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COVID-19 Vaccines: Legal Considerations in Light of Latest Developments

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The information in these materials was current as of the date of the presentation (January 21, 2021), but it is subject to change in this quickly evolving legal environment.

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Polling Questions

Please take a moment to respond to the poll questions on the right side of your screen.

1. Will your company mandate that employees get the COVID-19 vaccine when able to do so?
2. Will your company recommend, but not require, employees to get the COVID-19 vaccine?
3. Is your company currently planning to give incentives to increase vaccination rates among employees?
4. If yes, what kinds of incentives are being considered?

The Vaccine and FDA Approval

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Update on Biden's COVID-19 Vaccine Product Team

- New Biden-appointed FDA commissioner (Dr. Woodcock?) may have a different approach to vaccine review and approval—science and credibility of transparent review will be a focus with a continued emphasis on speed.
- Operation Warp Speed head Dr. Slaoui has resigned and has been replaced by Dr. David Kessler.
- Co-chairs of Biden Vaccine Advisory Panel include Dr. David Kessler, Dr. Vivek Murthy (Surgeon General nominee), and Dr. Marcella Nunex-Smith; others include officials with BARDA and National Security Council experience, and a former global AIDS coordinator, suggesting an equitable and more global approach to managing the pandemic.
- Dr. Fauci, as chief medical adviser on COVID-19 to the president, should be a consistent presence in discussions and policy.
- Jeff Zients, as Biden's COVID-19 coordinator in the White House, has significant experience running large government programs.

FDA Status of Vaccine Products

- Two vaccines currently approved under Emergency Use Authorizations (EUAs)—Pfizer and Moderna
 - Both require two shots and reported to be above 90% effective
 - Both require freezer storage
 - Both reported to cost above \$25/dose
 - Adverse effects reported in persons prone to food and related allergies; new possible serious adverse event report for Pfizer product
 - Biden administration has pledged to release all COVID-19 vaccine doses for immediate use, notwithstanding approval restrictions

FDA Status of Vaccine Products

- Several other vaccines reported to be close to final review or submission of request for EUA—AstraZeneca and Johnson & Johnson (J&J)

AstraZeneca

- Approved in UK for emergency use
- Also requires two shots, but questions raised about efficacy with one shot
- Can be stored at normal refrigerated temperature
- Cost reported to be below \$10/dose
- Submission to FDA expected sometime in February, with approval sometime in April

J&J

- One-shot vaccine, so it may have significant advantages over two-shot vaccines
- Reported that data to support EUA may be submitted to FDA in the next several weeks
- Issues with manufacturing have been reported to slow the availability of the vaccine until mid- to late spring
- Questions raised about whether J&J can meet its contract commitments under Operation Warp Speed

FDA Status of Vaccine Products

- Both AstraZeneca and J&J vaccines use different/more traditional technologies involving use of the adenovirus vectors
- Other vaccines in development continue to be administered in clinical trials
- Other global vaccines such as Chinese SinoVac vaccine and Russian vaccine Sputnik V, depending on efficacy issues, could disrupt global supply

Ongoing Regulatory Questions Concerning Vaccines for Biden FDA

1

Whether the efficacy standards for vaccine review will be the same once there are multiple different vaccines available—one-shot vaccines change the risk/benefit analysis.

2

Will FDA allow comparative statements to be used in connection with the vaccines?

3

How quickly will labeling changes under either EUAs or full approvals be required as adverse event data is compiled?

4

What additional data might FDA request for full approvals, beyond AE information, e.g., manufacturing, pediatric, and special-population clinical data, mixing vaccines?

5

What are the legal effects of state or local deviations in vaccine administration from FDA-approved labels, i.e., does cutting the dose, or varying the administration instructions, create liability for the entities? Will FDA move to amend the EUAs for these products to reflect actual administration patterns?

Vaccine Distribution

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Vaccine Distribution CDC Recommendations

Advisory Committee on Immunization Practices (ACIP)

Phase 1a

Frontline healthcare workers; residents of long-term-care facilities

Phase 1b

Frontline essential workers (teachers, childcare, meat plants, grocery stores, prisons, public transit); individuals age 75+

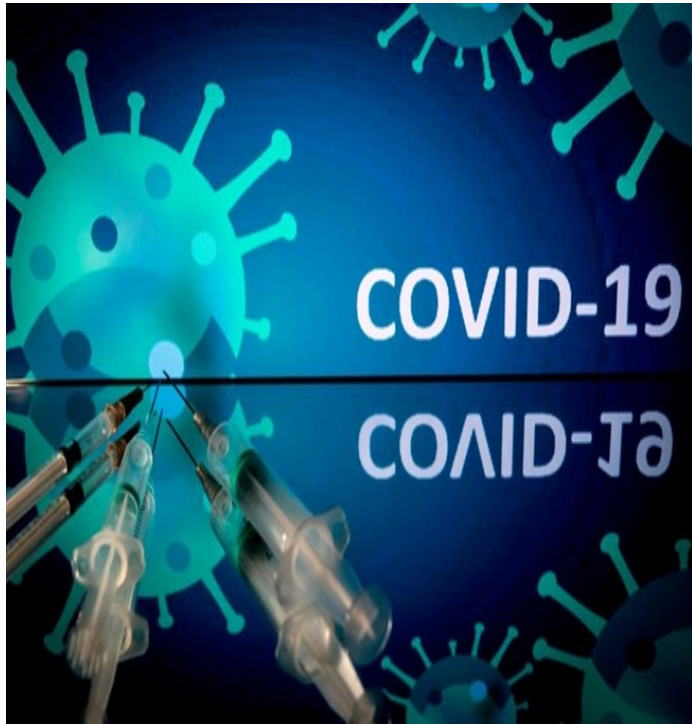
Phase 1c

Individuals age 65-75; individuals age 16+ with high-risk medical conditions; other essential workers

Implementation of ACIP's recommendations varies by jurisdiction

States may determine any limits and restrictions on vaccine distribution

Vaccine Distribution Rollout



- CDC ACIP guidelines followed by states, but distribution timing differs state to state
 - Practically, we have seen:
 - Supply isn't keeping up with demand
 - Disparity in distribution across US
 - Workforce capacity to put "shots in arms"
 - Vaccine hesitancy/folks jumping the line
- Biden–Harris transition team calls for release of vaccine more rapidly to put "shots in arms"
- Trump administration reverses course, calls for a more rapid release of stockpile and production

Vaccine Distribution Rollout

- States organizing distribution in a variety of ways:
 - Commissions under the state health department
 - Via the governor's office
 - Task forces that include stakeholders
 - State health officials and county/local health officials coordinate on distribution



Vaccine Points of Distribution (PODs)

Community Locations

- State/local agencies that dispense and administer vaccines

Closed PODs

- Closed PODs staffed and managed by organizations for their own workers (e.g., employees and possibly their family members)
 - Closed POD obligations:
 - Provide clinical personnel (or third-party vendors) qualified to administer the vaccine
 - Vaccine storage and transportation from the local public health agency to the workplace
- Reach out to local public health agencies to determine feasibility

Vaccine Legal Issues at the Federal Level

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No Federal Mandates . . .Yet

- Currently:
 - No federal requirement for employers to provide or offer to provide the vaccine.
 - No federal prohibition on employers mandating or recommending the vaccine.
- Caveats:
 - No word from OSHA . . .yet.
 - General Duty Clause
 - Temporary or permanent standard (e.g., Hepatitis B vaccinations)
 - State laws may provide otherwise, in terms of either prohibiting or requiring mandatory vaccinations.

EEOC: An Employer May Mandate COVID-19 Vaccines

- Provided that reasonable accommodations (absent undue hardship) are provided under the ADA (for disabilities) and Title VII (for sincerely held religious beliefs).
 - Qualifying disabilities likely narrow
 - May ask for proof of sincerely held religious beliefs, in some circumstances
- Caveats:
 - Likely a mandatory subject of bargaining for unionized companies (if permitted at all by a CBA)
 - EEOC position may not be accepted by the courts
 - State laws may provide additional exceptions or broader accommodation requirements (e.g., political objectors)

Supporting a Vaccine Mandate under the ADA

- EEOC: Vaccine requirement is a permissible safety-based qualification standard under the ADA, if an unvaccinated employee poses a direct threat to the health and safety of others in the workplace.
 - Direct Threat – “a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation.”
 - Must conduct individualized assessment and rely on current medical judgment.
 - “Direct Threat” is unlikely to exist for remote workers.
 - EEOC: An employer’s “conclusion that there is a direct threat would include a determination that an unvaccinated individual will expose others to the virus in the worksite.”
 - Assessment should be ongoing and evolve, as risk factors may change over time.

Accommodating Unvaccinated Employees

- Accommodations may include additional protective gear, isolating or moving an employee's workstation, modifying nonessential job duties, or temporary reassignment.
- EEOC: It is lawful to exclude an employee who cannot get vaccinated because of a disability or sincerely held religious belief if there is no available reasonable accommodation.
 - ADA: Consider undue hardship and direct threat analysis
 - Title VII: Consider undue hardship analysis (which may include safety risks)
- If no workplace accommodations are available, consider whether the employee may be able to perform the position remotely.
- If remote work is not possible, consider available leave options under federal, state, and local laws and the employer's policies.

Mandating Vaccines – Practical Considerations

Consider the impact on employee morale

- Safety concerns (particularly with respect to vaccines approved under an EUA)
- Ideological or political objections
- Potential for increased union organizing efforts

Potential turnover and staffing shortages

- Some employees may feel so strongly in their convictions that they choose to quit
- If a significant number of employees stand to quit, then what?
- Must be prepared and willing to terminate (otherwise high performing) employees who refuse vaccination

Voluntary Vaccines – Incentives Generally

Big Question: How to increase the number of employees who get vaccinated if it's not mandatory?

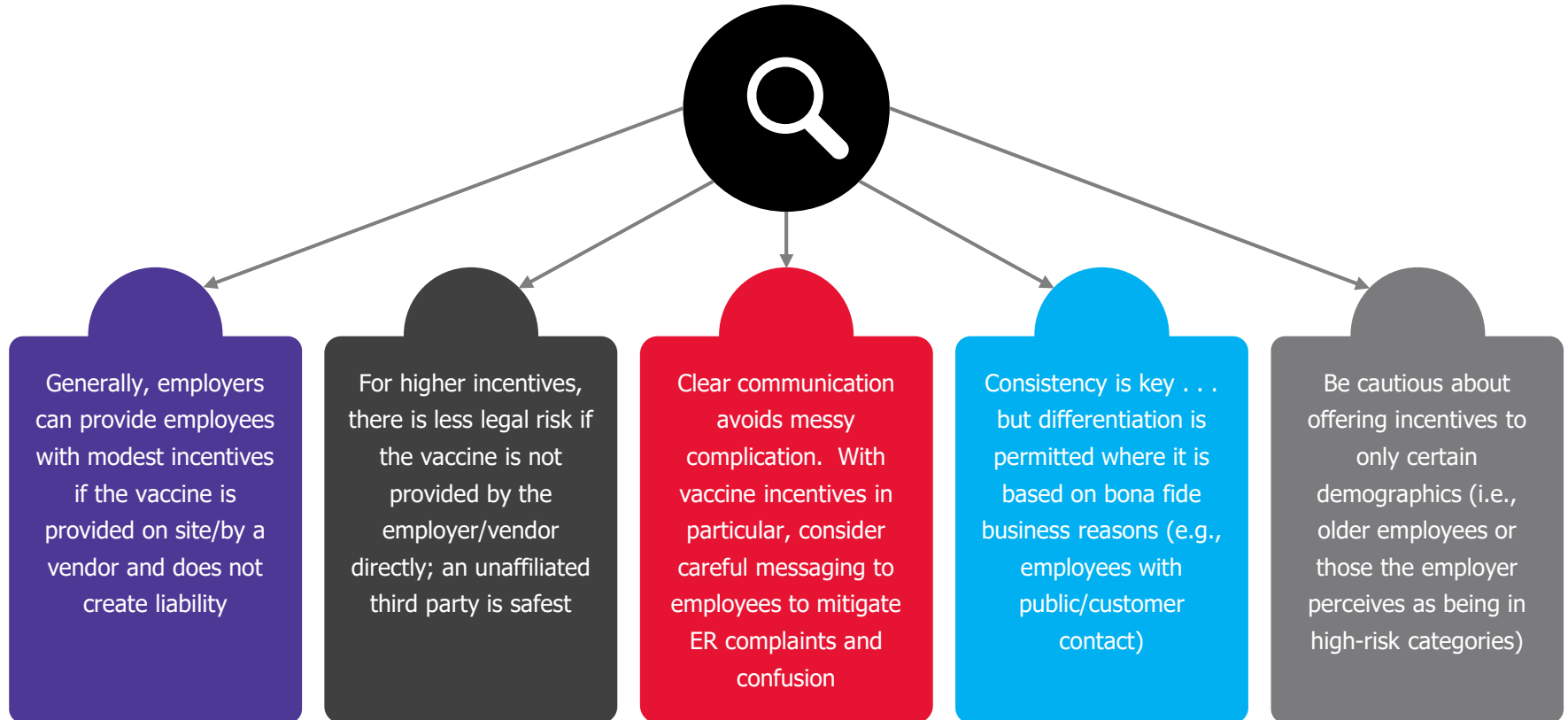
- Employers have broad discretion in encouraging employees to get vaccinated.
- Incentive efforts:
 - Financial incentives
 - Health and wellness campaign
 - Video of senior leadership getting vaccinated (if eligible)
 - Gift cards/swag/store credit
 - PTO time

Voluntary Vaccines – Financial Incentives

Big Question: Who is providing the vaccine?

- Any contractual relationship with the employer?
- If contractual relationship, federal employer wellness program regulations apply
- Although the vaccine itself is not a medical exam, prescreening questions are disability-related inquiries
- Prescreening questions must be “job-related and consistent with business necessity” OR part of a “voluntary” wellness program
- EEOC position is that if the financial incentive is too high, it could be deemed coercive
 - EEOC has not issued any guidance specific to giving incentives for a COVID-19 vaccine
- Proposed EEOC regulations say incentives can only be *de minimis*, but these are not final and have not been tested in court

Voluntary Vaccines – Incentives



Voluntary Vaccines: On-site vs. Off-site

On-site

- Easier to control, but there is a greater potential for liability
- Gain control of documentation on who was vaccinated and when
- Can provide vaccines to employees on scheduled work time (but be aware of side effects)

Off-site

- Less issues with liability, but more variance in how employees are vaccinated
- Can be difficult to get proof of vaccine status from employees
- If the vaccine is required or too heavily incentivized, may have wage and hour concerns, and time spent traveling and getting vaccinated can be compensable

Proof of Vaccination

Big Question: Can an employer require its employees to show proof of vaccination?

- Whether a vaccine is mandatory, incentivized, or purely voluntary, employers can ask for proof of vaccination.
 - However, questions about why an employee was not vaccinated can only be asked where they are job related and consistent with business necessity
- Vaccination documents should be treated as confidential medical records under the ADA.
- Employers with a mandatory vaccine requirement for new hires can refuse employment for those who have not received a vaccine.
 - But they need to provide accommodations to those who did not get vaccinated due to disability or religious needs.

Safety Measures after Vaccination

Big Question: Can we get rid of mask standards/social distancing for vaccinated employees?

- Not so fast; state and local guidance is still in place requiring safety measures for all in-person work
- This guidance generally is not premised on vaccinations and does not sunset for vaccinated employees
- Data are promising, but not definitive, regarding the possibility of transmission for vaccinated workers
- Potential liability if an employer relies only on vaccines to prevent the spread of COVID-19 and removes other workplace safety measures

HIPAA Considerations

- Do HIPAA privacy rules apply if an employer obtains medical information in connection with a vaccine program?
 - No, unless the employer is acting as a healthcare provider or insurer.
- Third-party vendors who administer vaccines are likely subject to HIPAA (and will likely require signed disclosure authorizations from vaccine recipients).
- Employers can ask employees about their vaccination status without implicating HIPAA's privacy rules.
- If a workplace wellness plan to distribute vaccines is offered as part of an employer's group health plan, HIPAA may be triggered.

ERISA Considerations

- Mandatory vaccine requirements may implicate ERISA.
- Section 3(1) of ERISA defines the term “employee welfare benefit plan” as an employer plan “established or maintained for the purpose of” providing medical benefits or benefits in the event of sickness.
- Arguably, a mandatory vaccine program is maintained to ensure the health and safety of the workplace, and the medical benefit to the employee is incidental.
- Current uncertainty about whether government agencies consider a mandatory COVID-19 vaccine program to be an ERISA plan.
- CARES Act mandates that all group health plans provide coverage for the COVID-19 vaccine. So, if the government stops providing payment for vaccines, then employer health plans will need to start covering the vaccine.

Vaccine Legal Issues at the State Level

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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

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Vaccine Legal Issues: Liability

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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

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 four times, most recently on December 3, 2020

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:



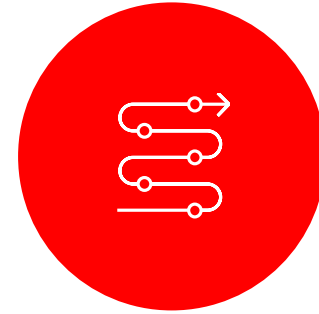
**Covered
Countermeasures**



**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 . . . 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 – 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

Additional Resources

Vaccine FAQs and **State-by-State Vaccine Requirements Tracker** available to Morgan Lewis clients for a flat fee.

Contact your ML lawyer or one of today's presenters for more information.

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View our [Questions on Vaccines](#) resource page

Prepare for the impact of global events on our [Navigating the NEXT](#) resource page

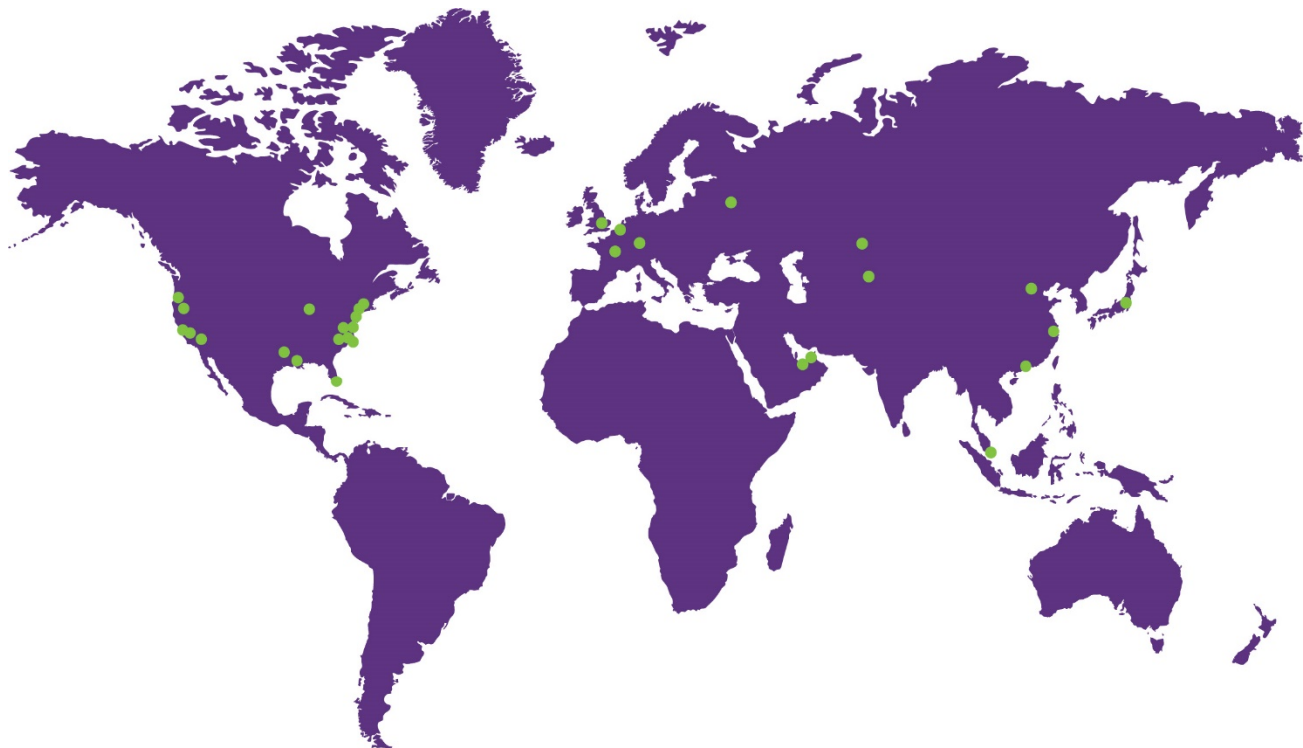


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