

Vaccine Readiness and Avoiding Employee Claims

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ACC Association of
Corporate Counsel
— NATIONAL CAPITAL REGION —

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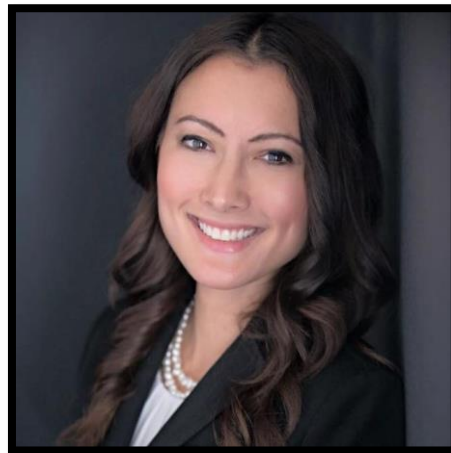


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Agenda

- **FDA Authorization vs. FDA Approval**
- **Legal Parameters for Vaccine Readiness**
- **Preparation – Best Practices for Encouraging or Mandating Vaccine**
- **Implementation – Encouraging Vaccine**
- **Implementation – Mandating Vaccine**
- **Vaccination Information Collection and Storage**
- **The Post-Vaccination Workplace**

FDA Authorization vs. FDA Approval

FDA Authorization vs. FDA Approval

- Decision to encourage vs. mandate vaccine impacted by FDA status as authorized but not yet approved
- Authorization status is rare – only when statutory circumstances exist, such as a pandemic (e.g., Ebola or Zika virus diagnostic test kits)
- Unusual circumstance has led to vaccine concerns and hesitancy
 - “How could a vaccine get on the market in less than a year?”
 - “The COVID-19 vaccines must not be as safe as other vaccines.”

FDA Authorization vs. FDA Approval

- What does “authorized” but not approved mean?
 - FDA may allow use of unapproved medical products—or unapproved *uses* of approved products—if HHS Secretary declares it permissible
 - Allows products to receive emergency use authorization (EUA)
 - EUAs have a different standard and therefore get on the market faster
 - Rigorous trials and research, but more limited data in compressed time
- Takeaway: Authorized vaccines are still safe, rigorously studied, and reviewed by FDA, but additional factors unique to the medical threat mean the standards are different

FDA Authorization vs. FDA Approval

- Three vaccines have been authorized so far
 - Pfizer-BioNTech – ages 16 and older (2 doses)
 - Moderna –ages 18 and older (2 doses)
 - Janssen/Johnson & Johnson – ages 18 and older (1 dose)
 - Note: Age thresholds are important if employ minors (even seasonally)
- Astra Zeneca planning to submit an EUA to FDA in first half of April

FDA Authorization vs. FDA Approval

- EUAs are temporary
 - When declaration of emergency terminates, EUAs no longer in effect.
 - At that point, EUA vaccine must have *approval* in place or be removed from the market and disposed of
 - All sponsors of existing EUA vaccines working toward approval status now

Legal Parameters for Vaccine Readiness

Legal Parameters for Vaccine Readiness

- Mandates
 - No federal, state, or local authorities currently mandating COVID-19 vaccine for general population
 - Some unsuccessful state efforts to mandate vaccine

Legal Parameters for Vaccine Readiness

■ Restrictions

- No federal authority prohibiting employer mandate
- U.S. Surgeon General cautioned against mandating vaccinations because not fully approved by FDA (not binding)
- Some States have proposed laws *prohibiting* employer mandates
 - MD – HB 1171 prohibits terminating employee for refusing vaccine. Mar. 15, 2021: bill sent back to subcommittee
 - FL – SB 364 prohibits requiring proof of vaccine status. Mar. 2, 2021: introduced in Senate
 - TX – HB 1687 prohibits discrimination based on an employee's vaccine status. Mar. 9, 2021: read for first time and referred to committee where it remains
 - KS – SB 213 prohibits adverse action against employees who refuse vaccine. Feb. 25, 2021: hearing took place in committee where the bill remains

Legal Parameters for Vaccine Readiness

- Restrictions (cont'd)
 - Some States have proposed or final laws requiring paid leave (whether or not employer-mandated)
 - NY – SB 2588-A/A.3354-B – signed into law by Governor Cuomo on Mar. 12, 2021
 - requires all employers to provide NY employees with up to four hours of paid time off per injection to receive a COVID-19 vaccine
 - CA – SB 95 – signed into law by Governor Newsom on Mar. 19, 2021
 - requires employers to provide full-time employees with up to 80 hours of paid sick leave & part-time employees with leave based on average hours worked
 - covers attending COVID-19 vaccine appointment (whether or not employer-mandated) & experiencing symptoms related to receiving a COVID-19 vaccine that prevents the employee from working/teleworking
 - paid leave is capped for each covered employee at \$511 per day and \$5,110 in aggregate

Legal Parameters for Vaccine Readiness

- Restrictions (cont'd)
 - EEOC Guidance (Dec. 2020) acknowledges (but does not expressly permit) employers mandating COVID-19 vaccination
 - Mandating is subject to disability, religion, and pregnancy discrimination and reasonable accommodation laws
 - Employers can exclude employees from workplace if:
 - Unvaccinated employees pose a “direct threat” (significant risk of substantial harm to health or safety of **self or others** that cannot be eliminated or reduced by reasonable accommodation)
 - Individualized assessment of direct threat required which considers duration, nature/severity, likelihood, imminence of harm
 - “Direct threat” factors satisfied if employer determines unvaccinated employee will expose others to virus at worksite

Preparation – Best Practices for Encouraging *or* Mandating Vaccine

Preparation – Best Practices

- Main factors driving employer decision to encourage or mandate:
 - Evolving legal guidance
 - Business model, mission, and necessity (e.g., extent of in-person or customer interactions)
 - Survey results and culture
 - Union status
 - Industry competition/trends among peers
 - Organizational vaccination rates
 - Vaccine availability
 - Employee relations
- Regardless of approach, best practices can drive more effective results and reduce claims

Preparation – Best Practices

- Messaging and education
 - Early, positive messaging and education about the vaccine is key to success
 - An overly-aggressive or poorly communicated vaccine program can lead to employee distrust and claims
 - Focus on safety and health benefits, as well as specific business objectives advanced by a vaccine program
 - Use protective language showing compliance and good faith
 - “closely monitoring CDC and other applicable guidance as they evolve”
 - “striving to develop responsible and compliant policies and programs”
 - “ongoing goal to provide safe and healthy workforce”

Preparation – Best Practices

- Messaging and education (cont'd)
 - Lay foundation for business necessity
 - Remind employees of mission and how keeping workplace safe and healthy is consistent with mission
 - Acknowledge that COVID-19 continues to pose a direct threat to the health and safety of employees, customers, vendors, etc.
 - Vaccine can be an effective tool to help keep the workplace safer

Preparation – Best Practices

- Messaging and education (cont'd)

- Getting employees informed – offer authoritative virtual resource center

- **CDC:** COVID-19 Vaccine EUA Fact Sheets for Recipients and Caregivers – <https://www.cdc.gov/vaccines/covid-19/eua/index.html>
- **FDA:** COVID-19 Vaccines – <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>
- **CMS:** COVID-19 Vaccine Resources (specific to healthcare employers) – <https://www.cms.gov/About-CMS/Agency-Information/OMH/resource-center/COVID-19-Vaccine-Resources>
- **WHO:** COVID-19 Vaccines – [https://www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines?adgroupsurvey={adgroupsurvey}&gclid=Cj0KCQjw9YWDBhDyARIsADt6sGZi_wkHDYBmBbty4SKQRnoyeFCLtjucgkhtPETqwG3iA3HDGabl7UaAnXUEALw_wcB](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey={adgroupsurvey}&gclid=Cj0KCQjw9YWDBhDyARIsADt6sGZi_wkHDYBmBbty4SKQRnoyeFCLtjucgkhtPETqwG3iA3HDGabl7UaAnXUEALw_wcB)
- **Mayo Clinic:** COVID-19 Vaccines: Get the Facts – <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859>

Preparation – Best Practices

- Messaging and education (cont'd)

- Be wary of posting news articles or opinion pieces – use disclaimers if others are doing so. For example:

“While news articles and other information may be posted from time to time regarding the COVID-19 vaccine, such information does not reflect the views of [employer], and are not intended to provide medical advice to any individual. While articles may help raise awareness and understand different points of view, **only the FDA, CDC, WHO, and other public health authorities provide official information regarding the COVID-19 vaccine.**”

Preparation – Best Practices

- Messaging and education (cont'd)
 - Ensure consistency of internal/external messaging regarding vaccine
 - Identify workplace points of contact and prepare them with appropriate messaging when questions arise
 - Never ask for medical information, give medical advice, or give the appearance of giving individual medical advice
 - Direct employee to own healthcare provider for individual medical issues

Preparation – Best Practices

- Review data on other employers in your industry to learn who is encouraging vs. mandating
 - Evaluate publicly-available information about negative or positive feedback from employees or customers to gauge potential employee responses
 - Learn from others' experience – review others' messaging

Preparation – Best Practices

- Utilize surveys to gauge employee interest and acceptance
 - Caution: surveys should not elicit disability related information of confidential health information protected by GINA or ADA
 - Funnel answers through drop-down menu to avoid open-ended (and uninvited) medical information or complaints that may trigger a duty
 - Use survey results to consider timing, approach, education
 - Example – if survey results show fear and misinformation, consider “myth-busting” educational campaign

Preparation – Best Practices

- Evaluate litigation risks in advance
 - Potential vaccine-related claims
 - ADA, Title VII, and Pregnancy Discrimination Act claims (disability, religious, and pregnancy discrimination claims, including reasonable accommodation denials)
 - OSHA and other state whistleblower retaliation claims (for raising a reasonable concern about infection control in the workplace related to COVID-19 vaccine issues)
 - Privacy-related claims (failure to collect or maintain vaccine information in compliance with privacy and confidentiality laws)
 - Workers' compensation claims

Preparation – Best Practices

- Evaluate litigation risks in advance (cont'd)
 - Potential vaccine-related claims
 - NLRA (retaliation for protected activity in protesting terms and conditions of employment
 - Employers may limit anti-vaccination ***misinformation*** within the workplace but be careful about interfering with or retaliating against anti-vaccination advocacy
 - CBA requirements to negotiate vaccine policies
 - FLSA or state wage law claims for failure to pay working time (if mandatory) or provide paid leave
 - State law claims governing COVID-19 or vaccine requirement

Implementation – Encouraging Vaccine

Implementation – Encouraging Vaccine

- Advantages
 - Encouraging vaccine first will strengthen foundation for mandating later
 - Increasing number of voluntary vaccinations now will reduce need to mandate large groups of employees later
 - Encouraging instead of mandating vaccine may avoid employee resentment

Implementation – Encouraging Vaccine

- Disadvantages
 - Depending on participation, may not be sufficient to create a safe and healthy workforce and worksite
 - Continued need to enforce restrictions and enhanced infection control protocols in the workplace (masks, etc.)
 - Continued threat of COVID-19 concerns and claims from customers and other third parties

Implementation – Encouraging Vaccine

- Consider incentives as part of encouragement
 - Nominal incentives are generally acceptable and can be very effective
 - Avoid incentives which:
 - Are impliedly coercive (e.g. aggressive and competitive goal contests)
 - Discriminate against individuals in protected class in terms and conditions of employment (e.g. substantial cash bonus)
 - Identify individuals who have or have not been vaccinated (by default) (e.g. outward rewards and prizes that identify vaccinated employees)
- Consider providing incentives to individuals who are in protected classes (and cannot get vaccine)

Implementation – Encouraging Vaccine

- Consider incentives as part of encouragement (cont'd)
 - Latest incentive trends for COVID-19 vaccination
 - Small discretionary bonus or gift card
 - Paid day off with use restrictions (in addition to recovery time)
 - Must be used in 2021
 - Scheduled with approval of supervisor
 - Cannot cash-out on termination
 - Defined in HR policy

Implementation – Encouraging Vaccine

- Consider sponsoring onsite vaccine clinics
 - Convenient for employees and boosts morale
 - Convenient for employer in collecting vaccination proof directly
 - Coordinate with vaccination provider to provide compliant consent forms
 - Resources for sponsoring an onsite clinic
 - **CDC:** Guidance for Planning Vaccination Clinics – <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>
 - **CDC:** Resources for Hosting a Vaccination Clinic – <https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm>

Implementation – Encouraging Vaccine

- Consider sponsoring onsite vaccine clinics (cont'd)
 - There is liability protection under the PREP Act for onsite clinics
 - Key to PREP Act coverage is compliance with FDA and CDC guidelines (i.e., proper vaccine storage and handling, preventing transmission, adverse event reporting)
 - Injuries from vaccination clinics covered by the Countermeasures Injury Compensation Program (CICP)

Implementation – Mandating Vaccine

Implementation – Mandating Vaccine

- Advantages
 - Creates a safer and healthier worksite and workforce
 - Creates more opportunities for relaxed guidelines, natural interactions, as permitted by CDC and other guidelines
 - Minimizes claims of unsafe or unhealthy workplace by customers or employees

Implementation – Mandating Vaccine

- Disadvantages
 - If not implemented effectively, can result in poor employee morale and resentment
 - If overly-aggressive, can result in employee claims

Implementation – Mandating Vaccine

- Create written vaccination policy
 - When announcing mandate, use qualified language: “We will mandate the vaccine as an essential job function, *subject to applicable laws and our policies*”
 - Policy of mandating must be subject to evolving laws, EEOC parameters, and the reasonable accommodation process
 - Identify which employees subject to mandatory requirements
 - Provide reasonable timeframe to comply (availability, waitlist, inconvenience, two shot requirement, etc.)
 - Articulate how vaccine requirement is job-related and consistent with business necessity, acknowledging COVID-19 continues to pose a “direct threat” to health or safety of self or others

Implementation – Mandating Vaccine

- Create written vaccination policy (cont'd)
 - Provide medical/religious reasonable accommodation resources
 - Address logistics and resources for receiving vaccine (e.g. onsite v. offsite with preferred provider(s))
 - Specify how to provide proof of vaccination– clarify that other medical information should not be provided
 - State that information will be maintained as confidential
 - Provide paid time for obtaining vaccination (including travel time) for hourly employees and paid leave for salaried exempt employees (2 hours unless state law requires more)

Implementation – Mandating Vaccine

- Create written vaccination policy (cont'd)
 - Reimbursement for out-of-pocket expenses
 - Explain consequences for noncompliance (e.g. banning from workplace, discipline, etc.), absent an approved accommodation request
 - Articulate effective date(s) for expected compliance
 - Consider how special groups will be handled (e.g. nonprofits with unpaid volunteers)
 - More flexibility to impose requirements
 - Check state laws which may provide discrimination protections to volunteers

Implementation – Mandating Vaccine

- Update job descriptions
 - The reasonable accommodation process turns on whether a job requirement is an “essential function of the job”
 - Consider requiring certain employees to have regular “face-to-face” interactions with customers, vendors, clients, employees, guests, visitors, etc.
 - Include a clearly-articulated rationale for face-to-face contact, consistent with mission and culture
 - Consider adding that compliance with employer vaccination and other health/safety requirements is an “essential function of the job”

Implementation – Mandating Vaccine

- Streamline accommodation process
 - Employee request forms should be detailed and require supporting documentation (for disability)
 - Include authorization to release documents (as necessary)
 - Include vaccine-related questions for health care practitioner certification
 - Explanation for:
 - why not safe for employee,
 - nature and probable duration of the medical condition
 - circumstances that contraindicate immunization with the COVID-19 vaccine

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious*
 - Grant/deny forms for supervisors/HR should be simple and ensure consistency in approach
 - Make it easy for supervisors/HR personnel to analyze and make with drop-down factors or check-the-box guides to ensure consistency and legal compliance
 - Keep request forms confidential and do not comment on validity of request or likelihood of being denied/granted
 - Act quickly – for *disability-related* accommodations, unnecessary delays in processing a request can violate the ADA

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious* (cont'd)
 - Interactive process
 - Interactive process *required* under the ADA
 - *Highly encouraged* for Title VII religious requests
 - Best practice for both
 - Use interactive process to discuss and consider options raised by both employee/employer
 - multiple communications
 - exchange information
 - Document the interactive process

Implementation – Mandating Vaccine

- Streamline accommodation process *disability and religious* (cont'd)
 - Third party documentation – ADA-specific issues
 - Employees may interface directly with medical provider to obtain information requested by employer
 - Employer can ask employee to sign release in case employer needs to follow up directly
 - If medical information is suspect (e.g. inauthentic) or incomplete, HR or clinical personnel may contact doctor to confirm authenticity or ask clarification questions
 - Maintain request and determination forms in a separate and confidential medical file for each employee and not in the employee's personnel file

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious* (cont'd)
 - Third party documentation – Title VII-specific issues
 - No supporting documentation required from employee at beginning of process, but reserve right to request such documentation later if needed (Note: this is a distinction from the ADA process)
 - If there is objective basis for questioning either religious nature or sincerity, HR or other liaison may request proof of the belief, but be cautious in doing so

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious* (cont'd)
 - Determination – Does accommodation pose direct threat or create undue hardship?
 - *Disability* – requires individualized assessment of direct threat using EEOC factors
 - *Religious* – lower standard for undue hardship (*de minimis* cost) on employer
 - When accommodation not possible, lawful to exclude employee from workplace
 - Notify employee, in writing, that accommodation has been approved or denied
 - If approved, include duration (***avoid*** permanent accommodations), whether there is trial period subject to evaluation, and other details and conditions of accommodation
 - Accommodation should be reasonable and can differ from what was requested
 - If denied, clearly articulate rationale as undue hardship or direct threat (use consistent forms)

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious* (cont'd)
 - Typical accommodations in context of COVID-19 vaccine
 - Additional time to get vaccinated (e.g. pregnancy or returning from FMLA leave)
 - Leave of absence (paid or unpaid)
 - Mandatory mask wearing and/or wearing additional PPE
 - Social distancing
 - Temperature checks
 - Routine COVID-19 testing
 - Teleworking – whether an employee can telework indefinitely depends on whether being in the office or face-to-face is an essential job function

Implementation – Mandating Vaccine

- Streamline accommodation process – *disability and religious* (cont'd)
 - Typical accommodations in context of COVID-19 vaccine (cont'd)
 - Eliminate or excuse from marginal duties that require face-to-face
 - Alternative assignments or positions that do not require vaccine
 - For *medical* exemptions relevant to a type of vaccine, offer different vaccine (e.g., employee may be allergic to component of an mRNA vaccine but not to the viral vector vaccine)
 - For *religious* exemptions, if the type or method of vaccine manufacturing is objectionable, allow alternative vaccine options that eliminate the objection
 - For temporary exemptions such as pregnancy, extension of time to obtain the vaccine

Avoid permanent accommodations that are not subject to re-evaluation

Implementation – Mandating Vaccine

- Implement flexible leave policies
 - Granting leave to employees who suffer from side effects after receiving the vaccine
 - Some state laws require paid leave for mandatory or encouraged vaccines

Vaccination Information Collection and Storage

Vaccination Information Collection and Storage

- Asking or requiring employee to show proof of vaccination is permissible under ADA and is not a disability-related inquiry
- There are many reasons an employee may not have received a vaccination
- Avoid asking why an employee has not been vaccinated
- Follow strict protocols

Vaccination Information Collection and Storage

- Keep vaccination status-related information in secure location
 - Keep in medical file, separate from personnel file
 - Access limited to specific HR member(s) on a “need to know” basis

Vaccination Information Collection and Storage

- If mandating vaccine, ask for confirmation of vaccination
 - Recommend employees provide copy of CDC vaccination card to HR, or bring card to HR for photocopying (return original to employee)
 - Instruct employees not to provide any medical information not related to receiving vaccine
 - Instruct not to have physician provide vaccination information – could result in receipt of medical information
 - Discourage unsolicited transmission of vaccination card or other vaccination documentation via email
 - If feasible, establish secure, encrypted means of transmission to HR
 - Alert employees that employer not responsible for any unauthorized data access while in transmission, even if secure transmission used

Vaccination Information Collection and Storage

- Prevent against privacy-related claims
 - Under certain state privacy laws, employers may not disclose who has received the COVID-19 vaccine without the employee's prior consent
 - Unlawful for employer to disclose to other unauthorized employees (who do not have a need to know) that someone has been granted an accommodation
 - Special precautions should be taken when medical information is received, even if not requested – keep in medical file
 - If third party (such as government or prime contractor) requires or requests vaccination status, consider providing certification or assurance that assigned employees comply with all requirements (rather than individually identify vaccination status)

The Post-Vaccination Workplace

The Post-Vaccination Workplace

- CDC: Interim Public Health Recommendations for Fully Vaccinated People (updated April 2)
 - Fully vaccinated employees of non-healthcare congregate settings and other high-density workplaces with no COVID-like symptoms do not need to quarantine following an exposure
 - Maintain existing safety protocols – masks, social distancing, hand hygiene
 - Precautions necessary until population reaches herd immunity (approximately 70% vaccinated)

The Post-Vaccination Workplace

- CDC: Domestic and International Travel (updated April 2)
 - Can travel within the U.S. while taking precautions; no testing required
 - Can travel internationally while taking precautions, getting tested upon return
 - All passengers entering the U.S., including U.S. citizens and fully vaccinated individuals, are required to have a negative COVID-19 test result or have documentation of recovery from COVID-19 before boarding a flight to the U.S.
 - Domestic and international travel not recommended if not fully vaccinated
- May continue to impact business travel
 - Some countries considering vaccine documentation (e.g., vaccine passports)

The Post-Vaccination Workplace

- Visitors in the workplace
 - Currently, there is no guidance regarding vaccination cards
 - Some States prohibit businesses' request of visitor vaccination card or other proof (e.g., Florida, Texas)
 - When screening based on vaccination, ensure clear business necessity:
 - Consider screening question requiring individual to confirm vaccination within period of time.
 - Consider requesting display of vaccination card and making internal note of confirmation, if permitted by applicable laws

The Post-Vaccination Workplace

- Visitors in the workplace (cont'd)
 - Screening (cont'd)
 - Be careful requesting and maintaining third party medical information
 - If place of public accommodation, subject to ADA Title III (enforced by DOJ)
 - Consider accommodation requests
 - To avoid security/receptionist screening issues, consider posting policy with resources for requesting accommodations
 - Individualized inquiry required to determine whether modification would be reasonable under the circumstances and necessary for that person, and yet at the same time not pose a fundamental alteration
 - “Fundamental alteration” – modification so significant it alters the essential nature of the goods, services, facilities, privileges, advantages or accommodations offered

The Post-Vaccination Workplace

- What can we expect in the future?
 - Guidance from CDC and other authorities continues to evolve and new issues will likely arise, such as:
 - More guidance related to requiring vaccination proof and third parties
 - Relaxed guidelines for vaccinated people
 - Additional travel and return-to-work guidelines
 - One or more of the vaccines that are currently authorized may become fully approved by FDA in the future, possibly eliminating some vaccination concerns
 - Additional vaccines may be authorized or approved, increasing availability



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