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Liability and Insurance Aspects of the Privatization of Vaccine Rollout

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May 6, 2021

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The information in these materials was current as of the date of the presentation (May 6, 2021), but it is subject to change in this quickly evolving legal environment.

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Vaccine Legal Issues: Liability

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Potential Liability Protections

- Federal PREP Act
 - Vaccine design, manufacturing, administration and distribution
- State law
 - Businesses, organizations and individual post-vaccination

PREP Act

- The Public Readiness and Emergency Preparedness (PREP) Act was signed into law (Public Law 109-148) in December 2005.
- Allows the Health and Human Services Secretary to issue a declaration to provide federal and state liability immunity to “Covered Persons” against any claim of “loss” relating to the manufacture, distribution, administration, or use of “Covered Countermeasures,” except for claims involving “willful misconduct.”
- Has been used, for example, for outbreaks including:
 - Ebola
 - Zika
 - H1N1

PREP Act – Application to COVID-19 Countermeasures

- The HHS Declaration pertaining to COVID-19 was published on March 17, 2020 retroactive to February 4, 2020, and continues through October 1, 2024.
 - Makes PREP Act applicable to COVID-19 countermeasures
 - Defines requirements and limitations of coverage
 - Amended seven times, most recently on March 11, 2021

PREP Act – Broad Protection from Liability

- PREP Act immunity applies to any “covered person” with respect to all “claims for loss” caused by, arising out of, relating to, or resulting from the “administration” or the “use” of a “covered countermeasure” if a declaration has been issued with respect to that countermeasure. 42 U.S.C. § 247d-6d(a)(1).
 - Immunity from federal or state law, including tort immunity, relating to death, injury, trauma, or damage to property
 - Claims for loss means any type of loss, including death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business-interruption loss
 - Covered claims also include “claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements”

PREP Act – Broad Protection from Liability

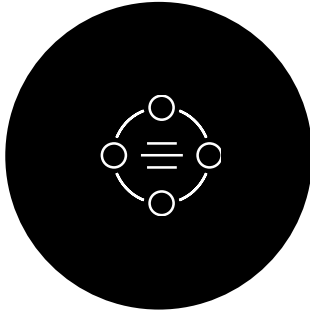
- Reasonable belief safe harbor: Immunity applies
 - Even if the product is not a covered countermeasure—if a person or entity reasonably could have believed that the product was a covered countermeasure
 - Even if the person at issue is not a covered person—if the entity or individual reasonably could have believed that the person was a covered person

PREP Act – Limitations on Protection from Liability

- PREP Act immunity does not extend to liability for:
 - death or serious physical injury caused by willful misconduct by the covered person
 - enforcement actions, whether civil, criminal, or administrative, brought by the federal government
 - claims under federal law for equitable relief (e.g., an injunction compelling or prohibiting some action)
 - foreign claims where the United States has no jurisdiction

PREP Act

HHS Declaration re: COVID-19 addresses the following key considerations:



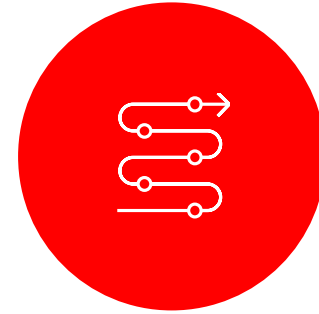
**Covered
Countermeasures**



**Recommended
Activities**



Covered Persons



**Limitations on
Distribution**

PREP Act – Covered Countermeasures

- Covered Countermeasures
 - Any antiviral, other drug, biologic, diagnostic, 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 product
 - A product to address a condition caused by a pandemic therapy, e.g., therapy to address adverse events
 - A product used to enhance the effectiveness of a countermeasure, e.g., vaccine adjuvant
- Covered Countermeasures must be “qualified pandemic or epidemic products” or “security countermeasures,” drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.
- **COVID-19 vaccines under EUA or that receive FDA approval are Covered Countermeasures**

PREP Act – Recommended Activities

- Recommended Activities
 - the manufacture, testing, design, development, distribution, administration, and use of the Covered Countermeasures
- Administration includes physical provision of the countermeasures, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures; management and operation of countermeasure programs; or management and operation of locations for the purpose of distributing and dispensing countermeasures.

PREP Act – Covered Persons



Manufacturers

Distributors

Program planners – State or local government . . . or other person who supervised or administered a program with respect to the administration . . . of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer . . . a covered countermeasure

Qualified persons – A licensed healthcare professional

PREP Act Amendments 5, 6 and 7

- Address Vaccine Administration specifically
- Express goal of reducing workforce barriers to further rapid vaccine administration across US
- 5th amendment ensures healthcare professionals can cross state lines to administer vaccines without fear of violation of state licensing or other prohibition
- 6th amendment adds qualified personnel to the category of qualified persons covered under the PREP Act to include any federal government employee, contractor or volunteer who would distribute or dispense the vaccine
- 7th amendment further expands protection to midwives, paramedics, advanced or intermediate emergency medical technicians (EMTs), physician assistants, respiratory therapists, dentists, podiatrists, optometrists, and veterinarians administering COVID-19 vaccines.

See our recent lawflash: [Additional PREP Act Amendments Accommodate Vaccination Administration Needs](#)

PREP Act – Covered Persons

- A private employer may potentially qualify as a “program planner” with respect to COVID-19 vaccination by:
 - Establishing a program for vaccination of employees;
 - Retaining a vendor to administer vaccines to employees; or
 - Providing the use of a company facility for administration of vaccines.

PREP Act – Limitations on Distribution

- In order to qualify for immunity, the Covered Person, Covered Activities, and Covered Countermeasures must be related to:
 - Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or
 - Activities authorized in accordance with the public health and medical response of the “Authority Having Jurisdiction” to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a “Declaration of an Emergency”
 - Expanded recently to include private distribution channels

PREP Act – Considerations for Private Employer Vaccination Programs

- Closed POD Operation is potentially protected by the PREP Act
 - Vaccine distribution coordinated with governmental entity (state or local health department).
 - Memorialize distribution arrangement to document and support the applicability of the PREP Act.
- Address in arrangements with vendors
- Need to document
 - Division of responsibilities for:
 - Registration
 - Vaccination forms
 - Compliance with labeling and government requirements
 - Adverse event monitoring and reporting
 - Role of the employer as a “program planner” in coordinating the administration of vaccines

Liability Protections In Post-Vaccination World

- No federal liability protection
 - PREP Act does not cover
 - No federal liability protection passed or on horizon
- State law protections
 - Vary from state to state
 - Rapidly changing
 - Protection of healthcare providers more widely provided
 - Some states have enacted laws granting immunity from COVID-19 claims
 - Intent to encourage reopening of businesses, schools and pre-pandemic activities
 - Generally tied to compliance with govt. requirements and standards

Liability Protections In Post-Vaccination World

Examples of state law protections



Pennsylvania

- Executive Order grants healthcare practitioners protection against liability for good faith actions in response to COVID-19 pandemic at healthcare facilities
- No broad COVID-19 liability protection currently in place for other businesses or entities

Liability Protections In Post-Vaccination World



Examples of state law protections

Florida

- COVID-19 liability claims against businesses and individuals subject to special pleading and physician affidavit requirements
- Court may dismiss if defendant made “good faith effort to substantially comply” with govt. health standards or guidance – immunity from civil liability
 - If conflicting standards compliance with one sufficient
 - Even if no good faith effort, gross negligence standard applies

Liability Protections In Post-Vaccination World



Examples of state law protections

Michigan

- Immunity from COVID-19 liability claims for person or entity “who acts in compliance with all federal, state, and local statutes, rules regulations, executive orders, and agency orders related to COVID-19 that had not been denied legal effect at the time” of exposure
- Isolated de minimis deviation from strict compliance “unrelated to plaintiff’s injuries” does not deny immunity

Vaccine Legal Issues: Insurance

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Workers' Compensation

- State-specific analysis, potentially dependent on:
 - Whether vaccination is mandated
 - Where vaccination occurs
- If mandatory, likely covered *
 - Resulting injuries from other required inoculations found to be “in the course of employment” or “for the employer’s benefit,” and, thus, compensable
 - Potential caveat for vaccines approved only under EUA
- If optional:
 - Vaccination at the workplace is potentially covered *
 - Vaccination at another location (e.g., public distribution) is likely not covered

Liability Insurance

- Commercial general liability (CGL) policies may provide defense and liability coverage
- Does COVID-19 pandemic constitute “occurrence” or “accident” that is covered?
 - Foreseeability -- availability of and compliance with guidance may be critical
- Potentially applicable exclusions
 - Communicable disease exclusion
 - Fungi, mold, pathogen and microbes exclusion
 - Pollution exclusion
 - Employer’s liability exclusion – extend to family members of employee?

Legal Issues Concerning Vaccine Mandates

- State authority to mandate vaccination
 - *Jacobson v. Commonwealth of Massachusetts* (1905) – question
- State laws mandating vaccines
 - Typically found in Human Resources Code; Education Code; child-care statutes (mandates to attend public school, college); or childcare centers to prevent the spread of measles, mumps, rubella, tetanus, and diphtheria
 - <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>
 - May require immunization of healthcare workers and of patients and residents in healthcare facilities
 - Mandates are not the norm due to the rise of the anti-vaxx movement
- Exemptions
 - Can be for medical, religious, and/or philosophical reasons – differs by state

Pending State Legislation

State COVID-19 vaccine legislation introduced but not yet enacted

More information: [National Conference of State Legislatures](#)

New York AB 11179

Mandates vaccination if public health officials determine that New York residents are not developing sufficient immunity from COVID-19

Tennessee HB 13

Prohibits state and local authorities from forcing, requiring, or coercing a person to receive an immunization or vaccination for COVID-19 against the person's will

New Jersey A 4659

Prohibits a government entity or school from requiring influenza vaccinations for persons who are 18 years of age or younger

Federal Regulation

- Protecting Statutory Conscience Rights in Health Care
 - Final rule promulgated May 21, 2018
 - 84 Fed. Reg. 23,170; 45 C.F.R. pt. 88
 - Vacated November 21, 2019
 - *New York v. HHS*, No. 19-cv-4676-PAE (S.D.N.Y. Nov. 6, 2019)
- Biden–Harris transition proposals
 - Establish federal vaccination centers to be administered by FEMA and/or the National Guard
 - Distribute all available vaccine doses to the states

POD Scenarios

- Employee Benefits In-House Provider deploys vaccine for employees on site.
- Employer seeks to deploy vaccine in multiple states on site.
- Employer contracts with pharmacy to vaccinate workforce.
- Employer On-Site Wellness Clinic Director seeks to obtain 100% vaccination rate – vows to travel state-to-state to personally vaccinate all employees.

Common Legal Considerations for PODs

- Employee Benefits Plans
- Insurance coverage for non-employees
- State licensure issues for personnel and scope of service
- Pharmaceutical/Drug Enforcement issues with receipt of vaccine and wastage
- CDC Guidelines for vaccination sites
- Compliance with vaccine storage
- Cross-state issues

Enforcement

Government Enforcement Activities Related to COVID-19

- Uptick in State AG and DOJ investigations related to CDC/HHS public health protocol compliance (infection control and prevention)
- Expect broad government scrutiny of vaccine roll-out issues to include distribution and supply chain issues
- Current DOJ COVID task force has focused on criminal scams in misuse of PPP and other COVID relief funds.
- FTC is ramping up on vaccine scams related to surveys, vaccine cards and purchase access issues.
- Maryland USAO seized website domains purporting to provide vaccines for purchase
- Initially, enforcement is low level fruit but increasing scrutiny of established companies.

Government Enforcement Activities Related to COVID-19

- No immunity for administrative, civil and criminal enforcement.
- Healthcare professional licensure and scope of practice have been the subject of potential immunity. The Coronavirus Aid, Relief, and Economic Security Act provides immunity for volunteer health care providers during the COVID-19 emergency declaration, if a volunteer acts in good faith and within the scope of their medical license.
- At least 27 states, the District of Columbia and Puerto Rico have provided some level of immunity for health care workers, health facilities or both during the pandemic through executive or legislative action.

Limited Case Law

CASE

***Parker v. St. Lawrence County
Pub. Health Dept., 102 A.D.3d
140 (N.Y. App. Div. 2012).***

***Casabianca v. Mount Sinai
Med. Ctr., Inc., 2014 NY Slip
Op 33583(U), 2014 N.Y. Misc.
LEXIS 5998 (NY Sup. Ct.
2014)***

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DETAILS

- Arose from H1N1 outbreak and Secretary Declaration in 2009
- Claim for the damages to a minor child from the administration of Peramivir (a recommended Countermeasure without parental consent)
- Court found Prep Act Immunity applied – preemption of state tort law “broad and sweeping”

- Another vaccine-related case arising from the Secretary’s H1N1 Declaration
- Claim for damages for patient who did not receive an H1N1 vaccine in connection with upcoming procedure
- Court held that the Prep Act did not preempt state malpractice claim because the covered countermeasure was not administered

Limited Case Law, *cont.*

- *Parker and Casabianca* are both New York state court cases
 - Limited precedent beyond New York
- Federal case in Eastern District of Missouri did not reach the merits of the Prep Act
 - Parties agreed Defendant drug manufacturer was covered by Prep Act immunity (*Kehler v. Hood*, Case No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. 2012))
- *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 253 (2011)
 - *Not a PREP Act case*
 - Broad statutory textual decision upholding immunities of National Childhood Vaccine Injury Act of 1986

Immunity Assessment

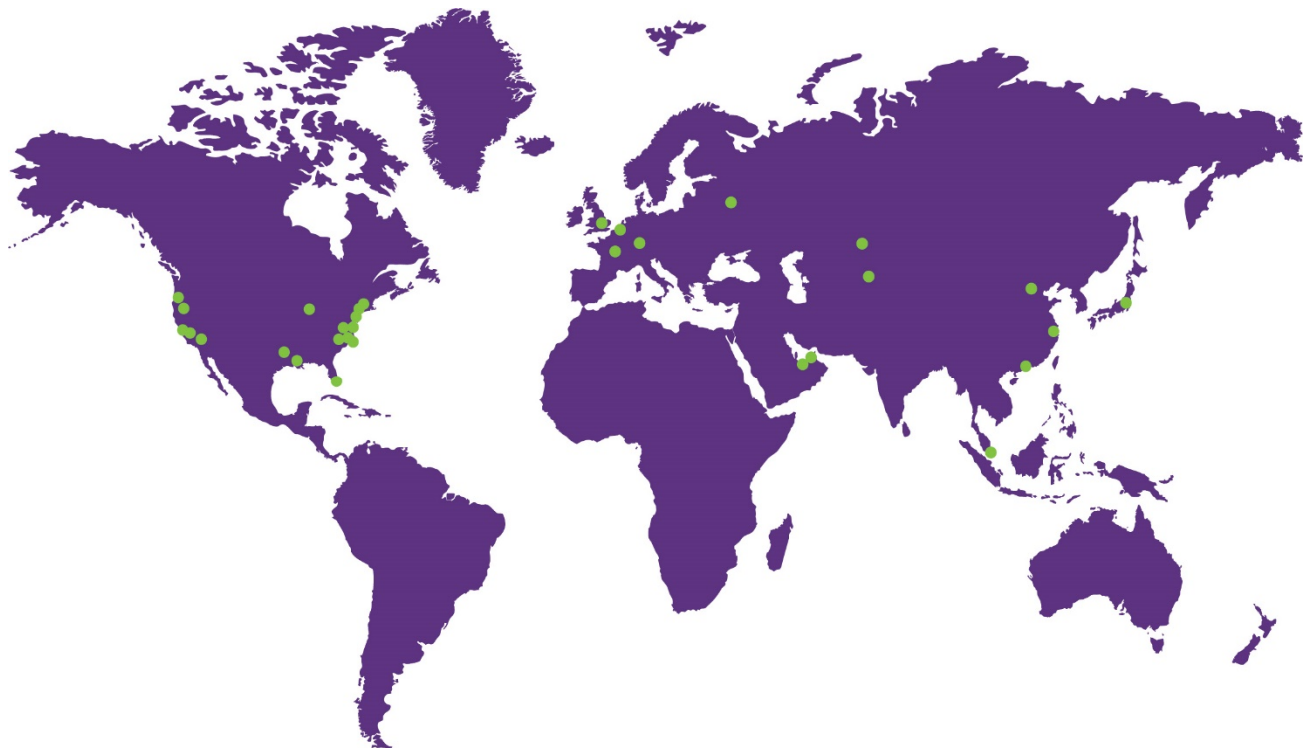
- Checklist and confirm all PREP Act requirements and specific Declaration COVID-19 requirements
- Assess and document steps to establish and comply with PREP Act requirements for covered countermeasures and status as qualified person
- Assure that the provider can meet good faith standard of covered persons engaging in recommended activities for covered medical countermeasures.
- Determine any actions through *Authority Under Jurisdiction* that may expand immunity, including for volunteers
- Investigate all state declarations, orders, and benchmark immunity requirements
- Assess use of COVID-19 waivers or contract amendments to incorporate PREP Act or other immunity provisions or establish assumption of risk defenses
- Determine insurer position on whether and how coverage (including duty to defend) is impacted by PREP Act and related immunities

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