



ACC Houston Healthcare Law Practice Group CLE Webinar: The PREP Act

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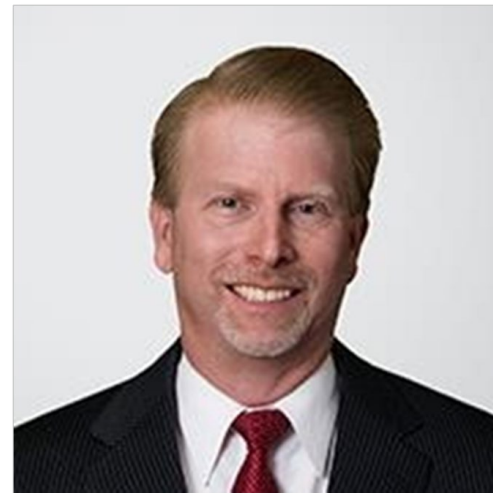
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Agenda



- 01** PREP Act Considerations
- 02** The Ongoing Saga of Interpretation
- 03** The Courts and the PREP Act
- 04** Practical Considerations
- 05** Questions

PREP Act Considerations

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PREP Act Considerations

107-38) shall be transferred to or from the Emergency Response Fund.

This division may be cited as the “Emergency Supplemental Appropriations Act to Address Hurricanes in the Gulf of Mexico and Pandemic Influenza, 2006”.

Public Readiness
and Emergency
Preparedness
Act.
42 USC 201 note.

DIVISION C—PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

SEC. 1. SHORT TITLE.

This division may be cited as the “Public Readiness and Emergency Preparedness Act”.

SEC. 2. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319F-2 the following section:

42 USC 247d-6d.

“SEC. 319F-3. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

“(a) LIABILITY PROTECTIONS.—

“(1) IN GENERAL.—Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

“(2) SCOPE OF CLAIMS FOR LOSS.—

“(A) LOSS.—For purposes of this section, the term ‘loss’ means any type of loss, including—

“(i) death;

“(ii) physical, mental, or emotional injury, illness, disability, or condition;

“(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

“(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

“(B) SCOPE.—The immunity under paragraph (1)

Secretary Azar's Declaration – COVID-19

- Issued March 17, 2020, as 85 FR 15198
- Effective February 4, 2020
- No geographic limitation
- Effective Time Period – February 4, 2020 – October 1, 2024 (or final day the Emergency Declaration is in effect, whichever comes first)
- Population – Any individual who uses or is administered the Covered Countermeasures in accordance with the Declaration

Secretary Azar's Declaration – COVID-19

- Covered Persons (Broadly Defined and Interpreted)
 - Manufacturers
 - Distributors
 - Program Planners
 - Qualified Persons
 - Persons Authorized by Emergency Use Authorization (Section 564 FD&C Act) or by an Authority Having Jurisdiction under the Act

Secretary Azar's Declaration – COVID-19

- Covered Countermeasures
 - Any antiviral, drug, biologic, diagnostic or other device, or 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 products and all components and constituent materials of any such product

Secretary Azar's Declaration – COVID-19

- Administration of Covered Countermeasures
 - Means the physical provision of Covered Countermeasures to recipients
 - Or activities and decisions directly relating to public and private delivery, distribution and dispensing of countermeasures
 - Or management and operation of countermeasures program
 - Or management and operation of locations for purpose of distributing and dispensing countermeasures

Secretary Azar's Declaration – COVID-19

- Limitations

- Liability immunity afforded to Covered Persons ONLY for Covered Countermeasures that are related to:
 - Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, MOUs or other federal agreements; or
 - Activities authorized in accordance with public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of emergency.

Countermeasures Injury Compensation Program

- Section 319F-4 of the PHS Act, 42 U.S.C. 247d-6e, authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.
- To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires “compelling, reliable, valid, medical and scientific evidence.”
- Funded through various sources, including CARES Act (\$27B to HHS), Coronavirus Preparedness and Response Supplemental Appropriations Act (\$3.1B)

The Ongoing Saga of Interpretation

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Original Declaration and Amendments

- **Original Declaration** (March 10, 2020) – Authorizes the Act
- **1st Amendment** (April 10, 2020) – Extends countermeasures to NIOSH respirators
- **2nd Amendment** (June 4, 2020)– Make countermeasures co-extensive with statute
- **3rd Amendment** (Aug. 19, 2020)– add state-licensed pharms to qualified persons
- **4th Amendment** (Dec. 3, 2020) – adds telehealth, invokes Grable doctrine
- **5th Amendment** ** (Jan. 29, 2021) - adds physicians with expired licenses to covered persons
- **6th Amendment** –(Feb. 11, 2021) adds fed employees to covered persons
- **7th Amendment** (March 16, 2021) – adds additional healthworkers to covered counterpersons

Advisory Opinions

Advisory Opinion 20-01 – reasonableness standard

- Date: April 14, 2020

Advisory Opinion 20-02 – PREP Act preempts state law

- Date: May 19, 2020

Advisory Opinion 20-03 – less stringent law not preempted

- Date: October 22, 2020

Advisory Opinion 20-04 – discusses program planner

- Date: October 22, 2020

Advisory Opinion 21-01 – PREP Act completely preempts

- Date: January 8, 2021

Advisory Opinion 21-02 – ACIP not precondition for coverage

- Date: January 12, 2021

Key Issues

- Clarification and expansion on program planners, means of distribution
- Continued expansion of covered persons and covered countermeasures
- Preemption of conflicting state law
- Complete preemption of state law private causes of action – federal question
- Federal jurisdiction under the *Grable* Doctrine
- Immunity for action v. inaction

The Courts and the PREP Act

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Case Law

- Reported decisions
 - Arise in federal district court on motion to remand
 - Concern long-term care
 - Claim negligence, malpractice, wrongful death, other torts and elder abuse
 - Allege insufficient PPE and safety measures
- In all but one case (Garcia / Welltower (C.D. Cal. Feb. 10, 2021) (appeal filed)), courts have rejected:
 - “Complete preemption” (complete preemption of state law cause of action)
 - Grable doctrine (state claims requiring interpreting / challenging a federal statute)
 - Chevron or Skidmore (HHS) deference (post advisory opinion)
 - Federal officer removal (action at the specific direction of federal authorities)
 - Remanded to state court. Removal not proper on basis of federal affirmative defense.

Other Considerations

- Failure to administer countermeasures
 - Purposefulness versus neglectfulness (Adv. Op. 21-01 at 3)
 - The PREP Act provides immunity to facilities “when a claim is brought against them for the countermeasures the facility actually utilized,” rather than failed to use. *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020) (on appeal).
 - Purposeful malpractice / failure to follow guidance (Adv. Op. 20-04 at 3)
 - If a physician “made a decision to do nothing,” despite a threatened outbreak, and that decision “lay outside the realm of reasonable medical judgment, it could give rise to a malpractice claim” that the PREP Act would not preempt. *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 2020 WL 4671091 (D.N.J. Aug. 12, 2020) (on appeal).
- Distinguish before, during and after administration of countermeasures
 - Before: Cold chain management; slips and falls; screening. *Kehler v. Hood*, 2012 WL 1945952 (E.D. Mo. May 30, 2012).
 - After: Monitoring. Slips and falls.
- Missing elements (covered person, causality, covered countermeasure)

Claims Beyond the PREP Act

- The PREP Act has no bearing on lots of claims that are associated with the pandemic such as, most notably:
 - Employment discrimination, retaliation and whistleblower claims
- But where the PREP Act does not apply, there is a chance in other kinds of cases that state immunity laws may apply.
 - The majority of states have by executive order or legislation approved immunities related to the pandemic.
 - Most of these protect healthcare providers, but some also protect organizations that volunteer to host vaccination sites.
 - Most exclude gross negligence and recklessness.
- Waivers, releases and indemnities may also protect. Their enforceability will depend upon state law.



Questions?

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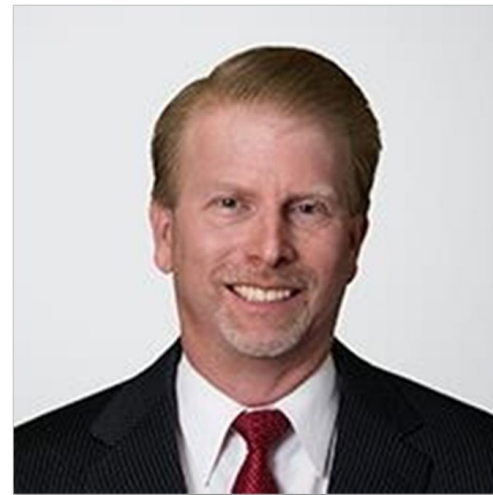
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Thank You

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