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Upping Hospitals' Liability Defenses For COVID Measures

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Law360, April 13, 2020, 4:56 PM EDT

The Public Readiness and Emergency Preparedness Act, along with the declaration by the U.S. Department of Health and Human Services on countermeasures against COVID-19, provide hospital systems with broad liability protections for measures taken in response to the pandemic.

There are limitations, however, to immunity under the PREP Act and hospital systems, which have been forced to use uncleared medical devices, such as modified and split ventilators, should understand those limitations. Hospitals also can take steps to mitigate their exposure to common law tort claims.

Liability Protections Under the PREP Act

The PREP Act[i] authorizes the secretary of HHS to issue a declaration that provides immunity from liability for individuals involved in the development, manufacture, testing, distribution, administration and use of countermeasures to address a public health emergency. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations issued by HHS or other government agencies.

A PREP Act declaration only provides liability immunity to covered persons against claims of loss related to covered countermeasures that are within its scope.

Covered persons include manufacturers, distributors, program planners of a countermeasure (e.g., state or local governments), and qualified persons who prescribes, administers or dispenses a countermeasure. Qualified persons include licensed health professionals and other individuals authorized to prescribe, administer or dispense countermeasures under the law of the state in which the countermeasure is prescribed, administered or dispensed.

Covered countermeasures include products that have been approved or cleared by the U.S. Food and Drug Administration, such as vaccines, drugs and medical devices like diagnostic tests and medical equipment (e.g., ventilators, respirators). Vaccines, drugs and devices authorized for emergency use also are covered countermeasures. Uncleared devices and unapproved medical products that are not authorized by the FDA are not considered covered countermeasures.

The limited exception to immunity under the PREP Act is when death or serious physical injury is proximately caused by willful misconduct. Immunity also is not

available for claims based on activities that fall outside the scope of a PREP Act declaration, and the PREP Act does not affect the "enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding … under any … applicable statute or regulation."[ii]

The PREP Act preempts state laws. The PREP Act's preemption clause provides that, during the effective period of a declaration of a public health emergency:

> No 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 from, or is in conflict with, any requirement applicable under this section; and (B) relates to the ... use, ... dispensing, or administration by qualified persons of the covered countermeasure.[iii]

The PREP Act also provides potential claimants with alternative administrative remedies, including access to a compensation fund. The PREP Act compensation fund was created to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration."[iv]

Covered Persons and Countermeasures Under the COVID-19 Declaration

On Feb. 4, HHS Secretary Alex M. Azar II issued a declaration under the PREP Act for medical countermeasures against COVID-19.[v] The declaration provides immunity for claims of loss caused, arising out of, relating to, or resulting from administration or use of medical countermeasures during COVID-19.

The COVID-19 declaration provides immunity for the manufacture, testing, development, distribution, administration and use of the covered countermeasures. "Covered persons" under the declaration include those under the PREP Act, and also persons authorized in accordance with local public health authorities to prescribe, administer, deliver, distribute or dispense a covered countermeasure.

Covered countermeasures include those defined in the PREP Act (e.g., antiviral, vaccine, diagnostic) to treat, diagnose, cure, prevent or mitigate COVID–19, or the transmission of SARS-CoV–2, and any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures and FDA Emergency Use Authorization

Under the PREP Act and COVID-19 declaration, only medical products that are approved or cleared by the FDA, or subject to emergency authorization from the FDA, may qualify as a covered countermeasure. The FDA has the authority to allow unapproved and uncleared medical products, or uncleared/unapproved uses of cleared or approved medical products, to be used in public health emergencies through its

emergency use authorization, or EUA, program.

During COVID-19, the FDA has issued multiple EUA letters, including letters authorizing COVID-19 diagnostic tests, personal respirators and most recently biological products. Each authorization letter sets forth the types of devices that qualify for authorization (e.g., product codes), the conditions for authorization (e.g., requirements for safety, performance and labeling), and the process for requesting authorization. The requirements under each authorization letter differ and reflect certain safety and performance expectations for the products being authorized.

Modified Ventilators as Covered Countermeasures

On March 24, the FDA authorized the emergency use of certain ventilators, anesthesia gas machines modified for use as ventilators, and ventilator tubing connectors and accessories. The EUA for ventilators (subsequently modified on March 27) covers ventilators not currently marketed in the U.S., and those that are legally marketed in the U.S., but are modified such that they would require a new premarket notification (i.e., 510(k)) to the FDA).

Notably, the EUA covers split ventilators, or those use for multiple patients. The FDA has published a list of authorized ventilators in Appendix B to the EUA. The FDA will add a ventilator to Appendix B upon submission of a request from a sponsor (as described in the letter) and after confirmation that the safety, performance and labeling criteria have been met pursuant to the conditions of authorization in the EUA.

Prior to March 24, modified ventilators — such as split ventilators — were not subject to an EUA and arguably were not a covered countermeasure under the PREP Act and COVID-19 declaration. Since March 24, however, modified ventilators that are authorized under the EUA fall squarely within the definition of a covered countermeasure under the PREP Act and COVID-19 declaration.

Hospitals that use ventilators authorized under the EUA are therefore afforded the broad liability protections in the PREP Act/COVID-19 declaration. Hospitals using unauthorized ventilators, however, may not qualify for the broad protection available under the PREP Act and COVID-19 declaration.

Prior Cases Have Upheld Immunity Under the PREP Act for Covered Countermeasures

Cases brought under the PREP Act are few and far between. In the only two cases that provide substantive analysis regarding administered countermeasures, both courts upheld the PREP Act's waiver of liability and preemption clauses.

First, the Appellate Division of the New York Supreme Court in Parker v. St. Lawrence County Public Health Department,[vi] upheld PREP Act protections for a county that conducted a school based vaccination clinic in response to the H1N1 outbreak. In

Parker, the mother of a child who was inadvertently vaccinated without parental consent filed negligence and battery counts against the county.

The Appellate Division dismissed the claims, holding that in the PREP Act, Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the secretary, including one based upon a defendant's failure to obtain consent. The court also reasoned that the compensation fund and federal action for willful misconduct claims provided the mother with alternative legal remedies.

In a second case brought as a result of the H1N1 outbreak, in Kehler v. Hood,[vii] plaintiffs sued the manufacturer of the vaccine, claiming it was in defective condition and the manufacturer failed to warn of the inherent danger of the vaccine. The U.S. District Court for the Eastern District of Missouri dismissed the claims because the manufacturer was protected by the PREP Act "and [was] absolutely immune from liability for any type of loss caused by the vaccine."[viii] There were no allegations willful misconduct in the Kehler case.

Steps Hospitals Can Take to Mitigate Liability Risk

Using or prescribing medical products authorized by the FDA in an EUA letter, and following the conditions for authorization in the letter, significantly reduce the risk of liability arising from the use of such products during the COVID-19 pandemic.

Even if immunity is not provided under the PREP Act, a number of common law tort defenses may apply to protect hospitals forced to administer unauthorized products. For example, defenses could include informed consent, a patient's assumption of risk, public necessity and that the decision to use the product is reasonable under the circumstances.

Particular to defending an alleged negligence claim, a court likely would consider industry standards of use, studies supporting the unauthorized products, actual data supporting that a hospital's use of the unauthorized product increased lives saved, and other measures that show that the hospital did not breach a duty of care and acted reasonably under the circumstances.

If a hospital is unable to use a product authorized by the FDA, or is unable to follow the conditions of authorization for the authorized product, the hospital should consider the following actions to mitigate its exposure under common law tort principles:

Obtain authorization from a local health authority.

If a particular product is not already subject to an FDA EUA letter, a hospital could seek authorization from a local health authority, such as the New York Department of Health.

Obtain patient-informed consent.

The hospital should advise patients of the circumstances, the benefits and risks involved in using the unauthorized product, and explain any departures from authorized or cleared/approved products. Where possible, hospitals should seek written consent.

Utilize informative product labeling.

Labeling for unauthorized products should state clearly the product is not cleared or approved by the FDA, advise of potential risks and how to mitigate risk, and provide adequate instructions for the intended use in the indicated environments of use.

Develop a protocol.

To the extent possible, hospitals should develop and enforce a protocol of when to resort to using a specific unauthorized product. The protocol should articulate the narrow circumstances in which departures from standard products cleared or approved by the FDA apply, and provide written justifications explaining how the benefits outweigh the potential harm.

Document and monitor use.

Hospitals should document the number of unauthorized products administered or dispensed and monitor any adverse events.

Conclusion

This article is not an unequivocal statement of the law, but instead represents our best interpretation of where things currently stand. This article does not address the potential impacts of the numerous other local, state and federal orders that have been issued in response to the COVID-19 pandemic, but which are not referenced in this article.

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[i] (42 U.S.C. § 243 et. seq.).
[ii] 42 U.S.C § 247d–6d(c)(5)(C).
[iii] 42 U.S.C § 247d–6d(b)(8).
[iv] 42 U.S.C §247d-6e(a).
[v] See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. 15,198 (March 17, 2020).
[vi] Parker v. St. Lawrence County Public Health Department, 102 A.D.3d 140 (2012).
[vii] Kehler v. Hood, 2012 U.S. Dist. LEXIS 74502 (E.D. Mo. May 30, 2012).
[viii] Kehler v. Hood, 2012 U.S. Dist. LEXIS 74502 (E.D. Mo. May 30, 2012).