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COVID-19 Health-Care Litigation: It's Big, It's Complex, and It's Going to Be With Us for the Long Haul

Sandra M. Cianflone*

Abstract: The human toll and widespread disruption of COVID-19 has triggered litigation in a number practice areas and industries. In this article the author discusses claims against aging services, hospitals, and other health-care providers, answering questions around what causes of action we are seeing, what we can expect, and some of the defenses available to providers. The author also discusses potential litigation surrounding the vaccine itself. Finally, she provides action that health-care providers can take immediately, before claims arise.

It seemed to happen overnight and many of us wondered if it would ever go away. It is possible it never will. In early 2020 the world was besieged by the novel coronavirus pandemic, ending the lives of many, damaging the health of many more, and disrupting the lives of the rest of us in ways big and small as it raced across continents.

Global, national, and local public health organizations and authorities scrambled to issue recommendations and advice based on the available science and knowledge at that time. And as soon as we incorporated that latest guidance into our daily routines, it would become obsolete as scientists gained a deeper understanding of how the coronavirus spread and the risks it posed to various subsets of the population. (Remember when we were supposed to quarantine our mail and Amazon packages for three days, and wipe down our groceries?)

As the pandemic raged on, these organizations and authorities emphasized an unprecedented need for health-care providers and facilities to make difficult decisions such as care prioritization, staffing changes, and purposeful allocation of personal protective

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equipment and diagnostic tests. Doctors, nurses, and other health-care providers had to wear the same N95 protective face mask for numerous patient visits across multiple shifts, which would have been unheard of before the pandemic.

Assisted living and aging-care facilities limited or halted visits from family members, and patients had to enter hospitals alone to limit exposure and spread of the virus.

It is in the context of these fast-changing situations and decisions made under unprecedented strain on our health-care system that COVID-19 litigation lies.

By some estimates, more than 15,000 lawsuits have been filed related to COVID-19, with approximately 350 filings directed toward the health and medicine communities.[1]

Aging-Services Claims

The majority of the claims we are seeing so far are primarily being filed against the aging-services community, although there is certainly no shortage of claims against hospitals, individual medical providers, airlines, cruise lines, and insurance companies.

The claims against the aging-services community are mostly based on the facility's infection-control protocols and staffing procedures at the time. These claims are typically wrongful death claims due to a loved one contracting COVID-19 while they were a resident at the facility or injuries as a result of a health-care provider's limitation of the types of procedures being performed.

We are also seeing claims against facilities for allowing health-care providers to provide direct patient care versus telemedicine, and we have also seen claims for the opposite scenario when the facility chose to provide care via telemedicine. These claims are typically pled in the general sense to avoid the litany of state and federal immunities and defenses available to these communities.

Claims Related to COVID-19 Treatment

The next largest subset of claims are those against hospitals and health-care providers for providing care and treatment directly to COVID-19 patients. These claims arise out of complications that occurred as a result of the specific treatment

rendered, such as intubation or off-label use of other vaccines and therapeutics.

Recently, we have also seen claims arising from delays in treatment due to public health organization recommendations regarding the prioritization of medical procedures. For example, rescheduling laparoscopic meniscal tear repairs with further development of the tear.

The other type of claims we are seeing filed at this juncture are within the employment context. These claims have been premised on wrongful termination/reduction in force, failure to notify of COBRA benefits, workers' compensation, and other employment related matters.

Another factor is that the statute of limitations may be approaching on many of these claims, depending on the state in which they are filed.

The Next Wave: Vaccine Litigation

The next wave of litigation that we anticipate will surround vaccinations. We expect there to be a wide variety of claims by plaintiffs' attorneys in the hopes that something "sticks" and is successful.

Vaccination lawsuits will probably focus on factors such as how and when the vaccine was administered, availability of the vaccine (or lack thereof), scheduling of second doses, conditions at the vaccination site (i.e., whether people had to wait outside in the heat in long lines), whether employers provided shot clinics, etc.

We expect to see vaccine lawsuits filed in the same sectors pertaining to similar issues as the core COVID-19 complaints—aging services, hospitals, health-care providers, and employment matters.

Defenses for COVID-19 Lawsuits

Virtually every organization and individual in the health-care industry is preparing to defend against coronavirus lawsuits, and there are some important defenses available for these claims.

Here is an overview of the most common defenses that we will likely see in the coming months and years as these cases make their way through the judicial system.

The Public Readiness and Emergency Preparedness Act

By way of background, the PREP Act was first enacted on December 30, 2005, as Public Law 109-148, Division C, Section 2. It amended the Public Health Service Act, adding Section 319F-3, which addresses liability immunity, and Section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively.

Originally, the PREP Act was intended to protect vaccine manufacturers from financial risk in the event of a federally declared public health emergency. As such, the PREP Act was specifically designed to encourage the rapid production of vaccines to protect American citizens in the case of a potential public health threat. COVID-19 was not the first time that the PREP Act was invoked. Declarations under the PREP Act were issued during the avian flu outbreak, H1N1 pandemic, and Ebola virus. The PREP Act protections in these instances were focused on their respective vaccines.

The PREP Act provides broad immunity from suit and liability to any "covered person" with respect to all "claims for loss arising out of, relating to, or resulting from" the "administration" or "use" of a "covered countermeasure" if a declaration has been issued with respect to that countermeasure.[2] The PREP Act states:

> [A] covered person *shall be immune from suit and liability* under Federal and State law with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.[3]

"Loss" is broadly defined as "any type of loss," including death, physical injury, mental injury, emotional injury, fear, property loss and damage, and business interruption loss.[4] Moreover, the immunity applies to any claim "that has a causal relationship with the administration to or use by an individual of a covered countermeasure."[5]

The powers and protections of the PREP Act lie dormant in the United States Code until the Secretary for HHS issues a Declaration

identifying the scope and applicability of the Act in response to a unique public health emergency.[6]

In this case, on March 10, 2020, the Secretary of Health and Human Services (HHS) issued the implementing Declaration, invoking PREP Act immunity for "recommended activities" undertaken in response to the COVID-19 pandemic from February 4, 2020, through October 1, 2024.[7]

Since its initial publication, the Declaration has been amended seven times, both expanding the scope of immunity, and clarifying and emphasizing that the PREP Act is a complete preemption statute.

The far-reaching coverage and implications of the COVID-19 PREP Act Declaration and amendments are enormous enough to write volumes of legal literature and dozens of law review articles.

For the purposes of brevity for this article, a short discussion of the terms and elements of PREP immunity are sufficient.

Understanding "Covered Persons"

"Covered Persons" under the PREP Act include manufactures, distributors, program planners, qualified persons and their official agents, and employees who prescribe or use covered countermeasures. The Declaration specifically states that immunity being conveyed is specifically to manufacturers distributors, program planners, and qualified persons.

Of the more ambiguous "Covered Persons" listed above, "program planners" include those who supervise or administer a program dealing with covered countermeasures and includes those people who establish requirements, provide policy guidance, or supply technical or scientific advice or assistance for a facility to administer or use a covered countermeasure.

A "qualified person" includes a licensed health professional or other individual authorized to prescribe, administer, or dispense covered countermeasures under the law of the state in which the covered countermeasure was prescribed, administered, or dispensed.

Additional entities would fall under a "Covered Person," as the PREP Act defines a person as "an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state or local government agency or department."

"Covered Countermeasures"

A "covered countermeasure" as it relates to this declaration must be a "qualified pandemic or epidemic product"; a "security countermeasure"; or a drug, biological product, or device authorized for emergency use.

As is relevant to this analysis based on the claims we are seeing now and anticipate later, "a qualified pandemic or epidemic product" includes any drug or device specifically manufactured, used, or designed to treat or cure a pandemic/epidemic or to limit the harm the same would otherwise cause. This would also include any drug or device used to treat a serious or life-threatening disease or condition caused by the pandemic, or one intended to enhance the efficacy of a drug, biological product, or device.

Note that a covered countermeasure must be approved or cleared by the Food, Drug and Cosmetics (FD&C) Act, licensed under the Public Health Services Act or authorized for emergency use under the FD&C. We have already seen this in the context of PPE, respiratory devices, and the three available vaccines in the United States.[8]

A product may also qualify as a covered countermeasure if it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption defined by the FD&C. Drugs/devices in this category are those that are presently the focus of research conducted to prevent COVID-19 at this time.

To this end, a provider will likely have to seek approval prior to administration of investigational countermeasures, such as COVID-19 vaccines.

"Recommended Activities"

"Recommended Activities" are those that are authorized in accordance with the public health and medical response of the federal, state or local authorities to prescribe, administer, deliver, distribute, or dispense the covered countermeasures following a Declaration of an emergency.

"Administration" is not defined by the PREP Act, but has been defined by the Secretary as:

> Physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and

> private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purposes of distributing and dispensing countermeasures.

Examples of "Administration" provided in the Declaration include physically providing a vaccine or handing drugs to a patient, and decisions or actions involving security and queuing as they relate to countermeasure activities.

Courts must dismiss claims brought against covered entities for any loss relating to "any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure."

The act also expressly preempts any state law that "is different from, or is in conflict with, any requirement" established regarding the covered countermeasures. The Declaration states that it is the specific intent of the Secretary to preclude liability claims such as allegations of negligence by a manufacturer in creating a vaccine or negligence by a health-care provider in prescribing the wrong dose.

The Declaration goes as far to state that liability claims such as slip-and-fall injuries or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location are precluded as they would relate to the management and operation of a countermeasure distribution program or site. However, if the claim is not directly related to a countermeasure activity, which we anticipate will be a point of dispute in any future litigation, no immunity would apply.

Causal Nexus to a Covered Countermeasure

As with any negligence claim, there must be a causal link between the covered countermeasure, the "recommended activity," and the injury at issue.

The most basic example of this would be someone suffering a bodily injury from a COVID-19 vaccine or from complications of COVID-19 treatments. Based on guidance provided by HHS, immunity would extend to the decision-making process for purposes of allocating and administering PPE in the context of an infection-control program. We see the latter arise when there

are claims that a patient/resident contracted COVID-19 within a facility during the height of the pandemic when there were PPE shortages.

As with each aspect of PREP immunity, a determination should be made at the earliest stages of litigation as to whether there is a causal relationship between the loss asserted and the covered countermeasures being used or administered. In some circumstances, this may require additional information and potentially limited discovery for purposes of asserting suit immunity.

Exceptions and Remedies for the Injured

The Declaration notes that individuals who sustain a "serious injury" or die as a result of the administration of a covered countermeasure are eligible to receive benefits from the Countermeasures Injury Compensation Program (CICP). In order to obtain these benefits, the individual is required to show "direct causation" between the covered countermeasure and a serious physical injury with compelling, reliable, valid, medical, and scientific evidence.

Notably, the immunity conveyed under the PREP Act, and which has been preserved pursuant to the COVID-19 Declaration, does not extend to willful conduct. "Willful Conduct" is defined as an act or omission that is 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. In these instances, the PREP Act designates the Federal District Court for the District of Columbia as the proper venue for these claims to be heard.

State-Based Immunity and Defenses Available

At the time this article was written, thirty-seven states passed some executive or legislative action providing defendants with immunity or an affirmative defense to liability. Although each state will be different, there are some common features to look for:

- When is the immunity/defense effective? Generally, the provisions will be effective as of the date of the local emergency declaration.

- What does it apply to? Does it apply to direct COVID-19 treatment or preventative measures taken?
- Is the immunity/defense conditional to compliance with state or federal guidance? Often the provision will not address the impact of different or conflicting guidance. It will also not distinguish between "strict" or "substantial" compliance. These are likely where the applicability issues will be litigated.
- Who does the immunity/defense apply to? Is it "health-care providers" or "health-care facilities"? How are these terms defined and distinguished within the provisions?
- Nearly all of the state immunity provisions will provide exceptions for "gross negligence" or "recklessness."

As more states join in the effort to protect health-care providers for COVID-19 claims, we anticipate that plaintiffs will attempt to circumvent the immunities and defenses provided to couch their claims as non-COVID related. Be aware of this tactic, but do not be afraid to assert the defenses available at the earliest stage in litigation.

Steps Health-Care Providers and Risk Managers Can Take Now

As vaccines roll out across the country, the most important thing providers can do now is document everything.

Work with managers to encourage training to address documentation with language that is contemporaneous with the period of the COVID-19 pandemic to help give context in the future of what treatment was being provided, even if it was not COVID-19 treatment. Essentially, we would use this to demonstrate the positive steps taken to meet what will eventually be established as the "crisis standard of care."

Documentation is not limited to adopting standard chart verbiage across every medical record, but it also includes compiling documentation. When a provider becomes aware of a potential claim, start to build a time line. In this time line, incorporate any anchoring events, waivers, patient consent, federal/state guidance, policy changes, and communications to the community and patients (written as well as verbal). This document will be the factual framework to guide the defense.

The next step is to start identifying witnesses. This is especially true for purposes of having designated individuals to authenticate documents. Taking the time now to identify these witnesses will allow attorneys to begin to prepare them for their role in the litigation. This is also true for department heads and corporate representatives. This approach to witnesses will save time and preserve memories should the matter proceed into the discovery phase.

In the same vein, take the time to foster experts. Begin identifying individuals across all practice areas (e.g., nursing home administration, public health policy, infectious disease, epidemiology) who have studied and have direct experience with COVID-19 care, treatment, and safety administration. These experts should be able to chronicle the standard of care so they can provide affidavits to support summary judgment motions and testimony at the time of trial.

Lastly, it is important to retain specialty counsel who have been involved with COVID-19 litigation across the country and have already been well versed in the intricacies of available defenses and complicated motion practice surrounding these claims.

Attorneys who are experienced in defending COVID-19 litigation will likely have pleadings, discovery, and briefs that may be applicable to the claim. They will also be more educated in federal and state-specific immunities, and can provide an efficient and cost-effective claims investigation process.

Notes

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1. https://www.huntonak.com/en/covid-19-tracker.html.
2. 42 U.S.C. § 247d-6d(a)(1).
3. 42 U.S.C. § 247d-6d(b)(1) (emphasis added).
4. Id. § 247d-6d(a)(2)(A).
5. Id. § 247d-6d(a)(2)(B).
6. See § 247d-6d(b).

7. Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 85 Fed. Reg. 7872 (Feb. 2, 2021, *corrected* Feb. 22, 2021), and 86 Fed. Reg. 9516 (Feb. 16, 2021, *corrected* Feb. 21, 2021) ("the Declaration").

8. U.S. Food and Drug Administration, *Coronavirus Disease 2019 (COVID-19) EUA Information*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas.