supervises or administers a countermeasure program or facility").

Additionally, "covered countermeasures" are preventative measures "used to treat, diagnose, cure, prevent, or mitigate COVID-19." This definition includes, but is not limited to, use of personal protective equipment ("PPE") —face masks, respirators, gloves, and gowns— as well as vaccines, thermometers, hand sanitizer, and COVID-19 tests. In addition to use of such items, "covered countermeasures" is also argued to include measures taken to prevent the spread of COVID-19, such as social distancing, closing facilities to outside visitors, staff checks at the door for symptoms of COVID-19, daily monitoring of patients for symptoms, and isolation of COVID-19 positive patients.

The defense bar has also been steadfast in the position that the PREP Act forces plaintiffs to bring their claims in federal court, rather than state court. As will be discussed in more detail below, defendants have argued that the PREP Act provides an exclusive federal cause of action for both negligence and willful misconduct claims. Additionally, defendants argue that they are federal officers, in that they worked on behalf of the federal government to combat the spread of COVID-19, and should be subject to federal officer jurisdiction. Third, the PREP Act raises a federal question, and claims must be heard in federal court.

The plaintiff bar has begun to artfully plead their COVID claims so as to avoid applicability of the PREP Act. First, many complaint are now being filed without specific allegations that discuss use or non-use of PPE, tests, etc. Plaintiffs generally allege "failure to provide adequate infection control measures" and file vague complaints in the hope that they do not give the defendants enough of a hook to combat the lawsuit with the PREP Act. Second, the plaintiff bar has attempted to take the position that non-use of covered countermeasures (for example, a claim that a nursing home did not provide PPE for staff to use) does not trigger the PREP Act because non-use should not be considered "administration." This argument has not gained traction to date; defendants are contesting this position in asserting that allocation of scarce resources is most certainly "administering" a strategy to combat COVID-19.

Current State of the Law Regarding the PREP Act's Applicability to COVID Cases

As to the date this narrative was prepared, 3 federal circuit courts have held that cases where the PREP Act has been raised as a defense are not subject to federal jurisdiction. The opinions that have been issued thus far are somewhat inconsistent, and it is expected that the US Supreme Court will eventually need to affirmatively decide whether PREP Act cases belong in federal or state courts.

The first circuit to examine the issue was the 3rd Circuit, which held that negligence claims brought by healthcare providers are not subject to federal jurisdiction in *Maglioi v. Alliance HC Holdings, LLC*, 16 F.4th 393 (3d Cir. 2021). The plaintiffs in *Maglioli* alleged that the patient contracted COVID-19 while a resident at Andover Subacute & Rehabilitation, which is a nursing home in New Jersey. The allegations include negligence, gross recklessness, and willful/wanton conduct for failure to take appropriate precautions to prevent COVID-19 infection and to protect residents, in that the facility only provided RNs and no other staff with face masks, failed to require visitors/employees to have their temperatures taken before entering the building and failed to require visitors/employees to wear protective masks/gear while in the building. In considering whether the PREP Act would subject these claims to federal jurisdiction, the panel from the 3rd Circuit held that the nursing home was not a federal officer and the PREP Act does not create an exclusive cause of action for negligence claims either through complete preemption of state law claims or by setting up a federal compensation fund for those claims brought under a negligence cause of action. *Maglioli* did recognize that claims for willful misconduct subject to the PREP Act are subject to the exclusive jurisdiction of federal courts. However, the court held that the *Maglioli* plaintiffs failed to "allege or imply that the nursing homes acted 'intentionally to achieve a wrongful purpose'", so their claims did not rise to willful

misconduct and should be heard in state court. The defendants did not choose to attempt to bring this case up to the US Supreme Court.

The second court to consider federal jurisdiction under the PREP Act was the 9th Circuit in *Saldana v. Glenhaven Healthcare, LLC*, No. 20-56194, --- F.4th ---, 2022 WL 518989 (9th Cir. Feb. 22, 2022). The plaintiff's decedent was a resident of the defendant nursing home and alleged contracted and died from COVID in April 2020. Plaintiffs alleged negligence, elder abuse, willful misconduct and wrongful death. The court held that the nursing home was not acting as or under a federal officer, the PREP Act does not provide for complete preemption of negligence claims, and the PREP Act does not raise a federal question. The *Saldana* court further confused the issue of whether the willful misconduct claims would be preempted, because they seemingly held that a PREP Act right or immunity must be an "essential element" of the willful misconduct claim and must be a "substantial part" of the complaint. The court upheld the district court's order remanding the case to California state court, including the willful misconduct claim, because that claim not a "substantial part" – "according to the complaint, only some of the steps Glenhaven allegedly took, and did not take, may have involved a 'covered person,' under the PREP Act." The ruling is unclear and at the present time, the defendants have petitioned the 9th Circuit for an en banc rehearing, which petition remains pending.

Finally, the 5th Circuit recently weighed in on the issue in the *Mitchell v. Advanced HCS, LLC dba Wedgewood Nursing Home*, No. 21-10477, --- F.4th ---, 2022 WL 714888 (5th Cir. Mar. 10, 2022) decision. The complaint was filed in Texas and alleges that the resident of the defendant nursing home passed away in May 2020 from complications of COVID, among other medical conditions. The complaint alleged negligence and gross negligence. The court held that the PREP Act did not completely preempt the complaint, as there were no claims of willful misconduct because the plaintiffs did not allege more than "negligence in any form or recklessness." The *Mitchell* court agreed with the *Maglioli* court that the fact that the PREP Act sets up a compensation fund does not create a federal cause of action for negligence claims within that fund. *Mitchell* further holds that the PREP Act does not create a federal question, and the defendant nursing home was not acting as a federal officer. However, this opinion further muddies the federal jurisdiction waters in that it implies that, had the plaintiffs brought claims for willful misconduct, the entire lawsuit – not just those willful misconduct claims within it – would be completely preempted by the PREP Act.

Additionally, the 11th Circuit is due to hear arguments on the *Schleider v. GVDB Operations, LLC* (Florida – currently on appeal, Docket No. 21-11765 BB (11th Cir.)) case. This lawsuit involves a plaintiff who contracted COVID-19 while residing at an assisted living facility. The complaint alleges negligence and willful misconduct for failure to provide PPE to residents and staff, among other things. Plaintiffs even went so far as to specifically plead within their complaint that the PREP Act does not apply because they allege failure to use countermeasures.

Given these decisions, federal courts even outside these 3 circuits have been reluctant to allow removal to federal court. Numerous courts have received a defendant's notice to remove the litigation and have issued an order to show cause as to why the case should not be remanded sua sponte. The best argument against this is to (1) differentiate the case at hand from *Maglioli*, *Saldana* and *Mitchell*, and (2) if your case is pending outside the 3rd, 5th or 9th Circuits, to ask the

court to – at the very least – stay any remand until the circuit in which the court sits opines on the issue.

To date, there is no binding federal caselaw deciding whether the substance of plaintiffs' COVID-19 related claims are subject to that immunity from suit provided in the PREP Act. This continues to be a heavily-litigated subject across the country.

State Immunities

In addition to the federal protections offered by the PREP Act, certain states have announced various executive orders, acts and statutes that offer immunity to liability related to the COVID-19 pandemic.

50-State Survey

There are a handful of states that have not passed any such immunities: Colorado, Maine, Minnesota, New Hampshire, New Mexico, and Oregon. While there were no immunities specifically put into place, certain states, such as California, did take other action that impacted lawsuits against medical providers during the COVID-19 timeframe. We will include those below.

In contrast, the majority of states have enacted immunities for healthcare providers in some fashion. Most state protections are immunities from *liability*, which is an important distinction, as the PREP Act provides immunity from *suit*. Similar to the PREP Act, most states also except from immunity any wrongdoing stemming from willful misconduct. Many also extended that exception to gross negligence.

The state protections and impacts on medical malpractice lawsuits have also seen various other forms, including tolling periods for statutes of limitations (eg, California and Connecticut) or more limited periods in which to bring suit (eg, Florida).

A number of states have expired their protections at this point. While the immunities would still remain in place for acts committed during the time period in which the immunity was in place, any new actions taking in fighting the pandemic would not be subject to immunity.

A Selection of Current Law in Those States That Have Enacted Immunities

Connecticut

To date, the Connecticut Superior Courts have been dismissing lawsuits brought by patients against healthcare providers when defendants argue that Executive Order 7 applies. EO7 provided immunity from liability to healthcare professionals, including hospitals and nursing

homes, from 03/10/20 through 03/01/21. The immunity applies to injury or death alleged to have been sustained while a healthcare professional was providing services in support of the state's COVID-19 response. The immunity does not apply to actions that were criminal, fraudulent, grossly negligent, malicious, or willful. The issue is currently before the Connecticut Appellate Court.

See, e.g., Mills v. Hartford Health Care Corp. dba Hartford Hospital, et al, Docket No. HHD-CV-20-6134761-S, 2021 WL ****** (Conn. Super. Ct. Sept. 27, 2021) (dismissal under immunity order holding that while hospital is waiting for COVID test results for symptomatic patient, immune from claim that there was a delay in transferring patient to cardiac cath lab) (*currently on appeal*)

But see, *Charles v. Riverside Health Care Center, Inc.*, et al, Docket No. HHD-CV-21-6142225S, 2022 WL ****** (Conn. Super. Ct. Feb. 15, 2022) (denying dismissal under EO7 to an employer based on an employee's claim that the facility was negligent and allowed her to contract COVID-19) (*currently on appeal*)

New York

New York Supreme Courts are split on whether the Emergency or Disaster Treatment Protection Act works to allow dismissal of lawsuits brought against healthcare providers. The EDTPA provided immunity from liability to healthcare professionals and facilities who treated COVID-19 patients, except for claims arising from gross negligence or reckless misconduct. This was in place from 03/07/20 through 04/06/2021, although facilities such as hospitals and nursing homes were excepted from immunities as of 08/03/20. This was a more narrow immunity than many other states. The issue is before the New York Appellate Division.

See, e.g., *Ruth v. Elderwood at Amherst*, Docket No. 804780/2021, 2021 WL ****** (NY Sup. Ct. Aug, 5, 2021) (dismissing suit on the grounds that the EDTPA applied against allegations of negligence when a patient at a nursing home contracted and died from Covid-19) (currently on appeal)

But see, *Robertson v. Humboldt House Rehabilitation & Nursing Center*, Docket No. 805232/2021, 2022 WL ****** (NY Sup. Ct. Mar. 14, 2022) (denying a motion to dismiss under the EDTPA because the defense did not establish that the patient's care from 3/23/20 – 04/19/20 was impacted by the nursing home's response to COVID-19)

California

California's State Judicial Council enacted Emergency Rule 9, which tolled statues of limitations from 04/06/2020 through 10/01/2020 for medical malpractice and wrongful death actions. While the intent of the Council remains unclear, CA practitioners are interpreting this to mean that any statute of limitations that partially ran during that period effectively had an additional

178 days added to it. For example, if a patient died from COVID on 04/07/2020, the normal statute for medical malpractice would have run after 1 year, or on 04/07/2021 and for wrongful death after 2 years, or on 04/07/2022. With Emergency Rule 9, a plaintiff would have had until 10/02/2021 to file for medical malpractice and will have until 10/02/2022 to file for wrongful death.

Additionally, California law existing prior to the pandemic specifies that hospitals and healthcare professions have no liability, absent willful act or omission, for any injury resulting from their services at the express or implied request of any state or local official or agency during a "state of emergency". Cal. Gov't. Code § 8659. On 03/04/2020, Governor Gavin Newsom declared such a health care emergency in light of the COVID-19 pandemic and, as a result, the statute may apply. The statute applies to hospital, physicians, pharmacists, nurses, respiratory care practitioners. On 01/27/2021, Governor Newsom issued executive order N-02-21, which expressly provides § 8659 immunity related to administration of COVID-19 vaccines. As of this writing, the COVID State of Emergency has been extended to 03/31/2022. We did not come across a case applying § 8659.

Louisiana

The Louisiana Health Emergency Powers Act, La. R.S. 29:760, et seq., has been in place since 2003. The Act expressly states that during a state of public health emergency, no healthcare provider shall be civilly liable for causing death or injury to any person or property except in the event of gross negligence or willful misconduct.

Under the Louisiana Health Emergency Powers Act, La. R.S. 29:771, healthcare providers are immune from negligence liability during a declared emergency. To prove medical malpractice which occurs during a declared state of emergency, La. R.S. 29:771.B(2)(c)(i) states that plaintiff must prove that his injury was caused by gross negligence or willful misconduct. In other words, plaintiff' s burden of proof is much higher than in a typical medical malpractice action.

In *Lejeune v. Steck*, 138 So.3d 1280 (La. App. 5th Cir. 2014), plaintiff sued for malpractice resulting from an uneventful surgery which occurred during a declared state of emergency after Hurricane Katrina stormed in 2005. The surgery was unrelated to the declared disaster. However, following the language of the statute, as the occurrence was within the period of declared emergency, the trial court found that the plaintiff failed to prove that a spine surgeon leaving a foreign body (i.e., sponge) in his patient during a surgical procedure in the aftermath of Hurricane Katrina rose to the level of gross negligence or willful misconduct to survive a summary judgment claim. The patient's claims were dismissed entirely prior to trial and the ruling was affirmed on appeal.

There is currently one challenge to the constitutionality of the breadth of the immunity, itself, and there are appellate circuit opinions differing as to how the revised standard applies to

Louisiana's administrative procedure of Medical Review Panels. It is anticipated that the Louisiana Supreme Court will entertain the issue of what standard of care is to be applied to medical review panels within the next year. Plaintiff's bar is challenging it for two reasons: first, the burden of proof for gross negligence is much higher, and they believe that medical professionals, who review the records during the administrative panel proceeding, are not qualified to make a legal determination of gross negligence, and if they were, the standard of gross negligence is not uniformly presented. Second, the constitutionality challenge is to the breadth of the immunity, itself. As written, Plaintiffs argue that it could apply to care not related to COVID19 or impacted as a result of COVID19, or to any act not even sounding in healthcare.

Florida

To date, Florida courts have not considered the impact of SB 72 on COVID-related cases. SB 72 provides immunity from liability to healthcare providers and facilities, with the exceptions of claims arising from gross negligence or willful misconduct, as long as said providers can demonstrate compliance with government health standards. This applies to all lawsuits filed subsequent to 03/29/2021, and the protection is extended through 06/01/2023. SB 72 also shortened the statute of limitations period to 1 year.

The panel would suggest watching the following cases currently pending in FL:

- *Estate of Burke v. Palace at Homestead, LLC, et al*, Docket No. 2022-000469-CA-01, pending in the Circuit Court of the 11th Judicial Circuit in Miami Dade County
- *Reisman v. AS Cooper City Lessee, LLC dba The Sheridan at Cooper City*, Docket No. 21-CV-61711, pending in the US District Court for the Southern District of Florida

Texas

To date, Texas courts have not examined the immunity law, enacted through SB 6. SB 6 provides civil immunity from liability to physicians, health care providers and first responders for treatment related to COVID-19. The defense must show that COVID-19 was the cause of the treatment rendered (or failed to be rendered) or that the plaintiff was infected with COVID-19 at the time. This also applies to health care services or decisions impacted by the pandemic, for example, allocating scarce PPE. SB 6 does not provide protections for claims arising from reckless conduct or intentional/willful/wanton misconduct. This remains in effect.

Substantive Discovery

If all efforts to avail your insured/client of PREP Act and state immunities have failed at the pre-answer stage and the case must proceed with substantive discovery, there are a few strategies we recommend the claims analyst and defense attorney use.

First, it is important to begin collecting documents and interviewing involved medical providers at the first whiff of a claim. Detailed documentation about the provider or facility's response to

the COVID-19 pandemic is vital to defense of the claim. Equally as important, preserving recollections of those people involved in fighting the pandemic should be done early and thoroughly – people tend to forget what those early days of COVID-19 were like, and being able to recreate the picture that the front line workers faced (no tests, no vaccines, a huge scarcity of PEE, a lack of understanding about how the virus spreads, etc.) for a judge or jury is crucial.

Along with that, you will want to ensure that a detailed timeline of guidance put forth by CMS and other federal, state and local agencies is created. The timelines should be at least daily, although we recommend looking at hourly guidance, as March and April 2020 saw changes in guidance very frequently. Pairing those actions the facility took alongside such a timeline can explain certain alleged deficiencies in their pandemic response. For example, in the very first days of the pandemic, whether masks were effective at slowing the spread of COVID-19 was a topic of much debate and on which much conflicting information existed. Being able to show that as soon as the facility was definitively directed to use masks for everyone, they did so, will be a great step in defense of the case.

Additionally, if the parties are forced to conduct discovery, defense counsel may want to consider asking the court to allow the parties to engage only in limited discovery for purposes of determining whether the PREP Act applies. This will allow for an early motion for summary judgment without placing the burden of full discovery on the parties.