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COVID-19 Vaccine – Frequently Asked Questions

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Who Needs to Know

All employers.

Why It Matters

Businesses should begin to address these issues now so that when COVID-19 vaccines are ready for widespread public distribution, they will be too.

On December 11, the Food and Drug Administration announced that it would be issuing emergency use authorizations for two COVID-19 vaccines, and shortly thereafter, the first vaccinations were administered on December 14. While initial doses of the vaccine have been allocated to health care workers and long-term care residents, all businesses should prepare for broader availability of the vaccine in early 2021. The COVID-19 pandemic and new vaccines present unique circumstances in which employers must balance employee rights with the overall safety and health of its workforce, customers, or clients when developing a vaccine strategy. This FAQ is intended to help employers across all industries understand the legal framework that regulates mandatory and voluntary employer vaccination programs.

We have only started to scratch the surface of the myriad questions that employers will face about a new COVID-19 vaccine. The Troutman Pepper Vaccine Task Force will maintain our COVID-19 Vaccine Frequently Asked Questions site to help our clients as they think through these issues. If you have questions specific to your business or COVID-19 vaccination policies, please feel free to contact us or visit the Troutman Pepper COVID-19 Resource Center.

This information is based on available guidance, as of April 1, 2021.

1. General Questions

a. Generally, what laws should employers consider when evaluating a vaccination program?

Employers must comply with the Americans with Disabilities Act (ADA), Title VII of the Civil Rights Act of 1964 (Title VII), Title II of the Genetic Information Nondiscrimination Act (GINA), the Occupational Safety and Health Act

(OSHA), the Public Readiness and Emergency Preparedness (PREP) Act, and federal and state privacy laws governing individual identifiable information.

b. What should employers do now to prepare for the vaccine's availability?

Below find a few suggestions on what employers can do now to prepare for the availability of a COVID-19 vaccine:

- Review all vaccine-related policies and procedures with legal counsel and consider whether updates are needed. To the best extent, clarify any ambiguity and ensure consistent treatment for similarly situated employees.
- Consider whether to mandate vaccination, encourage or incentivize vaccination, or remain silent on the issue and the ramifications of each decision.
- Communicate internal policies to your workforce in advance and educate them on the benefits and risks of getting the vaccine. Focus internal communication on maintaining a safe environment for employees, customers, and others.
- Assess prior internal processes for reviewing, granting, and monitoring medical or religious exception requests. Anticipate and prepare for an influx of questions and accommodation requests.
- Review vaccine alternatives offered to employees in the past and consider if they constitute viable alternatives in the context of COVID-19. Ask if the business should consider additional alternatives and work with leadership to evaluate these additional options, if any.
- Evaluate your collective bargaining agreements and determine whether the agreements speak to mandatory vaccines. If so, begin conversations with the union(s) early.
- Since the COVID-19 landscape is changing rapidly, stay current with advice and guidance issued by the Centers for Disease Control (CDC) and your state/local public health authorities.

c. Can the state government mandate COVID-19 vaccination for individuals?

Based on prior precedent, it appears that a state government may mandate that individuals get vaccinated. A 1905 Supreme Court case, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), considered whether a state could impose a compulsory vaccination law and found that it could. The Court held that the law was squarely within the police power of the state. It is unclear whether facts and circumstances surrounding the COVID-19 vaccine that distinguish it from the vaccine considered in *Jacobson v. Massachusetts*, including its EUA status, would result in a different outcome.

d. How does the most recent CDC guidance concerning fully vaccinated people impact any or all of the issues raised in these FAQs?

On March 8, the CDC released its first set of public health recommendations for fully vaccinated people. For the purposes of this guidance, people are considered fully vaccinated for COVID-19 at least two weeks after they have received the second dose in a two-dose series (Pfizer-BioNTech or Moderna), or at least two weeks after they have received a single-dose vaccine (Johnson and Johnson). Currently, the CDC suggests that fully vaccinated people can visit with other fully vaccinated people and with unvaccinated people from a single household at low risk for severe COVID-19 disease indoors without wearing masks or social distancing, and they can also refrain from quarantine and testing following a known exposure if asymptomatic. That said, employers of fully vaccinated people in the workplace should be aware of the following:

- Since the CDC continues to recommend wearing a well-fitted mask, physical distancing (at least six (6) feet), avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands often, and following other prevention measures for fully vaccinated people in public spaces, employers will want to ensure their employees are aware that the workplace prevention measures continue to apply for fully vaccinated people. Notably, the CDC does indicate that fully vaccinate people may be unmasked in indoor spaces if everyone in the space is fully vaccinated. If a private workplace is comprised of only fully vaccinated employees, the employer may consider easing its mask requirements (provided no state or local guidance recommends otherwise).
- The CDC counsels continued avoidance of medium- or large-sized gatherings for fully vaccinated people. This suggests that employers may need to postpone medium or large in-person gatherings in the workplace even after the vaccine has become more prevalent.
- The CDC still adheres to its current travel recommendations and requirements, meaning travel for work still may not be advisable for fully vaccinated people.
- With some exceptions, the CDC does not recommend quarantine for fully vaccinated people who have been exposed to a suspected or confirmed case of COVID-19. Thus, employers may be able to revise their leave policies and procedures for fully vaccinated people if such policies and procedures provide for leave in the event of exposure. Before doing so, employers should consult with any state and local guidance on point, which may differ from the CDC recommendations.

2. Emergency Use Authorizations

a. What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is an expedited process that allows the U.S. Food and Drug Administration (FDA) to authorize the use of otherwise unapproved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases when no adequate, approved, and available alternatives exists. The FDA acknowledges that a request for a COVID-19 vaccine EUA can allow for the vaccine's rapid and widespread deployment. The issuance of an EUA requires a determination by the FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial demonstrating the vaccine's safety and efficacy in a clear and compelling manner.

b. How long do EUAs last?

EUAs are temporary. They are only effective for the duration of the declared emergency under which authorization was originally granted. Generally, the secretary of the Department of Health and Human Services' (HHS) emergency declaration will terminate the earlier of: (1) a determination by the HHS secretary that the circumstances precipitating the declaration have ceased, or (2) a change in the product's approval status such that the authorized use of the product is no longer unapproved. For example, an EUA issued to allow an unapproved use of an approved product may no longer be needed if the FDA later approves that product for the use permitted by the EUA. Before an EUA declaration terminates, the HHS secretary must provide advance notice sufficient to allow for the disposition of an unapproved product.

c. Do EUAs constitute FDA clearance or approval?

The granting of an EUA does not constitute FDA clearance or approval. Rather, products are "authorized" for use pursuant to an EUA. EUA candidates wishing to commercialize their products beyond the timeframe set by the EUA declaration must seek FDA approval through traditional clearance or approval pathways, for example, NDAs,

BLAs, 510(k)s, and PMAs. Furthermore, the FDA requires that products commercialized under an EUA (with the exception of certain personal protective equipment, or PPE) prominently display disclaimers including:

- This product has not been FDA cleared or approved;
- This product has been authorized by the FDA under an EUA;
- This product is only authorized for the duration of the declaration under circumstances justifying the authorization of emergency use, unless the authorization is terminated or revoked sooner.

d. What happens when an EUA is no longer effective?

The FDA explains that, for any products that are not approved, cleared, or licensed, manufacturers may submit the appropriate premarket submission to legally market their product after the EUA declaration is terminated, or the EUA is otherwise revised or revoked. Manufacturers are encouraged to pursue premarket submissions through the appropriate regulatory pathway during the emergency so that products can remain on the market after the emergency.

e. What are the requirements for obtaining an EUA?

Medical products that may be considered for an EUA are those that "may be effective" to prevent, diagnose, or treat serious or life-threatening diseases or conditions identified in the HHS secretary's declaration of emergency or threat of emergency under section 564(b). The "may be effective" standard for EUAs provides for a lower level of evidence than the "effectiveness" standard that the FDA uses for product approvals. The FDA intends to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. A product may be considered for an EUA if the commissioner determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product. For the FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered "unavailable" if there are insufficient supplies of the approved alternative to fully meet the emergency need.

3. Employer Vaccine Mandates and Incentives

a. Can an employer mandate that employees receive a vaccine as a condition of employment?

Yes. Generally, employers can require employees to be vaccinated provided that the employer permits employees to request a reasonable accommodation if they have an ADA disability or a sincerely held religious belief, practice, or observance under Title VII that prevents the employee from taking the vaccine.

When an employee raises a disability-related or religious objection to the vaccine, employers must interact with these employees and implement reasonable accommodations, barring undue hardship. Under the ADA, an accommodation results in an undue hardship for the employer if it requires significant difficulty or expense. Under Title VII, an accommodation results in an undue hardship if it requires more than a *de minimis* cost.

While the EEOC opined that neither the ADA nor Title VII prohibit employers from requiring employee vaccination,

employers should review other considerations before implementing such a requirement. Practically speaking, vaccination will be more critical in some workplaces and workforces than others (retail or restaurant environments, call centers, or other close-quartered workplaces versus a largely remote or teleworking group of employees, for example). The employer should consider whether a requirement is appropriate for its workplace or workforce once a vaccine becomes publicly available and distributed. Further, an employer should consider the rollout plan chosen in the employer's applicable states of operation, which will limit the individuals initially eligible to receive the vaccine by job duty and/or high-risk category, in considering whether to require employees to obtain it.

Earlier this year, the EEOC updated its previous pandemic guidance that responded to the 2009 H1N1 pandemic flu outbreak. This guidance indicates that the EEOC prefers employers to encourage employees to get the COVID-19 vaccine rather than issuing a mandate. On December 16, with the vaccine rollout underway, the EEOC issued further guidance addressing employee vaccination issues in light of federal EEO laws (Section K of the link referenced). The guidance affirms the general framework discussed above and provides answers to specific questions that may arise for employers under these laws, as discussed in the relevant sections below.

b. Does the EEOC consider the administration of a COVID-19 vaccination to be a "medical examination" under the ADA?

The EEOC does not consider a vaccination to be a medical exam under the ADA. However, the agency cautions that pre-screening vaccination questions may implicate the ADA if such inquiries elicit information about an employee's disability. As such, employers should be prepared to demonstrate that any pre-screening questions asked of employees are "job-related and consistent with business necessity." According to the EEOC, to meet this standard, employers must "have a reasonable belief, based on objective evidence, that an employee who does not answer the questions and, therefore, does not receive a vaccination, will pose a direct threat to the health or safety of her or himself or others."

The EEOC further contemplates two scenarios in which disability-related questions can be asked without running afoul of the job-related/business necessity standard. First, if the employer implements a voluntary vaccination program, the ADA requires that the decision to answer any pre-screening questions likewise must be voluntary for employees. Employers may refuse to administer the vaccine to employees who refuse to answer pre-screening questions, but in that event, the EEOC warns that employers must not retaliate against employees for refusing to answer questions. The second scenario relates to mandatory vaccination programs where a third party not contracted by the employer (*e.g.*, a pharmacy or other health care provider) administers the vaccine to an employee. In that situation, the employer will not be held to the ADA's job-related/business necessity standard with respect to questions asked by the third-party provider.

On a related note, the EEOC does not consider an employer's request for verification that an employee has been vaccinated to be a disability-related inquiry. However, while a request for verification is not by itself a disability-related inquiry, further questions by the employer could run afoul of the ADA. For example, asking an employee why they refused the vaccine could elicit information about a disability and thus trigger the employer's obligation to meet the job-related/business necessity standard. See Question 5(c) below as to potential confidentiality obligations related to employer collection of various forms of vaccination status information. If the employee is vaccinated by a third party, the EEOC advises that any request for verification be coupled with a warning to the employee to not provide additional medical information that could trigger the confidentiality protections of the ADA.

c. Will the vaccine's EUA impact an employer's ability to mandate a COVID-19 vaccination?

While the FDA has issued EUAs for two COVID-19 vaccines, the text of the EUAs does not address employer mandates. The EUAs may include conditions requiring individuals receiving the vaccine to be informed of the option to accept/refuse administration; of the consequences, if any, for refusing administration; and of any alternative products available and their benefits/risks. The two vaccines issued thus far include required vaccine fact sheets to providers and recipients that address, among other things, the benefits/risks of the vaccines and necessary information for receiving the required second dose.

d. Can employers base a return-to-office policy on whether the employee has been vaccinated? Can an employer require a vaccine to return to the office?

Yes, an employer may require employees to receive the COVID-19 vaccine in order to return to the office (subject to any EUA restrictions and the exceptions noted above for disabilities and sincerely held religious beliefs). Telework or mask-wearing may constitute an appropriate and effective accommodation for appropriate positions in this instance. Regardless of whether a vaccine is required, as the EEOC recently confirmed, employers should avoid selecting individuals for return to work in the office (or telework) based on protected categories (*e.g.,* refusing to allow individuals over age 65 or pregnant individuals to return to the workplace).

e. Can employers include a vaccine requirement for employees who travel for business? What about employees who travel in their personal time? How would such a requirement interact with state laws limiting employers' ability to regulate off-hours activity?

As noted above, employers can generally require employee vaccination as a condition of employment, which would cover any instance of business travel. If vaccine quantities are limited, requiring only employees who travel for work as an essential function receive the vaccine may be one way to implement a vaccine requirement among a limited group of employees, so long as the employer considers requests for reasonable accommodations due to disability or sincerely held religious beliefs and any restrictions in the applicable EUA, and the availability of the vaccine to the employees at issue.

Employers should also be aware that the EEOC confirmed that questions about why an employee was absent from work and/or where an employee traveled would not be a prohibited disability-related inquiry. Further, if the CDC or state/local public health officials recommend that people who visit specified locations remain at home for a certain period of time, an employer may ask whether employees plan to return from these locations, even if the travel was personal.

f. Do employers who mandate the vaccine need to pay for the cost for employees to receive the vaccine? And how would this interact with existing benefit plans and programs?

As of now, it appears that employers cannot purchase or obtain batches of the vaccine on their own, at least initially, and many states will offer the vaccine free of charge (though providers may charge an administration fee). Employers could consider reimbursing employees for the cost of receiving a vaccine, even if they cannot run an employer-sponsored clinic, just as many do for the flu vaccine, so long as they do so consistently across the employee population. Covering the cost may be one effective way to ensure that employees comply with a

mandate or, even if an employer does not mandate the vaccine, encourage employees to receive it voluntarily. Employers should consult their particular benefit plans and providers to determine whether the cost of a COVID-19 vaccine may be covered under the terms of those plans.

g. Instead of covering the cost of the vaccine, can employers offer a bonus to employees who receive it? What if the vaccine isn't available to all employees because of limited distribution? Does the size of the bonus matter? And, if people receive a payment for getting the vaccine, is it coercive?

Yes, employers can likely provide a one-time gratuitous bonus or even another benefit, such as additional "paid time off" or a "dress-down" day or similar perk, to employees to encourage them to get vaccinated. If what is offered is truly a gratuitous benefit (and not unreasonably large, such that it could be considered coercive), the employer can offer enticements to encourage employees to get vaccinated even if the employer does not require it as a matter of course. Please see question 5(i) for additional information.

h. Do employers need to include a vaccine requirement in an Illness and Injury Prevention Program (IIPP)?

For the reasons noted above, an employer may require vaccination as a condition of employment, but OSHA has not yet opined as to whether vaccination is an appropriate or advisable component of an IIPP. Employers with California operations should be aware, however, that Cal-OSHA does expect IIPPs to be updated to address how the employer will handle COVID outbreaks in the workplace and how the employer will implement that state's emergency rules. All employers, even those outside California, should review their workforce and working environment to determine whether vaccination might reduce a substantial risk of infection, considering availability of the vaccine, in making a mandatory vaccine requirement determination for their individual workplace(s).

i. Does a vaccination mandate or proof-of-vaccination requirement create any issues under Title II of the Genetic Information Nondiscrimination Act?

The EEOC takes the position that vaccination mandates or verifications do not implicate Title II of GINA because they do not involve the use of genetic information to make employment decisions, or the acquisition or disclosure of genetic information, as defined by the statute. Although the mRNA technology deployed in the COVID vaccines coming to market might raise questions relating to genetics, the CDC has explained that the mRNA COVID-19 vaccines "do not interact with our DNA in any way," as the "mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept."

Regarding pre-vaccination screening questions, the EEOC guidance acknowledges that such inquiries may yield genetic information, including information about disabilities or genetic information about an employee's family members. The EEOC guidance notes that screening checklists for the current vaccines were not yet available at the time the guidance was published. The agency states that if the template questions do not include questions relating to genetics, GINA is not a factor. On the other hand, if such questions do become part of the vaccination protocol, the agency suggests that employers who want to ensure employees are vaccinated may wish to require proof of vaccination from a third-party provider in lieu of an employer administered vaccine program.

4. Exemptions and Accommodations

a. How should employers respond to employees who refuse the vaccine on the basis of disability?

Under the ADA, employers may implement a safety-based qualification standard requiring that the employee "shall not pose a direct threat to the health or safety of individuals in the workplace." In this context, if a vaccination requirement disproportionally screens out employees with disabilities, the employer would need to show that the unvaccinated employee poses 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."

In this scenario, the EEOC advises employers to conduct an individualized assessment based on four factors to determine the existence of a "direct threat," as follows: (1) the duration of the risk; (2) the nature and severity of the potential harm; (3) the likelihood that the potential harm would be realized; and (4) the imminence of the potential harm. According to the EEOC, it is necessary to demonstrate that an unvaccinated employee would expose others in the workplace to the virus before concluding that a direct threat exists, on an individual employee basis.

Even if this analysis confirms the existence of a direct threat, the employer may not exclude the employee from the workplace without first attempting to identify a reasonable accommodation. Employers may look to CDC recommendations to facilitate the reasonable accommodation analysis, as well as workplace safety guidance issued by OSHA. Where an employee is working pursuant to a reasonable accommodation, the EEOC advises employers to ensure that managers and supervisors know it is unlawful to disclose an employee's accommodation or retaliate against the employee for requesting an accommodation.

On the other hand, employers should be prepared to demonstrate how the specifics of their workplace preclude accommodation if that is indeed the case. If no accommodation exists, the employer can prevent the employee from entering the workplace, but any further steps could generate additional liability. The EEOC warns employers that terminating an employee in this situation could trigger protections under the EEO laws, as well as additional protections that may exist under other federal, state, and local laws.

b. May an employer validate an employee's proffered disability for refusing the vaccine?

Yes, employers may request clarifying information or documentation as part of the interactive dialogue to assess an employee's accommodation request based on disability. For example, an employer may require the employee to provide a doctor's note that describes a substantially limiting impairment and the reasonable accommodation needed as a result (*e.g.,* recommendation against receiving the vaccine). However, employers should be mindful of the balance between requesting information to sufficiently verify the validity of the employee's proffered disability and corresponding accommodation (such as a generic doctor's note stating the recommendation for the vaccination exemption), as opposed to scrutinizing why or how the proffered medical reason or disability may exempt the employee from the vaccination (such as requesting additional information about specific diagnoses or reasons why the exemption is recommended). Once the employer obtains sufficient information to describe a substantially limited impairment and any resulting need for accommodation, the employer cannot ask for additional information. Assuming the employee establishes that he/she has a disability within the meaning of the ADA, employers should focus on how the requested accommodation (*e.g.,* not receiving a vaccine) will impact the employee's ability to perform his/her essential job duties, and whether the exemption will result in an undue hardship to the employer. Employers must also be mindful of their obligation to maintain strict confidentiality of any

medical information received as part of the interactive process.

c. How should employers respond to employees who refuse the vaccine on the basis of a sincerely held religious belief or practice?

In order to warrant protection under Title VII, an employee must have a "sincerely held religious belief" that opposes or conflicts with receiving the vaccination for an employer to provide an accommodation or exemption. The EEOC's guidance broadly defines religion to include organized religions and religious beliefs, but does not include social, political, or economic philosophies or personal preferences.

As mentioned above, if an employee informs the employer of a sincerely held religious belief, practice, or observance that prohibits the employee from receiving the vaccination, Title VII requires the employer to provide a reasonable accommodation unless doing so would pose an undue hardship. According to the EEOC, however, if the employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, practice, or observance, the employer can request additional supporting information. Commensurate with disability accommodation requests, the employer may exclude the employee from the workplace if accommodation is not possible, although the agency again cautions against taking further action without analyzing the applicability of other federal, state, and local laws.

d. What constitutes a "sincerely held religious belief" to support an employee's religious accommodation request to refuse vaccination?

While an employee may have a sincere belief against or in opposition to the vaccination, the key inquiry is whether the employee's belief is rooted in religion or a religious belief. A nonreligious opposition is not covered under Title VII. The employee must establish that the objection is based on a legitimate, sincerely held religious belief in order to warrant an exemption as an accommodation.

Courts differ on what constitutes "religion" to warrant protections under Title VII. For example, the U.S. Court of Appeals for the Third Circuit recently affirmed dismissal of a Title VII religious discrimination claim for a hospital employee terminated for refusing a flu vaccination based on her holistic health lifestyle and personal belief that the vaccine was unnecessary. While the employee may have had a sincere opposition, the Court of Appeals noted that the employee must establish that "opposition to vaccination is a religious belief." Citing *Fallon v. Mercy Catholic Med. Ctr. of Se. Pa.*, 877 F.3d 487, 490 (3d Cir. 2017) and *Brown v. Children's Hosp. of Phila.*, 794 Fed. Appx. 226 (3d Cir. 2020).

On the other hand, the U.S. District Court for the Southern District of Ohio refused to dismiss a religious discrimination case where the employer terminated an employee for refusing to submit to a mandatory flu vaccination based on veganism. The employee claimed that the vaccination contained animal products that went against her religious and philosophical views as a vegan. The court found "it plausible that [p]laintiff could subscribe to veganism with a sincerity equating that of traditional religious views." See *Chenzira v. Cincinnati Children's Hospital Medical Center*, Case No. 1:11-cv-00917.

Based on the contrasting case law and fact-sensitive analysis, employers should consult with legal counsel before denying an accommodation request based on an employee's proffered religious belief.

e. What constitutes an "undue hardship" that would justify an employer's refusal of an employee's vaccine exemption request based on religion or disability?

Unfortunately, there is no bright line answer to what constitutes an "undue hardship" to justify an employer's refusal of an employee's request for accommodation. As noted above, the interactive process, including the determination as to whether a requested accommodation presents an "undue hardship," is an individualized assessment that employers must conduct on a case-by-case basis.

"Undue hardship" may also depend on the reason for the accommodation request. For example, in the context of a religious accommodation under Title VII, "undue hardship" is a lower standard that requires "more than *de minimis*" cost or burden to the employer. EEOC guidance explains that because the definition of religion is broad and protects beliefs, practices, and observances with which the employer may be unfamiliar, the employer should ordinarily assume that an employee's request for religious accommodation is based on a sincerely held religious belief. The EEOC identifies factors of what may constitute "undue hardship" in the context of religious discrimination under Title VII, including if the accommodation is "costly, compromises workplace safety, decreases workplace efficiency, infringes on the rights of other employees, or requires other employees to do more than their share of potentially hazardous or burdensome work." See EEOC Guidance on Religious Discrimination.

Under the ADA, "undue hardship" is a higher threshold that requires "significant difficulty or expense" based on the employer's resources and circumstances, or that the employee poses a "direct threat" to the health and safety of others. See EEOC Guidance on Undue Hardship and Section 4(c) above.

Regardless of the context, employers should assess several factors when determining whether the accommodation results in "undue hardship," ranging from financial costs to the type of operations. Employers should also be mindful of state anti-discrimination laws, which may impose even higher burdens of "undue hardship."

Accommodation determinations are regularly questioned and scrutinized through litigation — even without involving the controversial topic of a mandated vaccine. "Undue hardship" in the context of the COVID-19 vaccination in particular presents a unique twist to the traditional analysis because all employers have had to make at least some changes to their operations in response to the pandemic. Specifically, many employers have already implemented the alternative accommodations that a vaccination exemption would offer, such as minimizing employee interactions requiring PPE, telework arrangements, and social distancing — all of which could arguably constitute reasonable alternatives to vaccination.

f. Can an employee refuse to be vaccinated if they don't believe the vaccines are safe?

Typically, a generalized fear that COVID-19 vaccines are not safe is insufficient to warrant an exemption under the law. However, employers must consider any underlying basis for the refusal in order to assess any available protections under the law. As discussed above, an employee's refusal may stem from a religious belief or a disability, which may require accommodation. An employee who refuses vaccination due to a reasonable belief that it may result in serious injury or death (such as a serious reaction) may be protected by Section 11(c)'s whistleblower provision under the Occupational Safety and Health Act. Likewise, an employee or group of employees who refuse or protest a mandatory vaccination could claim to be engaged in concerted activity, which

is protected under Section 7 of the National Labor Relations Act. Some states also protect an employee's political views, which could potentially implicate political speech based on an employee's views on the COVID-19 vaccine in light of the political climate.

g. Can employers give an exemption to the same employees who obtained a flu shot exemption?

Not necessarily. An employee who received an exemption for a flu vaccine may receive, but is not necessarily entitled to, a COVID-19 vaccine exemption. Employers are encouraged to conduct individualized assessments in response to each accommodation request

h. Is there a concern that employees who cannot receive the vaccine because they have requested an accommodation for religious or medical reasons are being discriminated against by being left out of an incentive program?

If the vaccine incentive program is subject to the HIPAA nondiscrimination regulations that apply to wellness programs (see question 5.i.), the incentive must be provided on the same terms and conditions to all similarly situated employees. And employees cannot be divided into different similarly situated groups on the basis of religion, disability, or any other protected characteristic.

In designing its vaccine incentive program, employers must be prepared to handle employee exemptions due to accommodations on the basis of a sincerely held religious belief or disability. Depending on the types of incentive offered, employers may consider ways to allow employees who receive an exemption as an accommodation to still earn the incentive (or another comparable benefit) by alternative means, such as attending a COVID-19 training during working hours.

5. Vaccine Program Design

a. Companies with flu vaccine policies may wonder how to apply those to COVID-19 vaccine. Should they establish voluntary programs like they do for flu vaccines (hosting clinics at their workplace, for example)? How does the distribution plan for any vaccine impact this, and what about smaller employers who cannot host this type of initiative?

According to the CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (last updated October 29, 2020), "routine immunization and pandemic influenza program activities can serve as a foundation for COVID-19 vaccination planning." This includes implementing COVID-19 voluntary immunization programs, such as hosting vaccination clinics at the workplace, leaving open the possibility of establishing a vaccine mandate. So far, states have implemented various options for vaccine rollout and distribution, including directly to hospitals or long-term care facilities or through enrolled provider programs (not to employers directly). Employers that cannot offer on-site vaccination clinics should encourage employees to seek vaccination in alternative sites in the community (*e.g.,* hospitals, pharmacies, state and local public health departments, and potentially government-run mass vaccination sites). Note that the effectiveness of these voluntary programs will depend on further guidance on the allocation, ordering, distribution, and inventory management of the COVID-19 vaccine.

b. What documentation will employers require to demonstrate that an employee received the vaccine?

How will they maintain it?

There is currently little guidance on what documentation employers may require and keep to show that an employee received the vaccine. Generally, subject to additional guidance, employers should ask the employee to provide documentation from an immunization service validating the date on which the vaccine was administered.

c. What are the privacy implications involved in collecting and maintaining this type of employee medical information? How will it implicate confidentiality and recordkeeping requirements under federal and state-specific laws?

The ADA and similar state-specific laws generally require employers to keep an employee's vaccination status confidential and to keep employee medical information separate from employee personnel files. Therefore, employers should maintain COVID-19, vaccine-related medical information in existing medical files.

d. How should employers allocate the vaccine if there is a limited amount (at least initially)? If employers don't receive the vaccine for distribution, who should they encourage/mandate to get the vaccine? And how can they ensure they do not make this type of allocation decision in a manner that does not involve any characteristic protected by law (e.*g.,* not just requiring those over age 65 to receive the vaccine)?

The COVID-19 vaccine supply has been limited during the initial implementation of vaccine-response activities, with initial distribution prioritizing long-term care facility residents and health care providers. The CDC, along with input from other organizations like the Advisory Committee on Immunization Practices (ACIP), has indicated that it may recommend other high-risk groups (such as workers in essential and critical industries and people with certain underlying medical conditions) receive priority as vaccine supplies increase. For instance, during a December 20, 2020 meeting, the CDC and ACIP recommended that certain frontline essential workers (including first responders, educators, and certain food & agriculture, manufacturing, and grocery store workers) receive the vaccine next, in Phase 1b of distribution, along with persons over 75 years of age. However, CDC guidance (and states' reactions to the recommendations) continue to change as vaccine supplies increase, so business should continue to monitor both sources of information as applicable. States may follow or consult CDC guidance on this point or develop their own guidance, and both CDC and state determinations are expected to change as the vaccine becomes more widely available. In the event employers become eligible to distribute the vaccine once it is more widely available, employers should consult CDC guidance and that of the applicable state Department(s) of Public Health to determine the groups to prioritize for allocation. To ensure that the distribution is not administered in a discriminatory manner, employers should prioritize access to the vaccine on medical needs and public health grounds.

e. Can employees' time spent receiving a required vaccine count as compensable work time?

Generally, yes. Under the Fair Labor Standards Act (FLSA), employers must reimburse expenses an employee incurs on its behalf or that an employee must expend primarily for the employer's convenience. State or local wage and hour laws may have similar, if not more restrictive, requirements. If the employee is required to receive a vaccine that is job related and consistent with business necessity, an employer will likely need to compensate the employee for the time spent and any expense of receiving the vaccine.

f. How will vaccination policies be impacted if they include vaccines with two-dose regimens?

Currently, most COVID-19 vaccine products will require two doses for immunization, with the second dose given several weeks after the first. The different COVID-19 vaccine products also are not interchangeable. Thus, employers using vaccines with two-dose regimens should carefully track the doses requirements, and if they require confirmation of vaccination, they should follow up with each vaccinated individual to ensure they receive the same vaccine, with the second dose given at the proper time. Employers likely may not rely on existing vaccination policies since this two-dose schedule was not required for other mass-distributed vaccines, such as seasonal influenza or during the 2009 H1N1 pandemic influenza. The CDC and local jurisdictions are currently in the process of providing additional guidance on how to monitor COVID-19 vaccine administration through a vaccine tracking system, including issuing second-dose reminders.

g. Are there GINA pre-screening implications if employers contract with a third party to administer the vaccine in a voluntary program?

Yes. The EEOC has acknowledged that pre-screening questionnaires may elicit information about genetic information protected by GINA. See Section K of the EEOC Guidance (answer to question 9). For GINA purposes, "genetic information" means information about: (i) an individual's genetic tests; (ii) the genetic tests of that individual's family members; (iii) the manifestation of disease or disorder in family members of the individual (family medical history); (iv) an individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or (v) the genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual, and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology. Genetic information does not include information about the sex or age of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test. 29 C.F.R. § 1635.3(c).

The EEOC's guidance to date has confirmed that if pre-vaccination questions do not include any questions about genetic information as defined by GINA (including family medical history), then asking them does not implicate GINA. However, if pre-vaccination questions do include questions about genetic information, then "employers who want to ensure that employees have been vaccinated may want to request proof of vaccination instead of administering the vaccine themselves" — and, if an employer does require its employees to provide proof that they received the vaccine, "the employer may want to warn the employee not to provide genetic information as part of the proof."

The CDC published a sample/recommended pre-screening questionnaire January 5, and it does not include any questions about family member medical history. However, a third party who administers the vaccine may or may not follow the CDC's exemplar form. Thus, employers may consider requesting that any third-party provider include GINA safe-harbor language in its pre-screening questionnaires to the extent the third party will act as the employer's agent, particularly given that the EEOC's guidance is not clear that the same third-party provider/voluntary carve-out applicable in the ADA context described in Question 3(b) applies in the GINA context. However, the EEOC has confirmed that inclusion of such safe-harbor language would insulate an employer from liability if such information was collected. The guidance points employers to 29 CFR 1635.8(b)(1)(i) for model language that can be used for this warning, which reads as follows:

"The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. 'Genetic information' as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services."

Employers who require or request proof of vaccination status from their employees may also consider including the carve-out language above in any instruction to employees regarding providing such proof, coupled with an instruction not to provide genetic information.

h. What are considerations for employers who contract with a third party to host vaccination "clinics" at their locations (encouraging employees to get vaccinated, not mandating)?

When an employer contracts with a third-party vendor to host an on-site COVID-19 vaccination clinic for which the employer is paying some or all of the cost, that arrangement constitutes employer-provided medical care and thus is considered to be an ERISA group health plan. In order to satisfy all of the various statutory and regulatory compliance obligations that apply to ERISA group health plans, the on-site vaccine clinic program should be structured as part of the employer's existing group major medical plan or its employee assistance program (EAP) that is already a group health plan due to providing free counseling sessions. If considered part of the medical plan, the on-site vaccine clinic program should be included in the plan's summary plan description (SPD) or described in a summary of material modification (SMM) explaining how the program is designed, including who's eligible for the program. In deciding whether to structure the on-site vaccine clinic program as part of an existing EAP, employers should consider preserving the EAP's HIPAA-excepted benefit status as not providing significant benefits in the form of medical care or treatment.

Under either approach on how to structure the on-site vaccine clinic program as part of an existing group health plan, additional considerations include the following:

- **COBRA:** Like all ERISA group health plans, an on-site vaccine clinic program would technically need to be offered as part of COBRA continuation coverage to employees who lose coverage due to termination of employment or reduction of hours (or to their covered dependents in certain circumstances, if the vaccine clinic is available to an employee's family members). However, many employers have policies that do not permit former employees to return on-site and that would prevent former employees from receiving a vaccine at the clinic. Strategies for mitigating risk associated with not offering access to the on-site vaccine clinic to COBRA-qualified beneficiaries should be discussed with counsel.

- **HIPAA:** The third-party vendor with whom the employer contracts to run the on-site vaccine clinic is considered a HIPAA business associate of the employer-sponsored group health plan under which the clinic is provided, so a HIPAA business associate agreement must be included as part of the contractual agreement with that third-party vendor. In addition, any protected health information (PHI) created by the clinic must be protected under HIPAA's privacy and security rule requirements. For example, if the employer wants to receive individually identifiable information directly from the vendor about which employees receive the vaccine at the clinic, each employee would need to sign a HIPAA-compliant individual authorization permitting such disclosure of their vaccine record directly from the vendor to the employer.

- **ADA/GINA:** If the third-party vendor requires employees to complete a pre-screening questionnaire before receiving the vaccine, and if the employer wants to provide an incentive to encourage employees to get vaccinated, the questionnaire should be reviewed to ensure that it does not include any disability-related inquiries or family medical history questions. If it does include such questions, then the voluntariness requirements under the ADA and GINA should be reviewed with counsel.

Lastly, counsel should review carefully all third-party vendor contracts to ensure adequate legal protections are included for the employer.

i. Does offering an incentive for taking vaccine constitute a wellness plan subject to HIPAA?

Probably. If the incentive is related to the employer's existing medical plan — such as lower employee contribution rates or lower out-of-pocket costs (*e.g.,* a lower deductible or lower copayments) — then the vaccine incentive program is considered a wellness program subject to the HIPAA nondiscrimination regulations that apply to wellness programs that are part of a group health plan. If the incentive is cash or a gift card — something not related to the employer's existing medical plan — but the vaccine is paid for by the employer's existing medical plan (as required by the ACA's preventive care coverage mandate), then such a vaccine incentive program will also constitute a wellness program subject to the HIPAA nondiscrimination regulations. Only if the incentive is not related to the employer's existing medical plan and if the vaccine is not paid for in any way by the employer's existing medical plan might the employer be able to take the position that such a vaccine incentive program is not subject to the HIPAA nondiscrimination regulations that apply to wellness programs.

When a vaccine incentive program is subject to the HIPAA nondiscrimination regulations, there's some question as to whether the program would be considered a participatory program or an activity-only, health-contingent program. If the former, there's no specific limit on the value of the incentive, and generally the program just needs to be offered under the same terms and conditions to all similarly situated employees. If the latter, the value of the incentive is limited to 30% of the cost of the employer's medical plan, and a reasonable alternative must be offered to employees for whom it is unreasonably difficult or medically inadvisable to get the vaccine so that they can earn the same incentive. Employers considering offering an incentive for taking the vaccine should consult with benefits counsel when designing the details of such an incentive program.

j. How can an employer encourage employees who don't want a COVID-19 vaccine to get a COVID-19 vaccine?

Even if an employer offers incentives to employees (like those described in response to questions 3(g) and 5(i)), employees may still hesitate to get a COVID-19 vaccine. Employers should consider providing their employees with educational information about the safety and effectiveness of the approved COVID-19 vaccines. Information from reliable sources (including the CDC) can be shared via email and workplace postings. Employers can also encourage employees to post vaccine "selfies" (showing employees getting their vaccine shot with personal information redacted) on the employees' personal social media accounts, on the employers' social media pages, and on the employers' intranets. A "fear of missing out" could provide employees with the additional incentive they need to make a vaccine appointment.

k. Can employees pick which vaccine (J&J for example) they want or do not want?

Because the three currently available vaccines were approved for use pursuant to an EUA, they must be given with informed consent and the ability to refuse. This means that an employee likely does have the ability to select a preferred vaccine — and at least, to refuse to receive a dose of a particular vaccine. From a practical standpoint, it can be difficult to determine in advance which vaccine brand a provider will have on hand the day of the appointment. Employers who operate their own on-site clinics (or contract with third parties to do so) should ensure employees are informed as to which vaccine will be administered at or before the time of their appointment and allow them to reschedule if they do not wish to receive a given vaccine. Employees seeking vaccines at third-party health care provider locations (whether through an employer-mandated program or voluntary program) will have the ability to seek out a preferred vaccine from such third-party provider, but employers should be aware that employees with a particular preference may experience more of a delay in receiving the vaccine, depending on availability.

l. Can you require/mandate one set of employees to get the vaccine and not another set of employees?

Generally, yes depending largely on three factors: (1) the nature of the employer's business and operations; (2) the nature of a particular employee's job duties for the employer; and (3) whether certain employees object to the vaccine. For example, employers in critical infrastructure industries, such as health care and elder care, have a strong, legitimate basis for requiring all essential employees working on-site to become vaccinated. Outside of those industries, employers may have a combination of both essential and non-essential employees. In this scenario, employers should consider how closely together the employees work as part of their job duties and how much exposure the employees have to customers and other members of the public at large. For instance, while employers may require essential employees working on site to become vaccinated, the same mandate need not apply to non-essential employees that work remotely. Finally, employers may not require employees – whether essential or non-essential, and whether working on-site or remotely – to receive the vaccine if such employees oppose the vaccine based on religion, disability, pregnancy, or some other reason protected by state or federal law. Of course, subject to reasonable accommodations to these vaccine objections, employers generally are not precluded from limiting access to workplace premises to only those employees that have been vaccinated.

m. How should employers address employees who have adverse effects after receiving the vaccine? If they miss work, how should it be compensated?

As acknowledged by the CDC, people may experience various side effects after receiving the COVID-19 vaccination, regardless of the vaccination type. Some of these common side effects include the same symptoms as COVID-19, such as fever, chills, headache, and fatigue. As such, employers can reasonably anticipate that employees may request time off, ranging from a few hours to a few days, when employees are unable to perform their duties because of these potential side effects.

Employers should allow employees to utilize any accrued paid time-off benefits, such as sick leave or vacation, for vaccination, including any adverse side effects. While there are currently no federal paid benefits specifically for COVID-19 vaccinations, employers should monitor state and local legislation. For example, New York recently enacted a law that mandates paid COVID-19 vaccination leave of up to four hours per injection. However, New York's vaccination leave does not address time off for any adverse effects — just time off for the vaccination itself. Even if the law does not require it, employers may also consider providing additional paid time off for vaccinations and any adverse side effects as part of their incentive programs.

If employees develop vaccination side effects that are also symptoms of COVID-19, employers must consider how this will impact their pre-shift screening and quarantine procedures. For example, if a company takes employee temperatures, should an employee who develops a fever following vaccination be permitted to work and required to quarantine? Again, employers should monitor federal, state, and local guidance for any exceptions to quarantine requirements for vaccinated employees. However, in the absence of such guidance, the most conservative approach is to consistently follow any screening and quarantine procedures when an employee presents with any potential COVID-19 symptoms, regardless of whether the employee reports them as a likely side effect of vaccination.

n. Should employees be required to use PTO to get the vaccine?

Employers should first determine whether local laws require the provision of paid time off to employees to get the COVID-19 vaccine, and if so, how much time is required. For example, on March 12, New York enacted a new law that requires employers to provide up to four hours of paid leave per vaccine injection (for employees receiving the two-dose Moderna and Pfizer vaccinations, the new law requires employers to provide a total of up to eight hours of paid leave). Importantly, this New York law requires the paid leave for vaccines to be in addition to any preexisting leave entitlement. It is expected that additional jurisdictions will adopt a similar requirement. If local laws do not impose any requirements, then it is a question of business judgment. However, there are benefits to offering at least a few hours of paid vaccine leave to employees without requiring employees to draw down on accrued PTO. In addition to encouraging a healthy workforce and supporting morale, providing extra paid leave avoids the complications of what to do if an employee has already exhausted accrued PTO. In that case, the employer would need to decide whether to offer additional PTO to employees who have already used their PTO allotment, require the leave to be unpaid, or record a negative leave balance for that employee to offset future paid leave accruals.

6. Liability Questions

a. If employers mandate the vaccine and it results in an injury, is the employer liable?

Employers who mandate or administer a COVID-19 vaccine before employees return to work should be afforded liability protection under the PREP Act, assuming the employer acts in accordance with the PREP Act and other appropriate guidance. The PREP Act authorizes the HHS secretary to provide certain individuals and entities (referred to as “covered persons”) with immunity from liability arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (referred to as “covered countermeasures”) except for claims of willful misconduct.

A COVID-19 vaccine would be considered a “covered countermeasure” and thus covered by the PREP Act, so long as the FDA issues the vaccine an EUA. The secretary’s March 17 declaration under the PREP Act includes private sector employers who “supervise or administer” the dispensing, distribution, or use of a covered vaccine, including those who “establish requirements, provide policy guidance,” or “provide a facility to administer” a covered vaccine as “covered persons.” Therefore, employers who engage in these activities should be considered “covered persons” and afforded protection under the PREP Act. Furthermore, per the secretary’s fourth amendment to the March 17 declaration, the PREP act also offers immunity from liability to any entity that administratively supervises the allocation, dispensing, distribution, or use of covered countermeasures even if that

countermeasure is ultimately not administered.

To obtain immunity under the PREP Act, however, an employer would need to perform those activities "in accordance" with the secretary's declaration. Such declaration may include directions to vaccinate only certain groups or only under specific conditions, such as with a health agency's approval. An employer would not have immunity if it mandates or administers a vaccine for those excluded groups or if not in compliance with the agency's specific conditions. It is therefore critical for employers to ensure that any mandate or administration of the vaccine adheres closely to the secretary's declaration and any health agency's directions.

It is also important to note that PREP Act immunity is retroactive from February 4, 2020, and it extends only through October 1, 2024 or when the secretary announces the end of the COVID-19 public health emergency, whichever occurs first. Thus, any claims based on vaccines administered after such date would not receive immunity under the PREP Act.

Although the PREP Act is broadly drafted by including the terms "arising out of" or "relating to" or "resulting from," time will tell how courts define those terms and others, such as "willful misconduct" and "in accordance with." The definition of these terms is critical in determining the scope of PREP Act immunity, but courts have not yet interpreted them.

The PREP Act FAQs state that any compensability for injury will be paid from the Countermeasures Injury Compensation Program (CICP). The CICP is only available for "serious physical injury," including those that "warranted hospitalization" or "led to a significant loss of function or disability." However, even if applicable, the "CICP is payer of last resort, so benefits are reduced by the amounts payable by all other public private third-party payers (such as health insurance and workers' compensation)." These FAQs suggest that any illness or injury caused by an employer-mandated vaccine may result in liability under any applicable workers' compensation system. Depending on the state, workers who get sick from taking a required vaccine would need to prove their employer was reckless or grossly negligent to get around the workers' compensation system.

b. What if the CDC begins strongly recommending employers require employees to get vaccinated before returning to work? Do employers face liability concerns if they do not require a vaccine in that instance?

Typically, employers are prudent to follow CDC guidance on COVID-19 updates. However, the CDC's guidance has changed since the emergence of the pandemic, and it will likely continue to evolve. If the CDC issues guidance that recommends the vaccine, an employer's refusal to follow such guidance will not necessarily result in liability. In addition to CDC guidance, employers should monitor and comply with federal, state, and local legislation or orders regarding the COVID-19 vaccine, along with any other COVID-19 preventive efforts. Typically, state and local agencies and health departments have authority to enforce more or less restrictive requirements within their jurisdiction, which can result in conflicts between federal, state, local, and city requirements. For example, while the CDC may recommend the vaccine, certain states or localities may prohibit vaccination mandates or limit such mandates to certain industries.

Employers should also monitor guidance from relevant government agencies like the EEOC (described above) and OSHA (which has not yet issued guidance on COVID-19 vaccines). Employers also should know that state law may impact mandatory vaccination programs. At last count, there are at least 10 states with proposed

legislation that would ban employers from implementing mandatory vaccination programs. More such efforts may follow as vaccines becomes more widely available. Though none of these efforts have yet resulted in a law banning mandatory vaccination programs, employers should continue to monitor state-level activity as this trend continues.

c. How should employers requiring or recommending vaccines (or hosting employer-sponsored optional vaccine clinics) prepare for possible liability associated with these activities?

Although it is not a settled question, injury or illness attributed to an employer-mandated COVID-19 vaccine will likely receive compensation under any applicable workers' compensation scheme. Some states and jurisdictions do not allow COVID-19-related liability waivers in the employment context. In states allowing liability waivers, employers should consider using waivers for both those employees who are vaccinated, as well as those who are granted an exemption or choose to forego vaccination.

If an employer wanted to mitigate any potential liability associated with vaccine injury, the employer could consider making any vaccinations entirely optional and voluntary. To further minimize any connection to the employer, employers may consider providing information on where employees can obtain vaccinations instead of hosting or sponsoring a vaccination clinic during work hours.

d. Can vaccine manufacturers be held liable for injuries related to the COVID-19 Vaccine?

Manufacturers of vaccines for COVID-19 can be protected from liability under the PREP Act, so long as they comply with the terms of their FDA authorization or clearance, as well as any other applicable regulations. As previously mentioned, a vaccine would be considered a covered countermeasure under the PREP Act, as it is a drug 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." Generally, covered countermeasures are FDA or NIOSH cleared or approved products, or, at minimum, are product for which the FDA grants an EUA. An entity will be protected as a manufacturer or distributor of covered countermeasures "regardless of who receives the countermeasure or where it is administered or used." Furthermore, per the most recent amendment to the PREP Act declaration, manufacturers will be protected from liability for the administrative prioritization or purposeful allocation of a covered countermeasure, even if this results in the non-administration of said countermeasure.

e. What exceptions are there to vaccine manufacturers' liability immunity under the PREP Act?

Liability immunity granted under the PREP Act is not absolute. Vaccine manufacturers will not be immune from suits for willful misconduct. The PREP Act defines willful misconduct as an act or failure to act that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. All three conditions must be unequivocally proved for liability to exist.

Furthermore, the only exception to liability immunity under the PREP Act is an "exclusive federal cause of action" against the manufacturer for death or willful misconduct. Therefore, willful misconduct cannot be found against a vaccine manufacturer for HHS-regulated actions if neither the attorney general nor the HHS secretary initiates an

enforcement action. The only remedies available without this federal cause of action are administrative remedies, pursuant to 319F-4 of the PHS Act.

f. What remedies or compensation are available for people injured as a result of a COVID-19 vaccine?

The PREP Act establishes that, without a federal cause of action for death or willful misconduct, the only remedies available for injury claims are administrative remedies.

Any person claiming injury as a result of a COVID-19 vaccine (or any other covered countermeasure) can seek compensation through the HHS CICP. CICP is an administrative process, which can directly ascertain coverage and compensation by the HHS, including compensation for serious physical injury or death. To establish a covered injury, the CICP must determine that the injury sustained direct resulted from the administration or use of a covered countermeasure. Under the PREP Act, the CICP may only make such determinations "based on compelling, reliable, valid, medical, and scientific evidence."

7. Health Care

a. Can a health care provider require its staff be vaccinated?

Yes, provided that the health care provider makes an exception for those with a *bona fide* ADA medical condition or Title VII religious belief. In a 2016 case, a Massachusetts federal district court considered a hospital's mandatory vaccine policy and an employee's request for a religious exemption. The employee worked in the emergency room and came into direct contact with patients during registration. In response to the employee's claim for a religious exemption, the hospital offered several accommodations, including an alternative vaccine. The employee refused and was ultimately deemed to have voluntarily resigned based on her refusal to get the influenza vaccine. The court upheld the hospital's action, in part, because allowing the employee to continue working in her current role without getting the vaccine would constitute an undue hardship.

"…[I]t would have increased the risk of transmitting influenza to its already vulnerable patient population. Health care employees are at high risk for influenza exposure and can be a source of the fatal disease because of their job. Numerous medical organizations support mandatory influenza vaccination for health care workers…. Had the [h]ospital permitted her to forgo the vaccine but keep her patient-care job, the [h]ospital could have put the health of vulnerable patients at risk." See *Robinson v. Children's Hosp. Boston*, Civil Action No. 14-10263-DJC (D. Mass. Apr. 5, 2016).

However, employers should be aware that state law may limit health care providers' ability to mandate vaccinations for all employees in some locations. For instance, Oregon law prohibits health care providers from mandating that their staff receive a vaccination.

b. Can a health care provider adopt different vaccination requirements for different types of employees (*e.g.,* patient care/patient-facing employees vs. nonpatient care/patient-facing employees)?

Yes, health care providers can elect to implement different vaccine requirements for employees who engage in work that places them at a higher (or lower) risk. The CDC has indicated that health care personnel considered

first priority to receive the vaccine include any paid and unpaid people serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Some state rollout plans may further define this category. Consideration can be given if the employee provides direct patient care and/or has access to patient care or other vulnerable areas. Put a different way, if a health care provider elects to impose a mandatory immunization policy for the COVID-19 vaccine, such provider should consider the appropriate scope of the mandate. At least initially when the vaccine is in limited supply, it may be more advantageous to impose a mandatory policy on only those in direct patient care or vulnerable settings.

If a health care provider considered this approach, it should (1) articulate a clear and reasonable justification for using this approach based on patient and employee safety, and (2) implement the policy in a fair and nondiscriminatory manner, allowing for medical and religious exceptions as discussed in more detail elsewhere in this FAQ .

c. Can a nursing home participating in Medicare or Medicaid require its residents to get vaccinated?

The Centers for Medicare & Medicaid Services (CMS) require participating nursing homes to offer influenza and pneumococcal vaccines to residents. However, residents or their legal representatives may refuse immunization. Unless or until CMS provides guidance to nursing homes on the COVID-19 vaccines, these facilities should adapt their influenza and pneumococcal vaccines policies for the COVID-19 vaccines. This means that facilities should offer residents education on the benefits and potential side effects of immunizations, offer the immunization unless the immunization is medically contraindicated, provide the resident or resident's legal representative with an opportunity to refuse immunization, and document the education and immunization or refusal in the resident's medical record.

d. Can a private long-term care facility require its residents to get vaccinated?

A private long-term care facility that does not participate in Medicare or Medicaid may be able to require residents to receive the COVID-19 vaccine, depending on how the issue is addressed in the resident's agreement with the long-term care facility and other governing documents, as well as state law. Facilities in this situation should review their resident agreements, current policies and procedures, other documents that may address immunizations, and state licensure laws and amend any such policies or procedures in advance of the COVID-19 vaccine being released. They also should work with residents and family members to communicate such changes in advance of implementation.

In any mandatory immunization policy, the facility should make exceptions for those residents where the vaccine is medically contraindicated or who have a sincerely held religious belief prohibiting them from being vaccinated. Facilities should have processes in place to evaluate these requests and employees trained to handle them appropriately.

e. How should a long-term care facility prepare to handle residents who refuse the vaccination?

Facilities should have a plan for how best to care for residents who elect not to be vaccinated. For example, will the facility require that these residents and/or their assigned health care workers wear enhanced personal protective equipment (PPE)? Should they be moved to a particular area of the facility? Will the facility require them

to sign a waiver form documenting their decision not to be vaccinated and the reasons therefor? At a minimum, the facility should require staff to document its (1) discussion with the resident and/or family of the benefits and risks, and (2) the patient's and/or family member's refusal of the vaccine. This documentation should be made part of the resident's medical record.

f. Can a long-term care facility discharge a resident who refuses to be vaccinated?

If a facility wants to consider "discharge" as a result of a resident's refusal to be vaccinated, especially in the absence of a sincerely held religious belief or medical condition, it should carefully review its admission agreement, policies on transfers and discharges, and applicable state and federal law, including the Medicare conditions of participation (if applicable), and consult with legal counsel to ensure this step is appropriate under the circumstances.

g. How should health care providers handle COVID-19 vaccination records when they are providing the vaccine to employees?

Based on current guidance and historic practices in the context of the flu vaccine, when a health care provider is giving the immunization in its role as the employer (rather than in its role as a health care provider), it is appropriate to treat the records as occupational health or confidential employee medical information. This approach is consistent with the EEOC's most recent guidance, which said that "the ADA requires employers to keep any employee medical information obtained in the course of the vaccination program confidential." See K.2 at https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws. Records obtained by the health care provider as an employer under an employee's authorization will not be covered by the Health Insurance Portability and Accountability Act (HIPAA). HIPAA specifically excludes information "held by a covered entity in its role as employer" from the definition of "protected health information." See 45 C.F.R. § 160.103.

8. Education

a. Can colleges and universities mandate that students receive the COVID-19 vaccine?

Generally, yes. Colleges and universities may mandate that students receive the COVID-19 vaccine. The same exceptions discussed above based on a *bona fide* medical condition or religious belief would generally apply. It is important that schools consult their local state laws since many states have specific rules about vaccinations exemptions, which schools should follow if they choose to mandate a COVID-19 vaccine.

However, before adopting any policy requiring vaccinations, schools should consider some of the same factors identified above, including whether the vaccination will be in sufficient supply, and how they will administer and enforce compliance with the mandate. Schools should also closely follow guidance from the federal, state, and local government as it evolves on this issue.

b. Can schools release information about whether particular students were vaccinated?

Generally, no. The Family Educational Rights and Privacy Act (FERPA) would preclude release of information

absent written consent. FERPA, rather than HIPAA rules, would generally apply to colleges' and universities' release of such information. Schools should consult the FERPA regulations for any specific exemptions that might apply.

c. Should colleges and universities offer the vaccine to students at no cost?

Colleges and universities may consider covering the cost, or subsidizing part of the cost, of the COVID-19 vaccine to all students, but they are not required to do so.

d. Can colleges and universities mandate that employees (professors, administrators, coaches, etc.) receive the COVID-19 vaccine?

Yes, see above for the discussion on mandatory vaccinations of employees. Schools, however, should ensure that they follow their internal policies.

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