Immunity and Liability During and After COVID-19

I. Introduction

Who would have thought the last time we were together in Arizona in March 2020, that a worldwide pandemic would set-in requiring people to shelter in place, businesses to close and everyone to wear a mask. In the midst of all the craziness, our clients faced incredible challenges in meeting healthcare needs while at the same time keeping up with the ever-changing regulatory language, guidance and requirements. It has been a daunting if not an impossible task to stay current. Therefore, it is understandable that those front-line workers would be looking for some protection from lawsuits that will certainly be filed based on the COVID-19 pandemic.

As of the writing of this paper, there have been more than 10,000 lawsuits filed involving COVID-19 according to one law firm's "COVID-19 Complaint Tracker."[1] The cases range from contract disputes related to event cancellations, civil rights claims regarding safer at home orders, and the right to visit a loved one in a nursing home.[2] Not surprisingly, the majority of cases appear to involve insurance coverage, i.e business interruption.

Expecting more lawsuits to come, many states' lawmakers began discussing and considering the potential for immunity for businesses and health care providers as early as March 2020. There was even some discussion that the US Congress might take action, but those provisions hit the cutting room floor during negotiations on the relief bill.[3] For both state and federal immunity provisions, the stated goal has been to provide immunity to help businesses

[1] https://www.huntonak.com/en/covid-19-tracker.html
[2] *Id.*
[3] https://www.cnbc.com/2020/12/08/coronavirus-stimulus-update-checks-liability-among-relief-disagreements.html

remain open or reopen without the fear of being sued and allow health care providers to focus on care.

This presentation will focus on what immunity might be available, how it will apply and challenges to invoking it.

II. Federal law - PREP Act

The Public Readiness and Emergency Preparedness Act ("PREP Act") is a federal law enacted in 2005, in part as a response to the terrorist attacks of 9/11.[4] According to the Congressional Research Service, the PREP Act was intended to "encourage expeditious development and deployment of medical countermeasures during a public health emergency."[5] It is triggered when the Secretary of Health and Human Services ("HHS") invokes the Act in response to a public health emergency ("PHE").

Under the Act, a "covered person shall be immune from suit and liability under Federal and State law with respect to all 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" is made by the Secretary of HHS. The PREP Act covers "administration of medical countermeasures such as diagnostics, treatments, and vaccines."[6]

The types of losses covered include death, physical, mental or emotional injury; fear of physical, mental or emotional injury, including the need for medical monitoring, as well as loss of damage to property, including business interruption.[7] This encompasses a wide-range of possible claims that could be asserted against covered persons. So who is a covered person? A covered

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[4] Immunity for Immunizations, Lincoln Mayer, Stanford Law Review (2007) Volume 59, Issue 6, p. 1753-1789.
[5] *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures, CRS, Version 13, Updated December 21, 2020.*
[6] 42 USC 247d-6d(a)(1).
[7] 42 USC 247d-6d(a)(2)(A).

person includes (1) the United States; (2) manufacturers and distributors of covered countermeasures; (3) "program planners"; and (4) qualified persons who "prescribe, administer, or dispense covered countermeasures."[8] Healthcare providers fall under the definition of "qualified persons," which includes licensed health professionals or other individuals authorized to prescribe, administer or dispense covered countermeasures.

If a covered person using a covered countermeasure is entitled to immunity, the next analysis is, what is a covered countermeasure? The term is defined in the Act as (1) a qualified pandemic or epidemic product; (2) a security countermeasure; (3) a drug, biological product, or device that is authorized for emergency use; or (4) a respiratory protective device approved by NIOSH that the Secretary determines to be a priority during the PHE. The last countermeasure was added to the PREP ACT by the Families First Coronavirus Response Act and the Coronavirus Aid, Relief and Economic Security Act (CARES Act).

There is a willful misconduct exception to immunity as well as a compensation fund for individuals who believe they have been injured by a covered countermeasure. The compensation fund is available to individuals (or their representatives) who die or suffer serious injuries. Serious injury is defined as an injury that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.[9]

Application of PREP Act to COVID-19

On January 31, 2020, the Secretary of HHS declared a public health emergency and invoked the PREP Act. A PHE lasts until the Secretary deems it over or 90 days, whichever occurs

[8] 42 USC 247d-6d.
[9] 42 USC 247d-6d(i)(10).

first. The PHE related to COVID-19 was most recently extended by HHS on April 21, 2021.[10] It is expected that the current PHE will be extended through the end of 2021. Therefore, the PREP Act has application for the use of countermeasures associated with COVID-19.

As stated above, the PREP Act states that it provides immunity from liability under federal and state law, which on its face might sound like any alleged wrongful conduct "caused by, arising out of, relating to" the covered countermeasure would be preempted by the PREP Act. In fact, the PREP Act discusses preemption stating:

> no State or political subdivision of a State may establish, enforce or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that – (A) is different or is in conflict with any requirement applicable under this section and (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure…[11]

Consequently, it was anticipated that when an entity was sued related to COVID-19, the defendant would assert the PREP Act and remove the case to federal court for application of the federal law. This has happened but not with the outcome we had expected or hoped for.

In the cases filed to date, defendants have attempted to remove cases involving COVID-19 to federal court based on preemption of state law by the PREP Act, but in a majority of those, the federal courts have remanded the cases back to state court. The district courts remanding have

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[10] https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-15April2021.aspx

[11] 42 USC 247d-6d(b)(8).

found that the PREP Act may apply to the causes of action but the Act does not provide for federal jurisdiction. Some of these federal courts stated that just because federal jurisdiction did not exist did not mean there is not immunity under the PREP Act; while other district courts have stated, in dicta, that the causes of action alleged by the plaintiff are not covered by the PREP Act.[12]

In the *Estate of Maglioli v. Andover Subacute Rehabilitation Center*, the plaintiffs brought state claims for negligence the defendants removed the case that made allegations based on state law for negligence, wrongful death and medical malpractice against nursing facilities.[13] The removal was based on 28 USC 1441 and 1442 under preemption by the PREP Act and that the defendants were entitled to a federal forum as "federal officers." According to defendants, they were entitled to assert the PREP Act because the actions they took were in response to COVID-19 and involved decisions on who to use/administer countermeasures, such as personal protective equipment.

The plaintiff's allegations were that the nursing facilities and their owners failed to exercise "due care with respect to coronavirus infections." The plaintiff moved to remand the case. The New Jersey federal district court remanded the case stating that "the PREP Act does not so occupy the field as to squeeze out state court jurisdiction over what are state-law claims of negligence and require exclusive federal forum." The judge also noted that many of the allegations did not involve the use of "countermeasures" such as social distancing and quarantining and that these allegations would be covered by state law acts of negligence. He did at least note that the state court could apply the PREP Act to "this or that claim" so the door remains open if the state court is willing to do so.[14]

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[12] E.g. Block v. Big Blue Healthcare, Inc., 2020 WL 4815076 (Kan. D.C. 2020).
[13] *Estate of Maglioli v. Andover Subacute Rehabilitation Center I*, 2020 WL 4671091 (N.J. D.C. 2020).
[14] Id. at 11.

In a similar case filed in California, defendants removed a case against a nursing facility alleging elder abuse, negligence, wrongful death and fraud on the basis that the defendants were acting as federal officers in carrying out directives of the Centers for Medicare and Medicaid Services and the Center for Disease Control and Prevention to address the pandemic caused by COVID.[15] Additionally, defendants asserted the PREP Act as federal question grounds for removal. The plaintiffs moved to remand the case back to state court. The district court remanded finding no basis for removal as federal officer because the defendants were acting in response to "general regulations and public directives" and that there was no complete preemption under federal question jurisdiction. The court's order did not opine on whether the state court could find application of the PREP Act to the allegations by plaintiff.

III. *State law*

Although there may be some immunity protections afforded under the PREP Act for the use of "countermeasures," there will certainly be allegations that do not involve a countermeasure. In those instances, defendants will need to look to their state laws for some type of immunity. When many states were looking to reopen, several took action by way of a governor's executive order or by passing legislation. The intent was to allow businesses to resume operations without the fear of litigation or allow health care providers to provide services without the same fears, but the types of cases that each business entity or healthcare provider may face could look different post-COVID.

Types of cases

It may seem obvious that the plaintiffs' bar will assert wrongful death and negligence causes of action related to contracting and exposure to COVID-19, but there will likely be other

[15] *Martin v. Serrano Post Acute LLC*, 2020 WL 5422949 (C.D. Cal. 2020).

types of cases that might warrant further examination if immunity exists at the state level. For a healthcare provider, examination of the immunity statutes will be necessary to determine if a malpractice claim is asserted that does not directly relate to exposure. As with the PREP Act, a state immunity statute may cover claims related to a healthcare provider's lack of resources, like staff. If a nursing home provider is sued for a pressure injury that developed during the PHE, is the state's immunity statute broad enough to allow the facility to assert the liability protections. But for COVID, the facility would have had sufficient staff to ensure every resident was turned and repositioned in a timely manner or a failure to document turning and repositioning was a result of insufficient staff due to COVID.

Vaccine administration is likely to also become an issue. The PREP Act would most likely cover those types of claims but the state immunity provisions may also provide cover to those administering the vaccine. However, in some cases, the facility may not be the administrator of the vaccine. In long term care facilities, there was typically a third party entity that would hold a clinic at the facility and administer the vaccine to staff and residents. Could the facility be sued for arranging for the administration, and if so, would it be a covered person under the PREP Act? To be safe, asserting the state immunity would be wise to ensure protection.

Some state immunity provisions exclude workers compensation claims, likely because the state's workers compensation regime provides the exclusive remedy. In those cases, any employee who asserts a claim against an employer would either be covered under Workers' Compensation or if the complaint attempts to skirt Workers' Comp by alleging the exposure was not work related, the defendant should seek to rely on the immunity provisions.

One way in which a healthcare employee might try to avoid the Workers' Comp scheme is to assert a premises liability type claim. Even in states without specific healthcare provider

protections, most have protections for businesses who are sued by a patron who enters the business and alleges exposure or contraction of the virus. These types of claims might also be asserted by visitors of healthcare facilities.

Will the elements of the action be different?

In medical malpractice cases, the plaintiff must prove a breach in the standard of care. The level of care is usually the reasonable person standard. In COVID-19, there may be some argument as to what the reasonable standard is. In fact, some states may have implemented an alternate standard of care by way of an executive order or invocation of the state's emergency management act. For example, in Alabama, as part of the governor's executive order, she stated that alternate standards of care applied for those entities initiating their disaster preparedness plan.

The allegations may also dictate what the standard of care will be. For malpractice claims related to exposure, an infection preventionist or an infectious disease expert might be an expert to speak to the standard of care. Certainly, causation will present its challenges to plaintiffs as well.

As for damages, it will be important to understand whether the immunity statutes limit damages in some way. If able to proceed against the defendant, the plaintiff may only be entitled to economic damages.

Is there immunity?

Most if not all of the immunity statutes and executive orders limit the scope of immunity by excluding conduct that is willful, wanton, malicious or intentional. The burden for establishing these exceptions is generally placed on the plaintiff, and some provisions require the plaintiff prove the actions rise to this level by clear and convincing evidence. In proving such conduct, it may require an analysis of whether the entity was abiding by applicable federal, state and local

guidelines. Making matters more complex, there were times when those authorities may have had differing guidance and at times conflicting guidance. Therefore, it will be important to pinpoint when the act or omission occurred and what the guidance was at the time.

Timing is important for other reasons too. Is the immunity statute the defendant is seeking to invoke applicable to when the act or omission occurred? The statutes may be retroactive to March 2020 or may only apply to causes of action filed after the effective date. For any cause action filed prior to the passage of the legislation, the statute face constitutional hurdles if it seeks to deny that claimant its cause of action.

State by state review[16]

State	Executive Order	Legislation	Health Care/Other	Notes
Alabama	Yes	Yes SB30	Health Care and Businesses	No immunity if clear and convincing evidence of willful, wanton or intentional misconduct Retroactive to March 2020
Alaska		Pending HB4 (introduced 1/8/21)	Occupational licensees and businesses	Does not apply to gross negligence, recklessness or intentional misconduct Not retroactive to start of pandemic
Arizona	Yes	Yes SB1377	Persons acting in good faith/health care professionals and institutions	Excludes actions of willful misconduct or gross negligence Retroactive to March 2020
Arkansas	Yes	Proposed but		

[16] As of April 28, 2021.

	Effective June 15, 2020 through PHE	withdrawn (SB17)		
California		Pending bill	Post-secondary educational institutions and institutions of higher education	Does not provide any protection for healthcare providers
Colorado		Pending SB21-080		May provide some protection for allegations related to contracting COVID-19 on premises
Connecticut	Yes, Executive Order No. 7V	Pending HB5125	Profit and non-profit entities	Limited to exposure or transmission of COVID-19 on premises
Delaware	Public Health Order	None		
Florida		Pending SB72 SB74	Business entities Healthcare providers	
Georgia		Yes	Businesses and health care providers – extending into 2022 is pending Governor's signature	Georgia COVID-19 Pandemic Business Safety Act in 2020; 2021 legislation would extend the protections into 2022
Hawaii				
Idaho		Yes		
Illinois	Yes	Yes (proposed but did not pass in 2020)		EO- Providing services in response to COVID-19; does not cover gross negligence or willful misconduct
Indiana		Yes	Business/organization	Premises immunity passed Healthcare legislation pending
Iowa		Yes		
Kansas		Yes		

Kentucky		Yes	Healthcare provider	Good faith actions while rendering care or treatment of COVID patient
Louisiana		Yes		
Maine	No	No		
Maryland		Good Samaritan	Healthcare provider	Existed pre-COVID; healthcare provider acting in good faith during a catastrophic health emergency proclamation
Massachusetts	Yes – PREP Act expansion	Yes?		
Michigan	Yes, reversed by Michigan Supreme Court	Yes	Employers and businesses	Complying with federal, state and local safety laws
Minnesota		Pending HB688 SB512	HB- premises owners SB – healthcare	
Mississippi	Yes	Yes		No immunity for malice, reckless disregard or willful misconduct
Missouri		Yes SB1	Health care providers and premises owners	Immunity does not apply if clear and convincing of malicious conduct that intentionally damage plaintiff
Montana		Yes		Affirmative defense; exposure to COVID-19; must follow public health guidelines
Nebraska		Pending legislation LB52		
Nevada		Yes		
New Hampshire		Pending SB63		
New Jersey		Yes	Health care providers	

New Mexico	Yes			Uniform Emergency Volunteer Health Practitioners Act – out of state providing gratuitous care
New York		Yes		Governor amended to remove some protections
North Carolina		Yes		Insulates emergency management workers from civil liability
North Dakota		Pending HB1175	Employers – including healthcare employers	Retroactive No intentional conduct
Ohio		Yes		
Oklahoma		Yes		
Oregon		Yes	Schools only	
Pennsylvania	Yes			
Rhode Island	Yes			EO – extends immunity to health care workers acting as disaster response workers
South Carolina		Pending Senate passed	Businesses	Adhering to public health guidance
South Dakota		Pending HB1046	Business, healthcare providers and manufacturers and distributors of PPE	No intentional conduct
Tennessee		Yes	Healthcare providers, businesses and schools	No application to claims proven by clear and convincing evidence of willful misconduct or gross negligence
Texas		Pending HB2782 HB4481 HB3659		
Utah		Yes		
Vermont	Yes			
Virginia	Yes	Yes		
Washington	No	No		
West Virginia		Yes		Related to COVID-19; no willful wanton acts
Wisconsin		Yes		

Wyoming		Yes		Immunity for acting in good faith following instructions from state health officer; does not apply to willful or wanton conduct or gross negligence

Useful resources:
https://web.csg.org/covid19/executive-orders/

https://www.huschblackwell.com/newsandinsights/50-state-update-on-covid-19-business-liability-protections