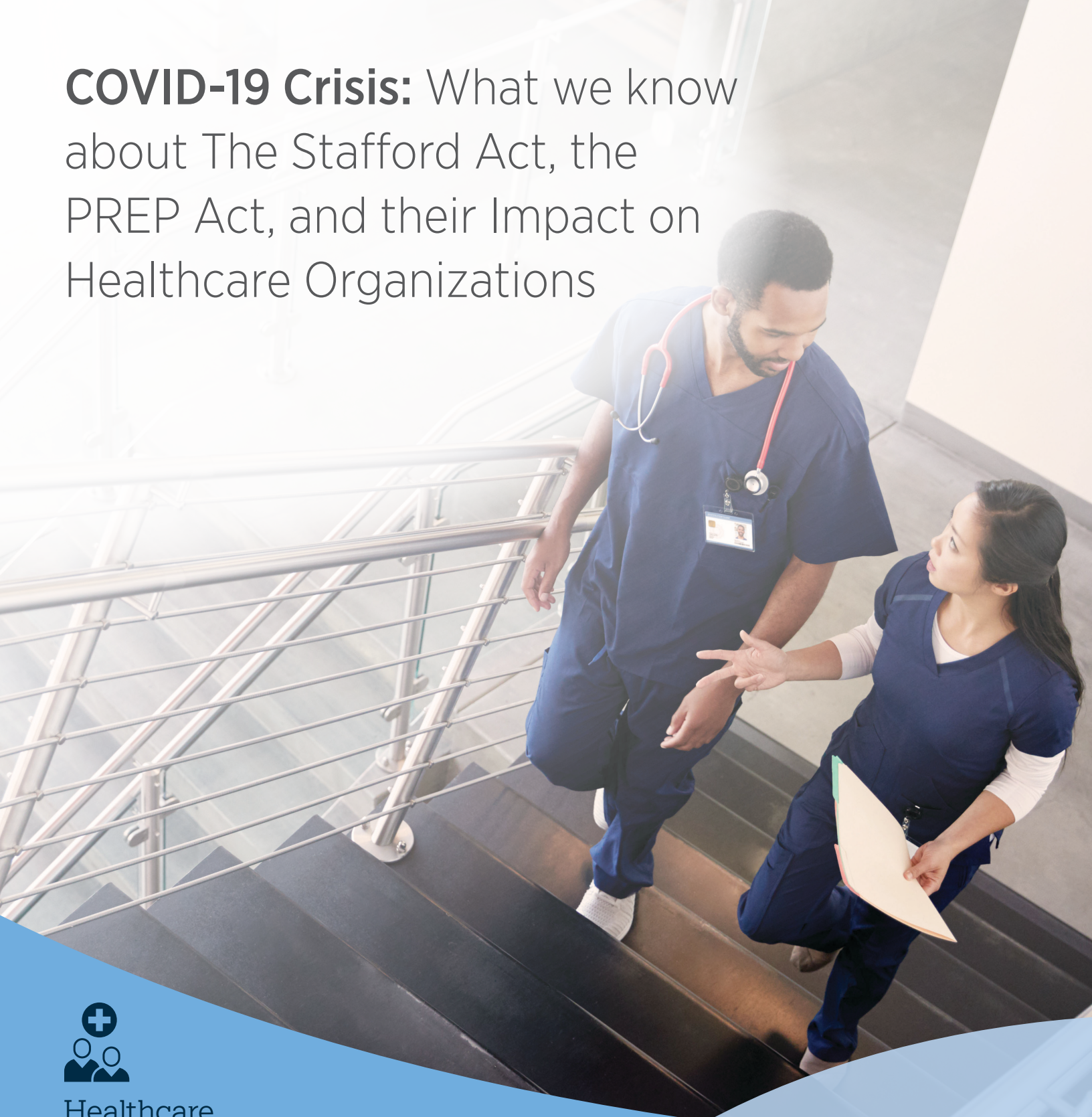


COVID-19 Crisis: What we know about The Stafford Act, the PREP Act, and their Impact on Healthcare Organizations



Healthcare

4/10/2020

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In this paper, we will provide insight on the following developments:

- 1 With the declaration of COVID-19 as a national emergency and the Trump administration invoking the Stafford Act, the Department of Health and Human Services (HHS) is able to waive traditional laws that impact healthcare organizations, including telehealth and physician licensing.
 - 2 The PREP Act provides some immunity for healthcare organizations that may face potential tort actions from plaintiffs, but it does not eliminate the need for medical professional liability coverage. We have identified some of the allegations healthcare organizations may face in the future.
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Invoking the Stafford Act

President Trump declared COVID-19 a national emergency on March 13, 2020. The emergency declaration was made, in part, under the 1988 Stafford Act, which is typically used for crop failures and natural disasters rather than public health emergencies. However, the Stafford Act declaration, used in conjunction with HHS Secretary Alex Azar's categorization of the disease as a public health emergency, allows for more flexibility, unlocking federal funds and allowing states the opportunity to request assistance for additional resources on the front line.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act is a federal law designed to bring an orderly and systematic means of federal natural disaster assistance for state and local governments to carry out their responsibilities to aid citizens. In addition, the Stafford Act authorizes the secretary of HHS to waive many laws, allowing for a more immediate response by allocating our limited resources more efficiently.

These legal deferments include:

- Waiving laws to enable telehealth services for remote doctor visits and hospital check-ins.
- Waiving certain federal licensing requirements so doctors from other states can provide services and cross state lines.
- Waiving requirements that critical-access hospitals limit the number of beds to 25 or the length of stay to 96 hours.
- Waiving a requirement for a three-day hospital stay before transfer to a nursing home.
- Allowing hospitals to bring additional physicians on board and obtain additional office space.
- Waiving rules that severely restrict hospital care of patients within the hospital itself, ensuring that emergency capacity can be enhanced.

Hospitals and nursing homes have since taken measures to limit or restrict all visitors and nonessential personnel to their facilities, with exceptions for end-of-life situations, in order to protect their patients and residents.

The PREP Act and Future Allegations

HHS also invoked the Public Readiness and Emergency Preparedness Act (PREP Act). The Prep Act was invoked on March 17, 2020, but made effective retroactively to February 4, 2020.¹ The PREP Act was previously used in response to Ebola, Zika and Anthrax.

The PREP Act was originally enacted in 2005 to address liability concerns raised by the use and distribution of countermeasures for pandemic viruses. The PREP Act authorizes the HHS secretary to issue a declaration that provides immunity from liability, with the exception of willful misconduct, for claims caused, arising from, relating to, or resulting from administration or use of countermeasures to diseases, threats, and conditions determined by the HHS secretary to constitute a present or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. The secretary must define the scope of protections afforded by each declaration, including the countermeasures, geographic areas, subject populations, time periods and means of distribution covered by the declaration.

¹<https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx>; online March 23, 2020.



The PREP Act also defines covered countermeasures as qualified pandemic or epidemic product, and how the liability immunity applies for covered persons. For healthcare organizations, a qualified person means 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, or a person within a category of persons identified as qualified in the secretary's declaration.

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered physical injury as the direct result of the administration or use of the covered countermeasures. The connection between the countermeasure and the physical injury must be compelling, reliable, valid, medical and scientific evidence in order for the individual to be compensated.²

Does the PREP Act eliminate the need for medical professional liability coverage?

While the scope of the PREP Act declaration is subject to interpretation and will likely evolve over time, it does not preclude the need for effective professional liability insurance in response to claims involving care of COVID-19. The breadth and reach of the immunity rests primarily in how administration of COVID-19 countermeasures will be interpreted. Therefore, it presently does not appear to grant healthcare providers immunity from professional liability on a wide-reaching basis for most actions related to COVID-19. As with any plaintiff allegation against a healthcare provider, the determination of coverage is based on the specific circumstances of the event and will depend on the particular facts of each case. Whether the immunity offered by the PREP Act applies will need to be reviewed as part of the investigation of the incident by the healthcare organization and the risk manager.

Some healthcare insurance carriers are issuing FAQs to their insureds outlining how their insurance policies will respond, and are trying to offer sage guidance in a very fluid crisis. It appears that these carriers are trying to do the right thing and indicating that the medical professional liability policy will respond. However, we strongly recommend that you review your specific policy terms and conditions, and work with your Gallagher broker and claims advocate as necessary.

²<https://www.federalregister.gov/documents/2018/08/07/2018-16856/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-zika-virus-vaccines>; online March 23, 2020.



Moreover, we anticipate the plaintiff bar will ultimately commence lawsuits aimed at circumventing the limited immunity provided via the PREP Act. For instance, a narrow reading of administration of the listed countermeasures would potentially not relieve liability for COVID-19 treatment unrelated to a countermeasure, such as alleged delayed or misdiagnosis of COVID-19. Further, in effort to prosecute civil cases, the plaintiff's bar might also allege healthcare providers acted in a willful manner. All such lawsuits, even if making allegations squarely within the immunity prescribed by the PREP Act, will require the retention of defense counsel and incurring of costs to defend and/or have them dismissed. We anticipate that allegations related to claims or incidences may arise. These may include but are not limited to:

- Failure to provide adequate protections for patients, residents or staff against hospitals and nursing home facilities from contracting COVID-19.
- Misdiagnosis of the disease that caused harm or death to a patient.
- Negligent actions that contributed to someone getting COVID-19, such as failure to sterilize/sanitize equipment.
- Potential understaffing, as the duration of the situation stretches on.
- Failure to timely secure medical supplies and devices required to treat patients suffering from COVID-19.

Claim investigations will be complicated with COVID-19 allegations due to the communicability of the disease. Gallagher has developed a [Coronavirus \(COVID-19\) Pandemic Information Hub](#) with several resources to help you develop additional questions and processes for these claims.

Government Resources

Even as the disease continues to spread, the amount of information that news sources are providing is overwhelming. We strongly recommend that clients continue to access responsible resources for accurate information and guidance, such as:

Centers for Disease Control	www.cdc.gov
World Health Organization	www.who.int
Department of Health and Human Services	www.hhs.gov
Public Health Emergency (PHE)*	www.phe.gov

*Note: PHE is part of the Department of HHS.

Additionally, the PREP Act declaration can be viewed here:

<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>



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Anthony D. DellaCroce, JD, has over 20 years of legal experience, of which over 16 years have been within the healthcare industry, focused on addressing the professional liability and regulatory exposures faced by health systems, individual providers, and other complex healthcare entities. He works with Gallagher’s Healthcare practice on the assessment of risk and liability placements for medical providers. Prior to joining Gallagher in 2019, Anthony spent over 11 years as a complex claims manager on the healthcare team of a Lloyd’s of London syndicate. There, he worked collaboratively with healthcare providers to develop litigation strategies in response to high-severity claims, directed counsel and attended mediations across the country. He addressed insurance coverage issues, and worked with executives and risk management departments on other concerns facing providers. Previously, Anthony was a litigator with a Manhattan-based law firm, defending hospitals and physicians at trials and depositions. Anthony started his career as an assistant district attorney at the Queens County District Attorney’s Office, working in the Narcotics Investigation Bureau. He has spoken nationally on litigation trends impacting the healthcare industry. Anthony obtained a Juris Doctor from Brooklyn Law School and a BA from Binghamton University.



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