STARNES | DAVIS FLORIE LLP

RE: PUBLIC HEALTH EMERGENCY: STATE & FEDERAL IMMUNITY

The State of Alabama and the federal government issued rules providing limited immunity from lawsuits to certain providers during the pandemic. Immunity under Alabama law is outlined by Governor Kay Ivey's March 13, 2020 "Proclamation," and federal immunity is outlined in a Declaration from HHS under the Public Readiness and Preparedness Act. The following summarizes these provisions.

I. GOVERNOR IVEY'S MARCH 13, 2020 PROCLAMATION

Governor Ivey's March 13, 2020 Proclamation declared a state public health emergency.[i] It can be read in its entirety here. The Proclamation grants certain immunity from lawsuits if a provider in a covered "health care facility" is practicing pursuant to an "alternative standard of care" plan. The "alternative standard of care" must be set forth in the "health care facility's" emergency operation plan, and the specific language or "standards of care" may differ from facility to facility. If a provider is not practicing in a covered "health care facility" *or* there is no "alternative standard of care plan" in place, the standard of care remains reasonable care under the circumstances.

A. The Standard of Care

The "alternative standards of care" in a covered facility's emergency operation plan serves as the equivalent to the statutory definition of the standard of care for a medical malpractice lawsuit under the Governor's Proclamation.[ii]

If an entity is not a covered health care facility, then the existing standard of care accommodates situations when a provider treats a patient during the pandemic.[iii] The existing standard of care also applies if an entity is a health care facility but does not have an emergency operation plan or an "alternative standards of care" plan. For these providers, the standard of care is that level of reasonable care provided by a similarly situated health care provider in treating a patient during the COVID-19 pandemic. The context of "during the pandemic" could include, but is not limited to, situations such as resource depletion, modified triaging, or modified treatment to account for transmission risk. Documentation of the circumstances surrounding each patient and the reasons for clinical decisions is important.

B. Limited Immunity From Lawsuits

Limited immunity from lawsuits is available when a covered facility has an emergency operation plan and implements its "alternative standards of care" plan. A covered "health care facility" and its personnel are entitled to the available immunity from

suit if that person (or entity) is practicing consistent with the methods of practice outlined in an alternative standard of care plan.[iv]

i. What is a covered Health Care Facility?

"Health care facility" is not defined by the Governor, but it almost certainly includes hospitals. The definition may extend to other facilities, including physicians' offices and urgent care clinics. The Alabama Department of Public Health ("ADPH") website contains a directory for the types of facilities licensed by the Alabama State Board of Health. Of note, physicians' offices are not included in the description of "Facilities" falling under this Division of the ADPH.[v] Citing the ADPH, an argument can be made that because a physician's office is not listed as a "facility," it is not a "health care facility" for purposes of the Proclamation. Other sources, however, support an argument to include a physician's office under the Proclamation. The Alabama Medical Liability Act defines a "Medical Institution" to include a physician's office.[vi] Materials from the CDC also suggest that outpatient treatment facilities or urgent care facilities are "health care facilities"[vii] and support the position that a physician's office or urgent care clinic is a "health care facility" for purposes of the Proclamation.

ii. What is an Alternative Standards of Care Plan?

ADPH guidance states that alternative standards of care are standards utilized in emergency situations to allow healthcare facilities to streamline and simplify support processes to save lives.[viii] Alternative standards of care are "fall-back" standards developed for use in circumstances when available care and the normal means of receiving that care are no longer available due to an emergency or disaster.[ix] These standards describe how the health care facility or medical provider will provide care in consideration of available resources and the needs of a vulnerable population.[x] Additional resources and guidance regarding "alternative standards of care" can be found here.

II. PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT & CARES ACT

On March 10, 2020, HHS issued a Declaration under PREP Act[xi] that provides limited immunity from lawsuits for the administration or use of "covered countermeasures" to "treat, diagnose, cure, prevent, or mitigate COVID-19…."[xii] The PREP Act explicitly covers providers for the administration or use of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine" used in the treatment of a COVID-19 patient.[xiii] The full scope of decisions or treatments that will be deemed a "covered countermeasure" is not specifically defined, but the language would appear to encompass decisions made in the event of a shortage of supplies, medications or equipment in the treatment of a patient with COVID-19.[xiv] There is arguably a level of judgment and possible leeway in application of the PREP Act, but it will depend on the specific circumstances presented in view of the numerous requirements that must be satisfied.[xv]

On March 27, 2020, Congress passed the CARES Act that provides limited immunity for health care providers treating patients during the public health emergency as a volunteer.[xvi] The immunity extends to treatment of all patients. To qualify for this immunity the provider must receive no compensation, in any form.

III. SCOPE OF STATE AND FEDERAL IMMUNITY

The limited immunity afforded under the Governor's March 13, 2020 Proclamation covers more types of treatment than the immunity under the PREP Act. As an example, if it is argued that ventilator allocation does not fall within the purview of the PREP Act as a "covered countermeasure," the State of Alabama has set out *Criteria for Mechanical Ventilator Triage Following Proclamation of Mass-Casualty Respiratory Emergency* under its Emergency Operations Plan. Assuming a "health care facility" has adopted this plan or a different plan as its "alternative standard of care" regarding ventilator use, it would have the immunity provided under the Governor's Proclamation, and an action could only be brought for willful misconduct, gross negligence or bad faith.

Further, the limited PREP Act immunity is arguably unavailable for treatment of a patient who does not have COVID-19 but whose care is affected by COVID-19. Examples might be a patient who is infected by COVID-19 because of a shortage of masks/gowns resulting in reuse of the equipment leading to infection, or a patient that is denied medication or equipment created by a shortage.

If the care of a patient who does not have COVID-19 is affected because of COVID-19, there may still be immunity under the Governor's Proclamation and a facility's "alternative standards of care" plan. If neither the PREP Act nor the Governor's Proclamation apply to a situation, providers should remember that the "reasonable" standard of care based on the totality of the circumstances will apply.[xvii] Again, documentation of the totality of the circumstances is important during these times.

Citations:

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[i] Governor Ivey's March 13, 2020 Proclamation ("Proclamation").

[ii] *See* Proclamation at I.(B) & (C). In view of the immunity provision (discussed below), the reference to the "standard of care" can be read as a promulgation that practicing in good faith pursuant to the procedures outlined in an "alternative standard of care" plan meets the standard of care and does not amount to "willful misconduct, gross negligence or bad faith."

[iii] Ala. Code § 6-5-542(2); *see also* Ala. Code § 6-5-548(e).

[iv] Proclamation I.(C); Providers are not immune from lawsuits involving willful misconduct, gross negligence or bad faith. *See* Ala. Code. § 31-9-16(b).

[v] http://www.alabamapublichealth.gov/providerstandards/descriptions.html. Also note that private physician's offices are specifically *excluded* from the description for "ambulatory surgical centers."

[vi] Ala. Code § 6-5-481.

[vii] "It is critical for healthcare facilities to continue to provide care for all patients, irrespective of COVID-19 infection status, at the appropriate level (e.g., home-based care, **outpatient, urgent care**, emergency room, or hospitalization)." (emphasis added) available at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html

[viii] *See* Webcast: Alternative Standards of Care in Disasters, available at: https://alabamapublichealth.gov/alphtn/ondemand/2009/03-26.html.

[ix] *See* Webcast: Alternative Standards of Care in Disasters.

[x] *See* Webcast: Alternative Standards of Care in Disasters.

[xi] 42 USC §247d-6d.

[xii] https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx. The Declaration is effective retroactively to February 4, 2020 and extends immunity to liability through October 1, 2024. *See* 85 Fed. Reg. 15198-01 § VI. PREP Act immunity is not available for cases of willful misconduct. 85 Fed. Reg. 15198-01 § IX. Covered persons will not be found to have engaged in "willful misconduct" if (1) they act in accordance with applicable directions issued by the Secretary regarding administration and use of a Covered Countermeasure and (2) either the Secretary or a State or local health authority is notified about the serious injury or death from the Covered Countermeasure within seven days of its discovery.

[xiii] *See* 85 Fed. Reg. 15198-01 § VI. It should be noted that at least one court has held that immunity under the PREP Act was not available for a claim alleging negligence in failing to provide an individual with a vaccine. *See Casabianca v Mount Sinai Medical Center*, 2014 WL 10413521, No. 112790/2010, (N.Y. Sup. Ct. Dec. 02, 2014) (holding that because the PREP Act "consistently speaks of administering or using the countermeasure," "the vaccine must be administered to or used by a patient" for the Act to apply). Under this theory, a plaintiff could argue that providers making decisions regarding non-use of a covered countermeasure—i.e. an anti-viral, any other drug, etc.—or withholding mechanical ventilation would not be afforded the available immunity under the PREP Act.

[xiv] 85 Fed. Reg. 15198-01 § VI. (defining "covered countermeasures")

[xv] *See* 85 FR 15198-01 § IX (stating "whether immunity is applicable will depend on the particular facts and circumstances")

[xvi] CARES Act, Section 4216. Immunity does not extend to willful or criminal misconduct, or gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the patient, and does not extended if the professional renders the service under the influence of drugs or alcohol.

[xvii] CMS has also recently issues sweeping federal waivers and guidance that could also inform certain situations related to the care of all patients during the national emergency. Those can be read, in their entirety, here.

No representation is made that the quality of legal services to be performed is greater than the quality of legal services performed by other lawyers.