# NC Shamber

Vaccine Rollout:
Workplace & Legal Implications



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# Vaccine Rollout: Workplace and Legal Implications

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# OSHA v. COVID

- Currently no NC or federal OSHA standard on COVID-19
  - Enforcement currently based on General Duty Clause and existing standards (e.g. PPE, respiratory, "housekeeping," recordkeeping, and reporting standards)
- Despite vaccine distribution ramping up and decline in numbers, federal OSHA set to release Emergency
   Temporary Standards (ETS) on COVID-19 by March 15
  - OSHA must show "grave danger" to employees that can be addressed by an ETS to bypass normal rulemaking procedures

# What will the ETS Look Like?

## ■ Possible Approaches:

- Virginia COVID Standard
  - May be viewed as more reasonable, "middle-ground" approach
  - Easy to implement but many reasons why federal OSHA may not adopt
- Infectious Diseases Standard
  - Started in 2010 but never finished or released following feedback
  - Could be applied to future pandemics
  - Possible "one size fits all" approach across all industries
  - More likely to face legal challenges due to impact and implementation

# **Common Themes**

- Conduct Hazard Assessment and Adopt a Written
   COVID-19 Prevention Program
- Adopt Measures to Limit the Spread
  - Distancing, Barriers, Face Coverings/PPE, Ventilation, Hygiene, Cleaning
- Keep Infected/Potentially Infected Workers Out
- No Retaliation for Employees Reporting Issues

# Where does this leave NC?

- NCDOL denied an October request by labor advocacy groups to create a statewide COVID standard
- Same groups filed a complaint with federal OSHA claiming NCDOL did not adequately investigate COVID complaints that is still pending
- Normally have 6 months to adopt a permanent standard from federal OSHA; federal and NC OSH laws not clear on timeline for adoption of a temporary standard
  - ETS good for 6 months then OSHA must issue permanent standard

# Federal OSHA and the Vaccine

- Make vaccine available at no cost to all employees (but no requirement to mandate)
  - Provide information and training on the benefits and safety of vaccinations
- Make no distinctions between vaccinated and non-vaccinated workers on protocols
  - All workers must follow same face covering and distancing protocols

# ADA Implications for Vaccine

- Vaccine itself not a "medical examination"
  - Can therefore require proof of vaccination for employment
- If vaccine **required** by employer, screening questions must be "job-related and consistent with business necessity" if asked by the employer **or** a contractor of the employer
  - Must be able to show employee who does not answer questions and does not receive vaccination is "direct threat"

# Screening Questions Not Implicated If:

- Employer has offered a vaccination to employees on a voluntary basis only
  - Employee's decision to answer disability-related screening questions also must be voluntary
- An employee receives an employer-required vaccination from a third party that does not have a contract with the employer

# Other Potential Pitfalls

- Family medical history questions violate GINA
- Must perform direct threat/reasonable accommodation analysis for employees unable to receive employer-required vaccine due to disability or sincerely held religious belief or practice
- Vaccine incentives may implicate wage and hour,
   ADA, Title VII, and tax concerns

# **Concluding Thoughts**

- Consider OSHA "Common Themes" as a baseline
- Encourage employees to get vaccinated but only require if there is a direct threat to safety and health of employees or others if some not vaccinated
- Additional PTO/scheduling flexibility to get vaccine and recover from side effects may be best incentive
- Keep information on vaccination status and employee medical information confidential

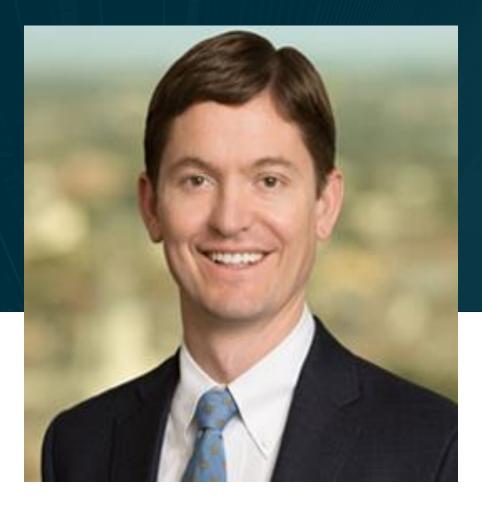
## Resources

- OSHA: https://www.osha.gov/coronavirus/safework
- **EEOC:** https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws
- Ogletree Deakins Resources:
- https://ogletree.com/coronavirus-covid-19-resourcecenter/
- https://ogletree.com/webinars-seminars/

# Thank You and Questions

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## **Vaccine Rollout: PREP Act**

Using the PREP ACT to reduce liability risk

## Roadmap

- 1. What are the risks to my business?
- 2. What is the PREP Act and how can it help?
- 3. What do I have to do to ensure my business is covered?
- 4. Examples, takeaways and resources



## What are the liability risks?

#### **Lawsuits**

- 1. Vaccines very safe but not perfect
- 2. Failure or delay in administering vaccine
- 3. Failure to prevent spread



#### What is the PREP Act?

#### **Public Readiness and Emergency Preparedness Act (PREP Act)**

- 1. Federal Law passed in 2005
- 2. Purpose: to encourage participation in the fight against public health emergencies
- 3. When is it in effect? Declaration by Secretary of HHS
- 4. What does it do? Provides immunity from liability for certain legal claims
  - a. Example
- 5. Notes/Exceptions



## Is the PREP Act currently in effect?

#### Yes!

March 10, 2020: Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (85 FR 15198)

- "I have determined that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency."
- "I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures" and subject to "limitations on distribution"



## Will the PREP Act protect my business?

If you meet general requirements of the Act and the Declaration

- Covered Person
- Recommended Activity
- Covered Countermeasure
- Limitations on Distribution



## Is my business a "covered person"?

- <u>Statutory Definition:</u> manufacturers, distributors, *program planners*, and qualified persons, and their officials, agents, and employees, and the United States.
- Program Planners:
  - a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure.
  - May be a private sector employer or community group
  - Schools, businesses, places of worship
  - Government workers and volunteers
- HHS Secretary Broad Interpretation



## Is my business engaged in "Recommended Activities"?

". . . the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." 3/17/20 DHHS Declaration

#### Includes:

- 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 purposes of distributing and dispensing countermeasures."
- Theme connection between the activity and the COVID countermeasure



### What is a "covered countermeasure"?

"any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective 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" 3/17/20 DHHS Declaration

Vaccines are included, but they must be authorized for investigational or emergency use.



### PREP Act: Limitations on Distribution

#### Recommended Activities must relate to:

- Present or future federal contracts, agreement, grants etc.
- "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."
- "Authority Having Jurisdiction": public agency or its delegate
- December 3, 2020 Amendment adds an additional distribution channel that would provide more protections for private distribution channels
- <u>Translation:</u> acting in accordance with official guidance from public health officials



## PREP Act: Example



The CDC prioritizes certain populations to receive the COVID-19 vaccine while there are limited doses. A pharmacy prioritizes the CDC-designated populations for receiving the COVID-19 vaccine. Because of that prioritization, someone seeks but does not receive the COVID-19 vaccine from the pharmacy because of the limited quantity of vaccine doses. That person gets COVID-19 and sues the pharmacy.

#### HHS OGC: PREP Act immunity applies

- Pharmacy is a program planner (Covered Person)
- The decision applying the prioritization falls under definition of "Administration" (Recommended Activity)
- Authorized vaccine (Covered Countermeasure)
- Administering the vaccine pursuant to CDC prioritization complied with an Authority Having Jurisdiction (Limits on Distribution)



## PREP Act - Takeaways

#### **Liability Protection**

#### 4 Requirements

- Covered Person
- Recommended Activity
- Covered Countermeasure
- Subject to the Limitations on Distribution

Trend – more expansive application



#### Resources

https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf

https://www.phelps.com/protecting-your-company-against-covid-19-vaccine-suits-12-18-2020

https://www.phelps.com/COVID-19



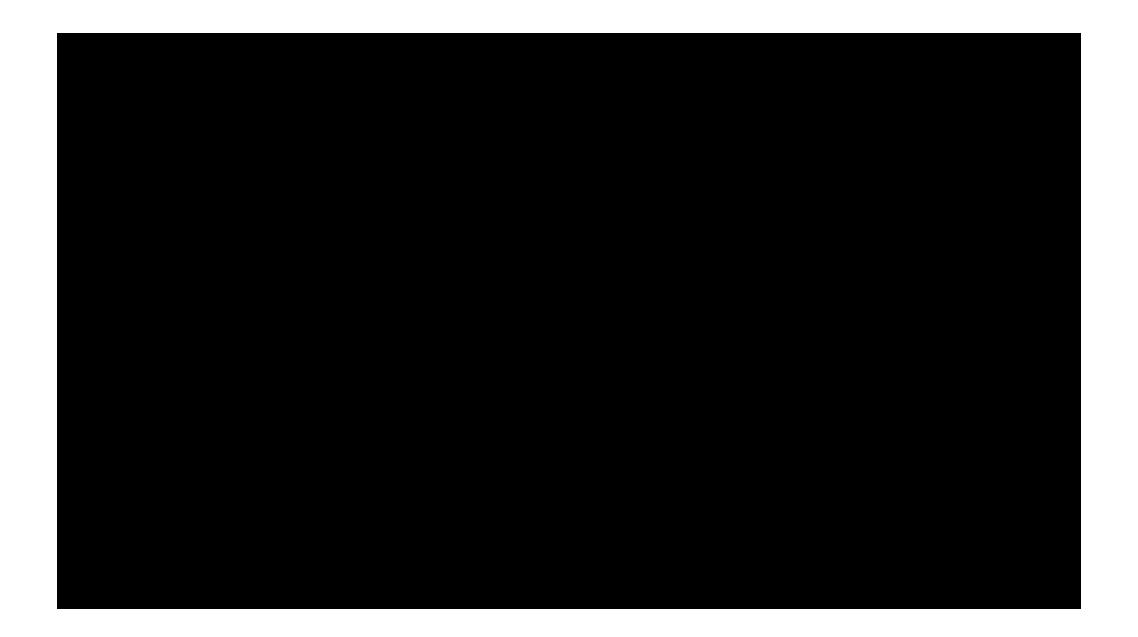
## **Questions?**

# Thank you for attending! Please contact me with any questions.

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