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Health Care Provider Liability During the COVID-19 Pandemic: Ways to Ensure **Protection**

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April 7, 2020

Across the country, hospitals and providers are preparing to receive an unprecedented surge of patients afflicted with coronavirus symptoms – all while continuing to care for patients with other medical conditions necessitating inpatient care. The federal government and many state governments have loosened a number of licensing, credentialing, and point-of-care restrictions that were designed to ensure the highest quality of care during ordinary times. Whether it is relaxation or waiver of licensing requirements, area of practice restrictions, the use of retired or "volunteer" health care providers, the deployment of medical students close to graduation, the "sharing" of ventilators, or repurposing of beds and units never intended for ICU care, the common theme for health care providers now is expanding capacity to handle possibly overwhelming caseloads.

These health care providers are justifiably being hailed as heroes. But even heroes are entitled to worry about not only their physical health and well-being, but also about legal liability. Fortunately, state and federal governments have the power and ability to limit the liability exposure faced by providers. The federal government has provided important but limited immunities to frontline health care providers. State governments have been inconsistent in their grants of immunity; some have done so, and others may follow.

This Alert explores the authority and efforts of the federal government, as well as of various state governments, to limit the scope of potential liability of health care providers resulting from the care of patients during this period of crisis. Some of these limits and immunities exist in long-standing statutes and regulations that are applicable to the present emergency. Others have been put in place recently in direct response to the COVID-19 crisis. Providers need to be aware of all of them, and they also need to take practical steps to protect themselves against future liability claims.1

Malpractice Liability Limits and Immunities

1. The Coronavirus Aid, Relief, and Economic Security (CARES) Act

On Friday, March 27, 2020, President Donald J. Trump signed into law the CARES Act, which included provisions that can potentially limit or immunize specific health care providers from liability during the COVID-19 pandemic.

Section 3215 establishes a specific limitation on liability for "volunteer" health care providers during the COVID-19 emergency declaration. With certain exceptions, it provides that such providers "shall not be liable under Federal or State law for any harm caused by an act or omission of the professional in the provision of health care services" during the COVID-19 public health emergency. In addition to volunteer status, the services being rendered must be within the scope of the provider's license (including applicable state law emergency expansions of scope of practice). Providers are not protected from liability for harm resulting from the provider's willful or criminal misconduct, gross negligence, reckless misconduct, or "conscious flagrant indifference" to the patient's rights or safety. Further, providers are not protected from claims resulting from care given while the provider is under the influence of drugs or alcohol.

2. The Public Readiness and Emergency Preparedness (PREP) Act Declaration

The CARES Act provision outlined above protects only "volunteers." Another important federal immunity protection associated with treatment offered to COVID-19 patients is found in the 2005 Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. 247d-6d. This Act empowers the Secretary of Health and Human Services (HHS), through written Declaration, to provide that a "covered person," including a qualified person who prescribes, administers, or dispenses "pandemic countermeasures," "shall be immune from suit and liability under Federal and State law with respect to all claims for loss covered by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" during a declared disease-related public health emergency.

Countermeasures under the PREP Act are defined as "qualified pandemic or epidemic products," which generally include FDA-approved drugs, devices, and biological products that are "manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause," as well as other "drugs, biologic products, or devices authorized for investigational or emergency use." Section 3103 of the CARES Act extended this protection to entities and persons who manufacture, test, distribute, prescribe, or administer "respiratory protective devices," such as the N95 mask, during the public health crisis period.

On February 4, 2020,² a Declaration from the Secretary providing a basis for the invocation of immunity described in the PREP Act became effective. The Declaration provides "liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving 'willful misconduct' as defined in the PREP Act." It specifically states, however, that, "[i]n each case, whether immunity is applicable will depend on the particular facts and circumstances."

The PREP Act provides an administrative claims process against the federal government for injuries caused by "countermeasures" covered under the Act, but it leaves open the possibility of personal liability for claims of "willful misconduct." The burden of proof is on the plaintiff to demonstrate willful misconduct by "clear and convincing evidence." Importantly, however, just as the CARES Act protects only a limited group of providers – volunteers – the immunity provided under the PREP Act is only for activities involving "countermeasures;" garden variety claims of negligence not having anything to do with such countermeasures, including treatment involving patients who do not have COVID-19 symptoms, are not protected.

3. State-Specific Provisions That Limit or Immunize Providers From Liability

Health care providers should also look to state-specific laws, executive orders, and provisions to determine if additional protections might be available. In Virginia, for example, a state statute applicable to "disasters" provides liability protection to health care providers during state or local emergencies, where the exigencies of the emergency "render[] the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency..."³ The immunity, however, is inapplicable to cases involving gross negligence or willful misconduct. In Tennessee, the Governor is empowered to declare through executive order "limited liability protection to health care providers, including hospitals and community mental health centers" providing care to "victims" of an emergency.^{4, 5} Once again, however, the immunity is inapplicable to claims found to involve gross negligence or willful misconduct.

Click here to view a chart that summarizes those provisions for the states and jurisdictions in which Baker Donelson has offices, including Alabama, Florida, Georgia, Louisiana, Maryland, Mississippi, South Carolina, Tennessee, Texas, Virginia and Washington, D.C. If additional information is sought for states not discussed herein, please contact the authors of this Alert.

4. Additional Avenues of Possible Grants of Immunity

On March 24, 2020, HHS Secretary Alexander Azar sent a letter to all state governors which included the following statements relevant to liability immunity for care provided during the COVID-19 emergency: "For health care professionals to feel comfortable serving in expanded capacities on the frontlines of the COVID-19 emergency, it is imperative that they feel shielded from medical tort liability." The letter recommended that "[s]tates should issue guidance summarizing the statutory scope of protections offered under their laws and the process necessary to attach those protections to a health professional's service." Secretary Azar noted that "[i]t is particularly important for states to issue guidance publicly, outlining the available liability protections during the COVID-19 emergency" and he stated, "I do not want state variations in liability protections to confuse or deter health professionals in this COVID-19 emergency. I ask that your office quickly develop a list of the relevant state liability protections and waivers for health professionals during a national or state emergency." Based on this directive, we anticipate that states will soon be promulgating guidance regarding malpractice liability limits and immunities for care provided during the COVID-19 pandemic.

On March 30, 2020, Senator Ben Sasse (R-Nebraska) introduced a Bill that would grant broad legal immunities to health care providers who provide treatment outside of their specialties to COVID-19 patients during the national health emergency. The intent of the proposed legislation is to immunize health care providers from federal, state, and local liability for testing or treating coronavirus patients with the use of a medical device for an unapproved purpose, for practicing outside their specialty under the instruction of a provider within such specialty, or for providing care outside of a standard health care facility. According to Senator Sasse's statement on this issue, "In ERs and ICUs across America, doctors and nurses are writing the playbook as they fight this virus one day at a time. These heroes need a common-sense liability shield so that they don't have to worry about lawsuits while they're scrambling to save lives. ... Congress needs to make sure that phase four legislation protects our doctors and nurses from a plague of lawsuits."

Protecting Against Future Liability Claims

None of the federal or state law immunities described in this Alert provide "absolute" immunity from legal claims against health care providers. Absolute immunity provisions for providers are rare, and they are generally confined to claims made against federal and state employees and contractors.

Terms such as "gross negligence" and "willful misconduct" are not absolute; they depend, as the federal declaration expanding the scope of the PREP Act noted, on "the facts and circumstances" of individual cases. While health care providers might ultimately be entitled to immunity under applicable laws, and would very likely be vindicated if a claim alleging "gross negligence" relating to the care of a COVID-19 patient went to trial, they would still need to defend themselves in court if a plaintiff alleged the applicability of one of the "exceptions" to immunity status. A court would then have to decide whether a fact issue existed on the allegations so as to permit the action to proceed further.

With the exception of the CARES Act protections for volunteers, none of the immunities enacted into law referenced in this Alert would protect a provider from a claim that the provider neglected the proper care and treatment of a non-COVID-19 patient. The Bill sponsored by Senator Sasse would plug a gaping hole in liability protections for health care providers during this crisis. There will be a lot of these patients and the circumstances involving their care during a COVID-19 patient surge will be challenging. Some states are already taking similar actions to immunize providers caring for non-COVID-19 patients. For instance, legislation in New York State, which was enacted on April 2, 2020, includes broad language, at Section 3082, that appears to establish protections for providers caring for all patients during the public health emergency, including non-COVID-19 patients.

There are practical steps providers can take to protect themselves from liability claims. Providers, particularly those who may be granted a special certification to work across state lines or those who may be asked to care for patients outside of their core competencies, should make sure they are properly protected by malpractice insurance coverage. Providers who are considering volunteering their services during the COVID-19 pandemic do not have absolute liability protection. They should check with the insurance company they previously had coverage with, as some carriers are offering coverage at no cost for physicians returning to practice as volunteers during the emergency timeframe. Hospitals and other health care entities will also want to ensure that the providers working in their facilities have proper insurance coverage, either under the entity's policy or individually (or both).

It will be very important for providers to carefully document their thought processes and actions, even in an environment that will be stressful and potentially chaotic, in the event that these are questioned at a later date. And providers should always remember that many legal claims arise from miscommunications or failures to communicate in a caring and meaningful way with anxious family members. Although opportunities for face-toface interaction will be limited, this only makes the nature of communications that do occur that much more important.

Finally, if state governments allow for hospitals or other health care entities to implement policies or guidelines allocating scarce medical resources, providers should understand that these are not meant to infringe on their rights or status as treating physicians. Instead, these policies or guidelines may serve to insulate providers from claims alleging that they should have taken extraordinary steps to provide a level of care that may simply not be possible in the event of a surge of patients and limited medical resources. Hospital-specific guidelines involving allocation of possibly scarce resources during a COVID-19 surge are intended to reflect the urgency and extraordinary nature of the circumstances that may be presented. In the end, it will benefit both providers and health care entities to work together to implement and carry out such policies or guidelines.

With these common sense and practical steps, health care providers will be able to fully focus on the care they provide – without worrying (too much) about the potential fallout of malpractice claims.

We will continue to monitor these developments, and if you have any questions regarding ways to limit health care provider liability during the COVID-19 pandemic, or if you need information about specific states not covered in this Alert, contact Buckner Wellford or a member of Baker Donelson's Health Care litigation team. Also, you may visit our Coronavirus (COVID-19): What You Need to Know information page on our website.

- ¹ This Alert identifies information available as existing on April 7, 2020. Please note that this Alert is not intended to be an exhaustive recitation of all liability limits, immunities, considerations, and guidelines, and confirmation of such is recommended, as state and federal governments may change their laws and guidelines over time and without notice.
- ² The Declaration was issued on March 10, 2020, but it was made effective as of February 4, 2020.
- ³ Va. Code § 8.01-225.02.
- ⁴ Tenn. Code Ann. § 58-2-107(I)(2).
- ⁵ As of the date of this Alert, the Governor of Tennessee has not yet issued such an Order.