

Threading the Needle

Understanding the Laws, Limitations, and Best Practices for COVID-19 Vaccinations



January 7, 2021

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Today's Discussion

- Welcome
- How Does the Vaccine Rollout Work?
- Mandatory vs. Voluntary Vaccination: Policies and Considerations
- Benefits Considerations and Incentives to Vaccinate

How Does the Vaccine Rollout Work?

FDA Emergency Use Authorization



- For unapproved medical products to be used in an emergency to diagnose, treat, or prevent emerging infectious disease agents when there are no adequate, approved, and available alternatives.
- FDA determines that the known and potential benefits outweigh the known and potential risks of the vaccine.
- Can be based on a final analysis or interim analysis of a phase 3 clinical efficacy trial.

PREP Act

- Immunity from suit and liability except in cases of willful misconduct.
- Any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (includes vaccines).
- Gives Pfizer and Moderna general immunity.
- Can protect employers holding onsite vaccinations.
- Caution: There are specific requirements for PREP Act coverage.



CDC Priority List

Advisory Committee on Immunization Practices

- Phase 1a: Health care personnel and long-term care facility residents.
- Phase 1b: Persons aged ≥ 75 years and non-health care frontline essential workers.
- Phase 1c: Persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.
- Phase 2: All other persons aged ≥ 16 years not already recommended for vaccination in Phases 1a, 1b, or 1c.



State Priority Lists

- Submit to CDC and based on CDC guidance.
- Vary widely.
- Continuously amended.
- CDC distributes vaccines to states. States distribute at the local level (e.g., counties), local level distributes to vaccination providers.
- As of January 5th, nearly 5 million people in the U.S. had received the first dose of the vaccine.



Herd Immunity

- When a virus cannot spread because it repeatedly encounters people who are protected against infection. Any new outbreak peters out.
- If 80% of a population is immune to a virus, four out of every five people who encounter someone with the disease won't get sick (and won't spread the disease any further).
- Percentage of people who need to be vaccinated varies with each disease.
- When virus is still circulating freely (high community infection), those who have been vaccinated can still be infected.



Healthcare Rollout as a Bellwether

High rates of vaccine rejection in some pockets among frontline workers.

- 20%-40% of frontline workers in Los Angeles County.
- Up to 50% in Riverside County have turned down the vaccine.
- Ohio reported that 60% of nursing home staff have declined the vaccine.

Could play into federal policy about travel and state policies about mandatory vaccinations for school attendance (once the vaccines are approved for children).

Affects return to work and workplace policies.



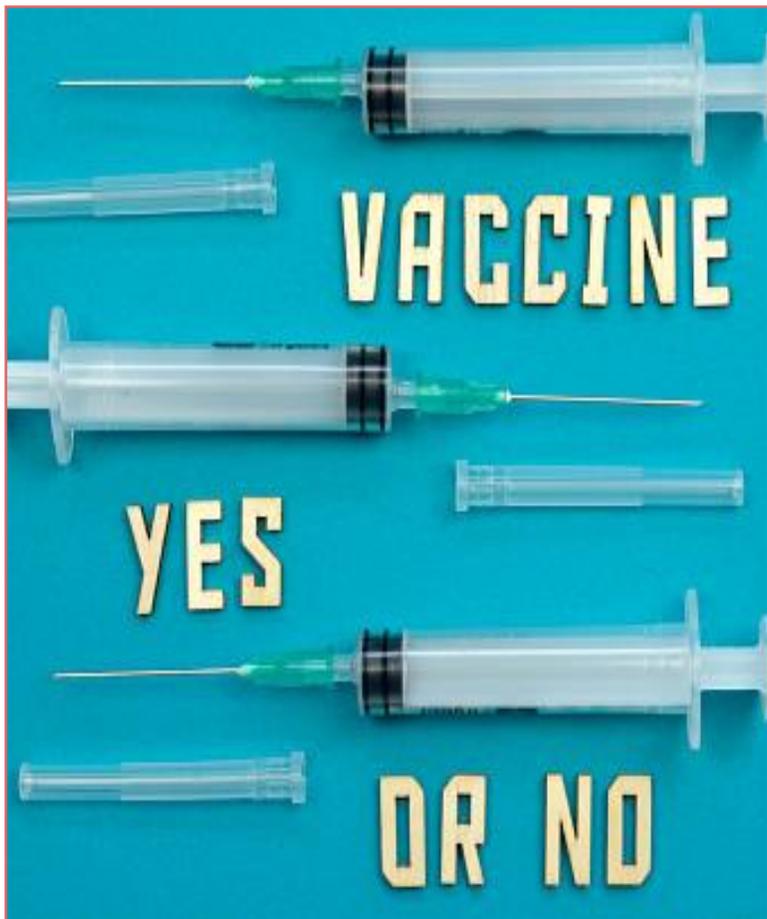
Employers: Tending to the Herd



- Masks and social distancing measures will need to remain in place at the workplace for the foreseeable future.
- Policies about quarantine after an exposure remain in place.
- Employers consider their role in educating workers, promoting vaccination.
- Considerations about when to bring people back into the office.

Mandatory vs. Voluntary Vaccination: Policies and Considerations

Mandatory or Voluntary – How to Decide?



- **There are several factors to consider:**
 - Are mandates lawful under federal law, state law?
 - What are the other obligations (and potential pitfalls) for employers with mandatory vaccination requirements?
 - Does a mandate fit our business? Our industry? Our company culture?
- **No single factor should be considered in isolation.**

Mandatory or Voluntary – How to Decide?

- **Threshold question:** Is a mandate lawful?
- **EEOC Guidance:** Mandates, by themselves, do not violate the ADA or Title VII
- **But:**
 - Guidance may/will evolve;
 - Collective bargaining obligations may apply;
 - State and local law may deviate from federal law; and
 - Practical considerations should be weighed, too.
- **So, whether a mandate is lawful will depend on location, workplace, and industry.**

Mandatory or Voluntary – How to Decide?



- Mandates will trigger other obligations:
 - Who/how will vaccine be administered?
 - Options: Employer-administered; contract with third party; or simply require proof of vaccination.
 - Screening questions may qualify as “medical exams” under the ADA; proof of vaccination does not.
 - When will the vaccine be required?
- Mandates may also trigger workers’ compensation claims for adverse side effects

Mandatory or Voluntary – How to Decide?

- Employers will also need to think through what to do when employee(s) refuse.
 - One vs. many
 - Potential retaliation claims.
 - Protected concerted activity
 - Work stoppages if you do.
 - Work stoppages if you don't.
 - Logistical challenges – not all employees may be able to get vaccinated within weeks or even months of each other.
- Employers will have to accommodate those with disabilities and those who object for sincerely held religious reasons.



Accommodations

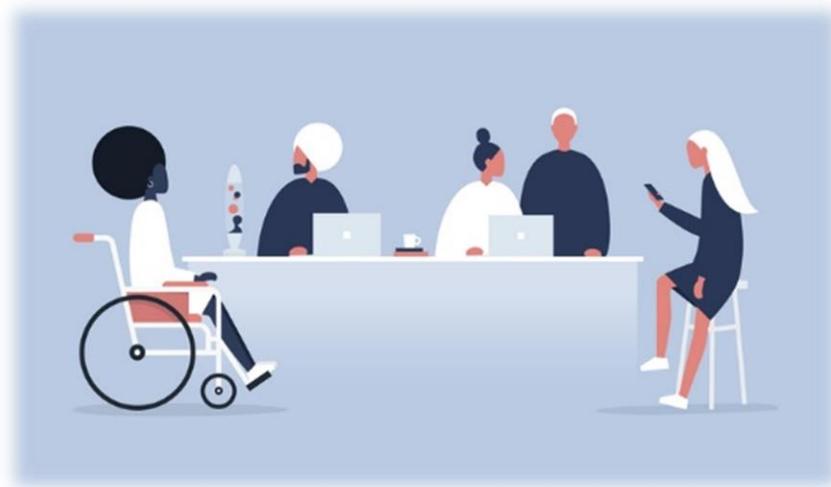
Employers remain under a duty to extend reasonable accommodations to qualified individuals whose disability or religious conviction precludes them from getting vaccinated, unless doing so would cause undue hardship or direct threat of significant harm.

How is Disability Defined?

An individual with a disability is a person who:

- Has a physical or mental impairment that substantially limits one or more major life activities;
- Has a record of such an impairment; or
- Is regarded as having such an impairment.

The definition is construed broadly.



Religious Accommodations

Sincerely held religious belief or practice must *preclude* administration of the vaccine.



Religious Accommodations

Examples:

- Muslims refusing to receive vaccines using pork byproducts.
- Catholics refusing to receive vaccines derived from stem cells/fetal tissue.
- Vegans refusing to receive vaccines derived from any animal products.

Religious Accommodations

“Whether or not a practice or belief is religious is not an issue ... the Commission will define religious practices to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of religious views.”

29 C.F.R. § 1605.1

What is a direct threat?

An employer should be prepared to show that an unvaccinated employee would pose a direct threat due to 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.”

29 C.F.R. 1630.2(r).



Is a direct threat presented?



1. The duration of the risk;
2. The nature and severity of the potential harm;
3. The likelihood that the potential harm will occur; and
4. The imminence of the potential harm.

What May Be a Reasonable Accommodation?



Some alteration (of policy, duty, schedule, workspace, etc.) so that a person with a disability can perform the essential functions of his or her job.

- Special equipment
- Schedule changes
- Structural changes to workplace

What is Reasonable?

“[I]f an employer excludes an employee based on an inability to accommodate a request to be exempt from a vaccination requirement, the employee may be entitled to accommodations such as performing the current position remotely.”



What is an Undue Hardship?

- **Undue Hardship Factors for Disabilities:**

- Nature and cost of the accommodation.
- Financial resources of the facility/entity, number of employees, effect on expenses, and resources, impact on operations.

- **Undue Hardship Factors for Religious Beliefs:**

- Something more than a *de minimis* cost or burden.
- But see state and local laws.

“The prevalence in the workplace of employees who already have received a COVID-19 vaccination and the amount of contact with others, whose vaccination status could be unknown, may impact the undue hardship consideration.”

Must Certain Accommodations Always Be Approved?

Employers must always do an individual assessment.



Keys to Success

1. Engage with the employee and manager immediately when there is an accommodation request.
2. Understand and document essential functions of roles.
3. Always do an individualized assessment and document accommodations.
4. Never promise a specific result. Instead preserve flexibility.
“We cannot guarantee...,” “depending on our business needs.”
5. Never assume you know, can diagnose, or prescribe the treatment.
6. Don’t lose patience.
7. Maintain confidentiality of medical information.
8. When in doubt, escalate.

OSHA Considerations

- No current standard regarding COVID vaccines.
 - Potential for a new standard.
 - No expectation that new administration will require employers to “mandate” vaccinations.
- Employers are required to provide employees a workplace that is free from recognized hazards that are likely to cause serious harm or death.
 - Even with vaccinated employees, existing COVID precautions remain necessary.



OSHA Whistleblower Claims

OSH Act Section 11(c)

Must be due to “reasonable belief” that vaccine is unsafe

- Can be individual-specific

May overlap with other claims

Benefits Considerations and Incentives to Vaccinate

Mandated Coverage of Vaccines

CARES Act §3202 requires non-grandfathered insured and self-funded group health plan and insurers to cover *without cost-sharing*.

- COVID-19 vaccines (including cost of administering).
- Other items and services “integral” to the furnishing of the vaccine.

Coverage must begin no later than 15 business days after recommendation from CDC or from US Preventive Services Task Force.

Applies whether services received in-network or out-of-network.

- After public health emergency ends, only applies to in-network providers.

Amendment to plan document/SPD may be needed.

Does ERISA apply?

ERISA applies to an “employee welfare benefit plan” which is a plan, fund or program established or maintained by an employer for the purpose of providing medical care.

- Vaccinations are likely “medical care,” but is administering them a “plan, fund or program” and is it “for the purpose of” providing medical care?
 - Former depends on number of shots/timeframe (i.e., ongoing administrative scheme?)
 - Latter may depend on whether vaccine program is mandatory (i.e., required more for the health of the workforce than just employee’s own health?) but consider *Aloha Airlines v. Ahue*.
- If ERISA plan, subject to compliance requirements such as reporting and disclosure
 - Offer through existing medical plan/wrap plan for built-in ERISA compliance.
 - Offer to non-covered employees through excepted benefit EAP.
 - Confirm EAP is in compliance with ERISA – plan document, SPD, etc.
 - Exempt from certain ACA market requirements and some HIPAA mandates.



Use of Incentives with Voluntary Vaccination Program



Taxable cash or gift card offered through new or existing wellness program?

- **ADA compliance concerns:**

- Employee participation must be voluntary so dollar value should be limited
- Reasonable accommodation must be provided to enable employees with disabilities to have equal benefits and privileges of employment (including participation in wellness program).
 - Alternative activity to receive incentive or give incentive anyway.

- **HIPAA compliance concern:**

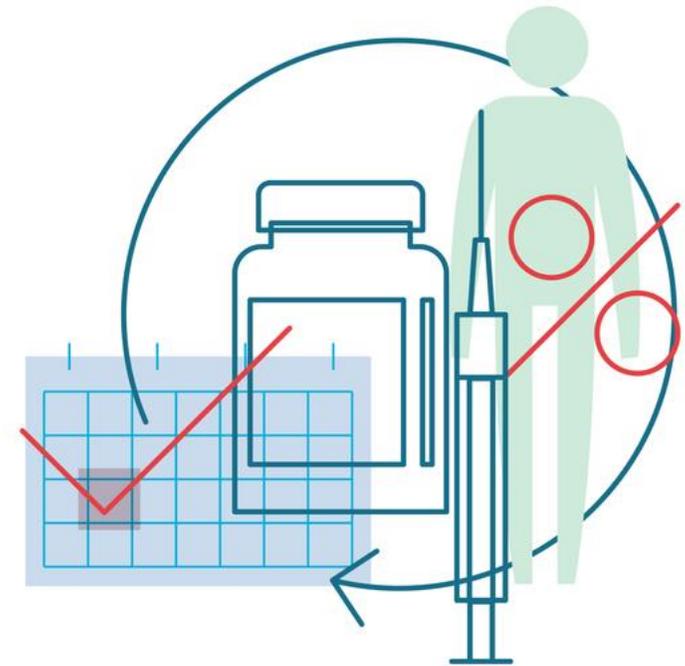
- Reasonable alternative standard must exist (or waiver of standard) for employees who are medically unable to receive vaccine so need alternative activity or give incentive anyway .

- **ERISA compliance concern:**

- Offer through existing wellness program which is already subject to/in compliance with ERISA.
- Confirm new wellness program is in compliance with ERISA – plan document, SPD, etc.

Time Off to Receive the Vaccine?

- Is requiring the vaccine a “business-related expense”?
- Is waiting for the vaccine and getting the vaccine “hours worked” under the FLSA?
- What about travel time?
- How should employers record the time?



Providing Time Off: Recovery from the Vaccine

- Common Side Effects from the Vaccine
- Reluctance to Receive Second Dosage
- Providing Time Off
 - Access to Existing Leave Buckets
 - Jurisdictions with Paid Sick and Safe Time (“PSST”)
 - Jurisdictions with Paid Family Medical Leave (“PFML”)
 - Creation of a Vaccination Recovery Time Off Policy



Questions?





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