Liability Immunity for Health Care Providers During the COVID-19 Crisis

SmithAmundsen Health Care Alert
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On April 1, 2020, Illinois Governor J.B. Pritzker entered Executive Order No. 19, 2020, granting **explicit immunity to health care facilities, health care professionals, and health care volunteers providing services in response to the COVID-19 outbreak**. The Order provides clarity to the issues and questions posed by these authors in their March 27, 2020 publication regarding provider immunity during the COVID-19 crisis. Executive Order No. 19 specifies that the civil immunities provided under various Illinois statutes *do* apply to health care facilities, providers, and volunteers responding to the COVID-19 crisis.

Furthermore, **the immunity covers the cancellation or postponement of elective surgeries and procedures** as set forth in the Illinois Department of Public Health's COVID-19 – Elective Surgical Procedure Guidance. Not only that, the Order specifically clarifies that **civil immunity extends to any injury or death alleged to have been caused by *any* act and/or omission by a health care facility or provider during the pendency of the Gubernatorial Disaster Proclamation** where such act and/or omission occurred at a time when the facility or provider was engaged in the course of responding to the COVID-19 crisis. It looks like Pritzker is giving New York Governor Cuomo a run for his money.

Executive Order No. 19 is clear and explicit. It cites to three (3) existing Illinois statutes that provide civil immunity for health care providers, reciting the following applicable statutory provisions:

WHEREAS, Section 15 of the IEMA Act, 20 ILCS 3305/15, provides that "Neither the State, any political subdivision of the State, nor, except in cases of gross negligence or willful misconduct, the Governor, the Director, the Principal Executive Officer of a political subdivision, or the agents, employees, or representatives of any of them, engaged in any emergency management response or recovery activities, while complying with or attempting to comply with this Act or any rule or regulations promulgated pursuant to this Act is liable for the death of or any injury to persons, or damage to property, as a result of such activity"; and,

PROFESSIONALS

Carmel M. Cosgrave
Of Counsel

Jennifer K. Stuart
Partner

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WHEREAS, Section 21(b) of the IEMA Act, 20 ILCS 3305/21, provides that "Any private person, firm or corporation and employees and agents of such person, firm or corporation in the performance of a contract with, and under the direction of, the State, or any political subdivision of the State under the provisions of this Act shall not be civilly liable for causing the death of, or injury to, any person or damage to any property except in the event of willful misconduct"; and,

WHEREAS, Section 21(c) of the IEMA Act, 20 ILCS 3305/21, provides that "Any private person, firm or corporation, and any employee or agent of such person, firm or corporation, who renders assistance or advice at the request of the State, or any political subdivision of the State under this Act during an actual or impending disaster, shall not be civilly liable for causing the death of, or injury to, any person or damage to any property except in the event of willful misconduct"; and,

WHEREAS, Section 3.150(a) of the Emergency Medical Services (EMS) Systems Act, 210 ILCS 50/3.150, provides that persons "who in good faith provide[] emergency or non-emergency medical services during a Department [of Public Health] approved training course, in the normal course of conducting their duties, or in an emergency, shall not be civilly liable as a result of their acts or omissions in providing such services unless such acts or omissions, including the bypassing of nearby hospitals or medical facilities in accordance with the protocols developed pursuant to this Act, constitute willful and wanton misconduct"; and,

WHEREAS, the Good Samaritan Act, 745 ILCS 49, provides that "the generous and compassionate acts of its citizens," specifically health care professionals, "who volunteer their time and talents to help others" should be exempt from civil liability unless such acts demonstrate willful or wanton misconduct.

Included in the Order is Section 21(c) of the IEMA Act, which was a subject discussed by these authors in the March 27, 2020 Alert. Section 21(c) of the IEMA Act provides civil immunity for causing the death or injury of any person in rendering assistance "*at the request of the State* or any political subdivision of the State" during a disaster. [emphasis added] *See* 20 ILCS 3305/21(c). Prior to the recent Order, many facilities and health care providers were uncertain as to whether the protection would apply, given the absence of a specific *request* by the State to render care in response to the COVID-19 crisis. What was formerly unclear about such provision was whether the "at the *request* of the State" portion applied to health care facilities and providers who render health care services as part of regular business operations. The new Order explicitly provides that:

Pursuant to Sections 15 and 21(b)-(c) of the IEMA Act, 20 ILCS 3305/15 and 21 (b)-(c) and the Good Samaritan Act, 745 ILCS 49, I direct all Health Care Facilities, Health Care Professionals, and Health Care Volunteers, as defined in Section 1 of this Executive Order, to render assistance in support of the State's response to

the disaster recognized by the Gubernatorial Disaster Proclamations (COVID-19 outbreak). **For Health Care Facilities, "rendering assistance" in support of the State's response must include cancelling or postponing elective surgeries and procedures, as defined in DPH's COVID-19 – Elective Surgical Procedure Guidance, if elective surgeries are performed at the Health Care Facility**. In addition, for Health Care Facilities, "rendering assistance" in support of the State's response must include measures such as increasing the number of beds, preserving personal protective equipment, or taking necessary steps to prepare to treat patients with COVID-19. For Health Care Professionals, "rendering assistance" in support of the State's response means providing health care services at a Health Care Facility in response to the COVID-19 outbreak, or working under the direction of IEMA or DPH in response to the Gubernatorial Disaster Proclamations.

[emphasis added] Section 3, Executive Order 2020-19. The looming question as to whether the cancellation of elective surgeries will be covered under the civil immunities afforded by Statute has now been answered: **yes, any decisions or recommendations to postpone elective procedures have been defined by the Governor as "rendering assistance" in support of the State's COVID-19 response**.

Furthermore, Sections 3, 4, and 5 of Order No. 19 provide that during the pendency of the Gubernatorial Disaster Proclamations, Health Care Facilities, Health Care Providers, and Health Care Volunteers, **"shall be immune from civil liability for any injury or death alleged to have been caused by any act or omission"** by the Health Care Facility, Health Care Provider, and/or Health Care Volunteer, **which injury or death occurred at a time when such Facility, Provider, and/or Volunteer, "was engaged in the course of rendering assistance to the State by providing health care services in response to the COVID-19 outbreak, unless it is established that such injury or death was caused by gross negligence or willful misconduct** of such [Facility][Provider] [Volunteer], if 20 ILCS 3305/15 is applicable, or by willful misconduct, if 20 ILCS 3305/21 is applicable."

The above-cited Sections of the Order reflect the Governor's intent to prioritize the health and safety of the public while ensuring that health care providers remain protected in responding to this unprecedented crisis. The plain language of the Order clarifies that, absent gross negligence or willful misconduct, the existing statutory protections apply to *all* alleged injuries or death occurring during the pendency of the Gubernatorial Disaster Proclamation, if such injury or death occurred in the course of rendering services in response to the COVID-19 outbreak. *See* Section 4, Executive Order 2020-19. This clarifies that the civil immunity afforded is not solely limited to the direct care of COVID-19 patients, but also to the care of patients afflicted with other maladies, and to medical decision-making during this Disaster. Such immunity is consistent with clear public policy goals of directing our medical resources and attention to fighting this pandemic.

Liability Immunity for Health Care Providers During the COVID-19 Crisis

Despite the seeming solidarity that this pandemic has brought among Illinoisians, there will undoubtedly be medical malpractice lawsuits filed in the months to come. Although the immunities clarified in Order No. 19 do not provide immunity from *suit,* they do provide clear immunity from *liability*. So while health care facilities and providers may face COVID-19-related suits in the foreseeable future, the civil immunities provided by statute and confirmed by Executive Order No. 19 afford our frontline responders with clear protection and an unequivocal defense. With the entry of Executive Order No. 19, Pritzker has not only provided peace of mind to health care providers responding to the crisis, but has reiterated to all Illinoisans that the preservation of public health and safety is of utmost importance.

---------- ***March 27, 2020 – ORIGINAL PUBLICATION*** ----------

On March 17, 2020 the Secretary of Health and Human Services ("Secretary") issued a Notice of Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19. The Declaration provides **liability immunity** to certain individuals and **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** except for claims involving willful misconduct. The Declaration is separate from the Public Health Emergency declared under Section 319 of the Public Health Service Act on January 31, 2020, and is part of the continued effort by the Federal government to promote an expeditious response and aid the nation's health care community in responding to the COVID-19 outbreak.

This liability immunity applies to hospitals and health care providers. **Covered countermeasures** are **any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19,** or the transmission of SARS-CoV-2 or a virus mutating therefrom, **or any device used in the *administration* of any such product, and all components and constituent materials of any such product**. 42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7). The PREP Act defines willful misconduct as "an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) 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." 42 USCA ¶247d-6d.

The PREP Act does not explicitly define the term "administration" but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX of the Declaration, the Secretary defines "Administration of a Covered Countermeasure," as follows:

Administration of a Covered Countermeasure means 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 purpose of distributing and dispensing countermeasures.

The definition of "administration" extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. **Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act**. **Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites**.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. **Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.** However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. **In each case, whether immunity is applicable will depend on the particular facts and circumstances**.

The above-cited text taken from the Secretary's interpretation of the Declaration would arguably cover, for example, a health care provider's decision to use a ventilator on a patient. This has been the subject of much legal speculation: how will facilities determine which patients will receive ventilators and which won't if hospitals are pushed to capacity? Little guidance has been provided by the government, leaving our hospitals to look at how the ethical dilemma has played out in other countries in an attempt to avoid worst case scenarios. It would seem that under the Federal Declaration, such decision making would constitute a "covered countermeasure", as it relates to "a device used to treat, diagnose, cure, prevent, or mitigate COVID-19."

Whether the PREP Act will indeed cover, for example, the allocation of ventilators is a question that remains unknown. However, health care providers may look to State law for additional protections. All states have procedures by which a person authorized to do so many declare a public health emergency or disaster. Sate laws also many confer certain emergency powers upon specific individuals (e.g., the Governor, Department of Health, etc.) when a **public health or disaster emergency has been declared**. Such emergency powers may include the **provision of statutory liability protections** for health care works or the power to suspend application of existing statutes and regulations. Whether health care providers are afforded with an additional layer of protection may rest on state action.

- **Immunity Under New York Law**

The State of New York has already contemplated the looming ventilator dilemma, years ago, in issuing its **2015 Ventilator Allocation Guidelines** ("Guidelines") in conjunction with the New York State Task Force on Life and the Law. The 272-pg. Guideline reads as an eerie foreshadowing of the very crisis we are now facing.

Recognizing that pandemic influenza is a foreseeable threat, the Guidelines aimed at providing a protocol that would save the most lives in an influenza pandemic when there are limited number of available ventilators. To accomplish this goal, **under the Guidelines, priority is given to those patients for whom ventilator therapy would be "most likely lifesaving."** The Guidelines define survival by **examining a patient's short-term likelihood of surviving the acute influenza episode, and not by focusing on whether the patient may survive any other given illness or disease in the long-term** (i.e., years after the pandemic). Under this scheme, patients with the highest probability of mortality *without* medical intervention, along with patients with the smallest probability of mortality *with* medical intervention have the lowest level of access to ventilator therapy.

The Guidelines discussed the ethical dilemma of allocating ventilators, and in setting forth its recommendations, elaborated on the various factors considered by the New York State Task Force on Life and the Law ("Task Force"). To ensure that patients receive the best care possible in a pandemic, the Guidelines recommend that "**a patient's attending physician does not determine whether his/her patient receives (or continues) with ventilator therapy; instead a triage officer or triage committee makes the decision**." The triage officer or committee would examine the data provided by the attending physician and make the determination about a patient's level of access to a ventilator based on such data. In coming to its ultimate recommendation on allocation, **the Task Force evaluated various non-clinical approaches** such as distributing ventilators on a first-come-first-serve basis, randomizing ventilator allocation (i.e. a lottery system), requiring physician-only clinical judgment in making allocation decisions, and prioritizing certain patient categories (e.g., health care workers). **In rejecting these non-clinical approaches to allocating**

ventilators, the Task Force believed that these approaches should not be utilized as the primary method to allocate scare resources because,

[. . .] they are often subjective and/or do not support the goal of saving the most lives. Furthermore, advanced age was rejected as a triage criterion because it discriminates against the elderly. Age already factors indirectly into any criteria that assess the overall health of an individual (because the likelihood of having chronic medical conditions increases with age) and there are many instances where an older person could have a better clinical outlook than a younger person.

(*See,* New York State Department of Health Ventilator Allocation Guidelines 2015).

The Task Force concluded that an allocation protocol should utilize clinic factors only to evaluate a patient's likelihood of survival and to determine access to ventilator therapy. Interestingly, because of a strong societal preference for saving children, **the Task Force recommended that *young age* may be considered as a tie-breaking criterion in limited circumstances, where all other clinical factors have been examined and the probably of mortality among adults and children are equal**.

Importantly, the Guidelines acknowledge that these clinical ventilator allocation protocols remain untested in actual circumstances, and that "issuing them as binding regulations may produce unforeseen consequences." The Task Force recommended the adoption of a modified medical standard of care in emergency situations, coupled with civil immunity and professional discipline protections to all health care workers and entities providing care in a pandemic emergency. That is just what Governor Andrew M. Cuomo has done in affording immunity from civil liability for health care workers responding to COVID-19. The March 23, 2020 Executive Order 202.10, provided that:

[...] all physicians, physician assistants, specialist assistants, nurse practitioners, licensed registered professional nurses and licensed practical nurses **shall be immune from civil liability for any injury or death alleged to have been sustained directly as a result of an act or omission by such medical professional in the course of providing medical services in support of the State's response to the COVID-19 outbreak**, unless it is established that such injury or death was caused by the gross negligence of such medical professional.

Governor Cuomo's Order reflects a clear interest in prioritizing patient care over all else in additionally providing that **health care providers are relieved of recordkeeping requirements to the extent as may be necessary to respond to the COVID-19 outbreak**. Such relief extends, for example, to any requirements to assign diagnostic codes or to create or maintain other records for billing purposes. The Order provides that **any person acting in good faith under the provision shall be afforded absolute immunity from liability for**

any failure to comply with any recordkeeping requirement. In order to ensure that protection will be afforded, the Order suspends or modifies any existing State laws or regulations to the extent necessary for health care workers to perform the necessary tasks to respond to the COVID-19 outbreak. *Id.*

With the President's recent announcement that New York should not rely on the federal government for ventilator aid, Cuomo's seemingly well-drafted Executive Order at least leaves New York health care providers on the frontlines with state afforded immunity. For New York City's Health and Hospitals Corporation, the Order may offer needed protection for its providers if faced with ventilator shortages. According to the New York Times' reporting as of March 26, 2020, the Corporation has said that it had no plans to implement the triage recommendation from the Guidelines and that every patient who needs a ventilator will get one.

- **Immunity Under Illinois Law**

Unlike New York, Illinois has yet to provide explicit protection by way of Executive Order. However, existing statutory provisions do provide for civil immunity. Similar to the language providing immunity under the Federal Declaration, the Illinois Immunity from Civil Liability Statute provides like protection:

Any person, agency or governmental body certified, licensed or authorized pursuant to this Act or rules thereunder, who in good faith provides emergency or non-emergency medical services during a Department approved training course, in the normal course of conducting their duties, or in an emergency, shall not be civilly liable as a result of their acts or omissions in providing such services unless such acts or omissions, including the bypassing of nearby hospitals or medical facilities in accordance with the protocols developed pursuant to this Act, constitute willful and wanton misconduct.

210 ILCS 50/3.150(a). In addition to the Illinois Immunity from Civil Liability Statute is the Illinois Emergency Management Agency Act ("Emergency Management Act") which provides that:

Any private person, firm or corporation, and any employee or agent of such person, firm or corporation, who renders assistance or advice at the request of the State, or any political subdivision of the State under this Act **during an actual or impending disaster, shall not be civilly liable for causing the death of or injury to, any person or damage to any property except in the event of willful misconduct.**

[emphasis added] 20 ILCS 3305/21(c). The Emergency Management Act also provides authority for the Governor to enter certain Executive Orders in times of crisis, such as the Illinois Shelter-in-Place Executive Order entered by Governor JB Pritzker on March 21, 2020 in response to the outbreak of COVID-19. (*See* 3-21-20 Executive Order). To date, Governor Pritzker has entered a number of Executive Orders pursuant to his authority under the Emergency Management Act, but

none have provided for explicit civil immunity for health care providers.

As such, Illinoisans are left to turn to the existing statutory protections. Although the Emergency Management Act does not define "willful and wanton conduct", such definition is provided under the Illinois Civil Immunity Statute as, "a course of action which shows an actual or deliberate intention to cause harm or which, if not intentional, *shows an utter indifference to or conscious disregard for the safety of others or their property*. This definition shall apply in any case where a 'willful and wanton' exception is incorporated into any immunity under this Act." 745 ILCS 10/1-210.

It is well settled in Illinois that 'willful misconduct' is that which goes beyond ordinary negligence to **misconduct that involves a conscious disregard for the safety of others.** *Burke v. 12 Rothschild's Liquor Mart, Inc.*, 148 Ill.2d 429 (1992); *Hernandez v. Chicago Park Dist.*, 274 Ill.App.3d 970, 974 (1st Dist. 1995). The Illinois Supreme Court has defined a willful or wanton injury to be an **intentional act**, **or an act that was committed with a reckless disregard for the safety of others**." *American National Bank & Trust Co. v City of Chicago,* 192 Ill.2d 274, 285, 248 Ill.Dec. 900, 735 N.E.2d 551, 557 (2000). Further, it has been held that where a provider renders emergency care in accord with established and instructions, such care will not be found to be willful and wanton. *Washington v. The City of Evanston*, 336 Ill. App. 3d 117, 125, 782 N.E. 2d 847, 853 (1st Dist. 4th Div. 2002).

Given the unprecedented scale and impact of the present circumstances, potential plaintiffs would be hard-pressed in meeting the burden to show that a hospital or health care provider acted with intent or reckless disregard for the safety of others in responding to the COVID-19 pandemic. Given the shortage of resources, limited research on the virus, and no existing vaccine (or medication proven effective) as of the present time, it would be hard to argue that any health care provider caring for COVID-19 patients during this crisis would be acting with intent to harm. As the Court held in *Gehm,* the American Red Cross was entitled to summary judgment as it was immune from liability under the Emergency Management Act. We anticipate that a similar argument and application will be applied as it relates to hospitals and health care facilities responding to COVID-19, however in the absence of any comparable emergency of this scale, we are navigating in uncharted waters.

An Executive Order providing for explicit civil immunity for COVID-19 health care providers like the one entered in New York would be of benefit to Illinois health care providers. While the existing statutory protections arguably protect health care providers from actions directly related to the care of COVID-19 patients, it is less clear whether civil immunity will extend to ancillary COVID-19-related decisions. One such looming concern is with respect to the **Illinois Department of Public Health (IDPH) recommendation for the cancellation of all "elective" surgeries and procedures**. On March 17, 2020, the IDPH issued its COVID-19 – Elective Surgical Procedure Guidance, which was aimed to "immediately decompress the healthcare system during the COVID-19 response."

(*See*, IDPH COVID-19 Elective Surgical Guidance).

The IDPH defined *elective* as "**those procedures that are pre-planned by both the patient and the physician that are advantageous to the patient but are NOT urgent or emergent**." Further, the **IDPH directs physicians to use their "*medical judgment* to determine the need for surgery."** [emphasis added] *Id*. With this recommendation, what happens if a pre-planned surgery is postponed as non-emergent, but the patient later suffers from some harm as a result of the delay? For example, a patient with a scheduled knee replacement surgery delays the procedure as it is considered not to be "urgent". While on walk, the patient's knee gives out and she falls on the sidewalk and sustains a concussion. In this hypothetical situation, the decision to postpone the patient's elective surgery was in an effort to abide with the Department's directive and allow for healthcare staff and resources to be directed to COVID-19 response efforts. The physician's recommendation to delay was in his/her best medical judgment. Will these judgment calls be covered by statutory immunity? Arguably, the physician's decision would not be considered "willful and wanton" as it was made under the recommendation of the IDPH with the intent to protect the would-be surgery patient from unnecessary exposure to the virus, while also ensuring that medical resources could instead be diverted to COVID-19 response efforts. On the converse, what happens when the physician decides that the patient should proceed with the knee replacement procedure, and while admitted to the hospital, contracts COVID-19? Is the same medical judgment protected from civil liability?

In the absence of case law addressing an analogous fact pattern, we are left with many uncertainties. One thing, however, *is* certain: the intent and purpose underlying the aforementioned Illinois Statutes is to protect health care providers from decisions of this very nature. As we wade through this uncharted public health emergency, it is increasingly important that our health care providers focus their efforts on patient care without fear for civil liability. While risking their own lives to save those of inflicted patients, an Executive Order like the one entered in New York would certainly provide just a little more comfort—and clarity—for Illinois health care providers.