

Morgan Lewis

[Our Practice](#)
[Our People](#)
[Our Thinking](#)
[Our Firm](#)
[Careers](#)
[Home](#) > [Our Thinking](#) > [Publications](#) > [COVID-19 Vaccines: Considerations for US Employers](#)
[SUBSCRIBE](#)

LAWFLASH

COVID-19 VACCINES: CONSIDERATIONS FOR US EMPLOYERS

November 09, 2020 (Updated December 16, 2020)

With the US Food and Drug Administration's first issuance of an Emergency Use Authorization for a COVID-19 vaccine, employers should consider the implications a new vaccine will have on their workplaces. Although much remains speculative, employers can look to the regulation of current vaccines as the basis for their preliminary planning. Those who begin to plan now will be better positioned to navigate the various risks and issues involved.

To assist with that planning, this LawFlash provides an overview of the vaccine approval process in the United States, key legal issues US employers should be aware of, and guidance on how to begin analyzing the major risks.

THE APPROVAL PROCESS

Vaccines are biological products typically approved and regulated by the US Food and Drug Administration (FDA) Center for Biologics Evaluation and Research under a Biologics License Application (BLA). For a vaccine to be approved, FDA must determine that it is both safe and effective, based on data from laboratory studies and clinical trials. FDA assesses both the quality and the quantity of the data provided when determining whether a vaccine meets this standard. This generally is a lengthy process.

FDA has the authority to expedite the development and review process for vaccines used to treat or prevent serious or life-threatening conditions and diseases, such as coronavirus (COVID-19). Even under an expedited approval process, however, priority review may take up to six months or more from the time of application.

On December 11, 2020, FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine (Pfizer vaccine), and it is expected that Moderna's vaccine will likewise receive an

AUTHORS AND CONTACTS



**SHARON PERLEY
MASLING**
PARTNER

Washington, DC



KATHLEEN M. SANZO
PARTNER

Washington, DC



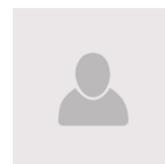
**LAUREN A. WEST
OF COUNSEL**

Dallas



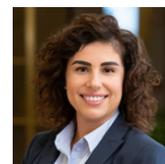
ALANA F. GENDERSON
ASSOCIATE

Washington, DC



**CHRISTOPHER P.
JAYNES**
ASSOCIATE

Dallas



MARIA KALOUSHI-TATUM
ASSOCIATE

Washington, DC



DANIEL A. KADISH
ASSOCIATE

New York

EUA in December. The issuance of an EUA signifies that the secretary of the US Department of Health and Human Services (HHS) has concluded that (1) COVID-19 is a serious or life-threatening disease; (2) it is reasonable to believe that the vaccine *may be* effective in treating or preventing the disease; (3) the known and potential benefits of the vaccine outweigh the known and potential risks; and (4) there is no adequate, approved, and available alternative.

Note that under an EUA, the standard is “may be effective,” as compared to “is effective” under a BLA. Further, as announced by FDA on October 6, the issuance of an EUA for a COVID-19 vaccine also requires at least two months of follow-up safety data after trial participants have been fully vaccinated.

While the issuance of the first EUA for a COVID-19 vaccine is an important and promising development, for the purposes of this LawFlash, our analysis assumes that a COVID-19 vaccine will ultimately be approved under a BLA.

PHASED DISTRIBUTION

Distribution of the Pfizer vaccine began December 14. However, available supplies are limited. As a result, widespread vaccines will not be available for most people or businesses right away.

The Centers for Disease Control and Prevention (CDC) is making plans for a phased distribution of the vaccine. While those plans are still being finalized, the CDC has announced that early vaccination efforts will likely focus on those persons who are critical to responding to the virus and those at greatest risk of developing severe illness from COVID-19. In particular, populations of focus for initial COVID-19 vaccination may include the following:

- Frontline healthcare workers who are treating people with COVID-19 or are likely to be exposed to COVID-19

- People at increased risk for severe illness, including those with underlying medical conditions and older adults, especially those living in congregate living facilities

- Critical infrastructure workers

Once more vaccines are available, and with the expected issuance of an EUA for the Moderna vaccine, we can anticipate more widespread distribution.

MANDATING VACCINES

One of the most common questions employers are grappling with is whether they may require employees to get a COVID-19 vaccine once it is widely available.

Neither the US Equal Employment Opportunity Commission (EEOC) nor the Occupational Safety and Health Administration (OSHA) has issued specific guidance regarding a COVID-19 vaccine. With the recent issuance of an EUA for the Pfizer vaccine, and expected EUA for the Moderna vaccine, it is more likely that these agencies may issue such guidance in the coming months. Until then, guidance issued by the agencies during the H1N1 epidemic and recently reissued during the current pandemic is instructive.

EEOC

In its [2009 guidance on pandemic preparedness](#), EEOC explicitly said that employers could require employees to get the flu vaccine so long as employers provided reasonable accommodations to people with

RELATED RESOURCES

SERVICES

- > Labor, Employment & Benefits
- > Employment Counseling

REGIONS

- > North America

disabilities and those with religious objections, as required by the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 (Title VII), respectively.

Under the ADA, employers must provide a reasonable accommodation to any employee with a qualified disability that prevents them from receiving the flu vaccine. An employer is not required to provide a reasonable accommodation, however, if none is available, if the reasonable accommodation would present an undue hardship to the employer, or if the employee would pose a direct threat to the health or safety of others that could not be mitigated through the reasonable accommodation.

As always, the reasonable accommodation and undue hardship analyses are individualized assessments that take into account the nature of the employee's disability, the conditions of the job, the vaccine, and the employer's circumstances. In the case of an employee who cannot be vaccinated, possible accommodations may include telework, protective equipment such as face masks and face shields, increased social distancing measures, or a modified work schedule. Of course, the range of potential accommodations may narrow for industries that require close face-to-face interaction with coworkers or the public.

Like the ADA, Title VII mandates employers that require vaccination as a condition of employment to also provide reasonable accommodations for employees with a sincerely held religious belief, practice, or observance that prevents them from taking the vaccine. This protection does not extend to nonreligious beliefs and would not exempt an employee who objects to vaccination due to political beliefs or other personal reasons, although such concerns might be protected under state law. Any employer faced with a request for a religious exemption may make a reasonable request for supporting information verifying that the basis for the request is, in fact, a sincerely held religious belief.

Additionally, as with the ADA, employers are not required to provide reasonable accommodations that pose an undue hardship under Title VII. Notably, "undue hardship" under Title VII is a much lower standard than under the ADA and requires only "more than de minimis" cost or burden to the employer. By contrast, an employer citing "undue hardship" under the ADA must show that the proposed accommodation poses a "significant difficulty or expense."

In its updated guidance on pandemic preparedness, which it recently reissued in light of COVID-19, EEOC specifically cautions that "[a]s of the date this document is being issued, there is no vaccine available for COVID-19." Thus, it is always possible that EEOC will issue different guidance regarding COVID-19. Given the fact that the agency has already proclaimed that COVID-19 poses a direct threat to the health and safety of others in the workplace, however, we presume that EEOC will apply the above legal analysis to the COVID-19 vaccine as well.

OSHA

Like EEOC, OSHA has not yet provided guidance on a future COVID-19 vaccine. However, in a 2009 letter of interpretation, OSHA previously said that employers that wished to require employees to receive a seasonal flu vaccine could do so, subject to certain exceptions.

OSHA emphasized that employees need to be properly informed of the benefits of the vaccinations. It clarified that if employees refuse the vaccine due to a reasonable belief that they have a medical condition creating a real danger of serious illness or death (for

example, a serious reaction to the vaccine), they may be protected as a whistleblower under Section 11(c) of the Occupational Safety and Health Act (OSH Act).

Regarding the COVID-19 vaccine, there is some speculation in the legal community that OSHA may use the OSH Act's so-called General Duty Clause to issue citations to employers that fail to offer COVID-19 vaccines. By way of background, OSHA issues citations under its General Duty Clause when no specific OSHA standard applies. At present, there is no OSHA standard that would mandate employers to offer a COVID-19 vaccine when one becomes available.

Ultimately, OSHA's statutory authority to issue a General Duty Clause citation will depend on a variety of factors, including (1) guidance from the CDC and OSHA on use of the vaccine in the workplace, and (2) the strength of the employer's COVID-19 safety and health program and whether it follows other guidance from public health officials. We will continue to monitor this issue as agencies publish guidance on the COVID-19 vaccine.

Alternatively, OSHA is facing substantial political pressure to publish a temporary standard covering COVID-19, which could address the vaccine issue. For example, OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030, which was issued in 1991 largely in response to the HIV epidemic, affirmatively requires employers to offer the Hepatitis B vaccination to all employees who may reasonably anticipate contact with blood while performing their job duties.

National Labor Relations Board

Finally, employers with unionized workforces should be mindful of the National Labor Relations Act (NLRA) and any labor contract obligations. Absent a "legal" mandate that employees be vaccinated (and there have been some bills proposed in various state legislatures to mandate COVID-19 vaccinations), a vaccine requirement likely would be considered a mandatory subject of bargaining that gives rise to a duty to bargain prior to implementation, unless there's an existing labor contract that provides for a management right to implement such a decision without bargaining. Employers also should consider any labor contract language that would foreclose mandatory vaccination. If there is no collective bargaining agreement in effect, the employer may be required to bargain to agreement or impasse before implementing a mandatory vaccination policy, depending on the circumstances and industry. Moreover, employers would have an obligation to bargain over the effects of a vaccine requirement, including, for instance, payment for the vaccine, the timeframe for getting vaccinated, time off to receive the vaccine, sickness caused by the vaccine, and consequences for employees who refuse the vaccination.

Even in a nonunionized setting, there are potential NLRA implications. Specifically, Section 7 of the NLRA grants employees the right to engage in "concerted activities" for the purpose of "mutual aid and protection." This provision may protect the rights of employees who engage in concerted activities with regard to a mandatory workplace vaccine. Examples of protected activities could include protesting against a mandatory vaccination policy, organized office communications or flyers among coworkers concerning a vaccination mandate, or simply coworker discussions about the vaccine.

State Laws

State laws may also play a role with respect to regulation of a COVID-19 vaccine.

For example, nearly all states require certain healthcare facilities to mandate or offer various immunizations, such as seasonal influenza, Hepatitis B, and Measles, Mumps, Rubella (MMR), to their workers. Some states strictly limit the reasons a vaccination may be declined; for example, Illinois provides that “general philosophical or moral reluctance to influenza vaccinations does not provide basis for an exemption” to healthcare employees. However, a significant number of other states—for example, Alabama, Kentucky, Massachusetts, North Carolina, Pennsylvania, and Tennessee—permit an employee to decline the influenza vaccination for any reason, so long as the employee was informed of the health risks beforehand.

A handful of other industries—for example, drug treatment centers and homeless shelters in California, or childcare facilities in Texas and Rhode Island—may be subject to various vaccine requirements on a state-by-state basis.

To date, we have not identified any state laws that have been enacted regarding the COVID-19 vaccine. However, various vaccine bills have been introduced in legislatures across the country that would either prescribe or restrict certain uses of a vaccine (such as making it mandatory for certain populations). Therefore, before implementing any workplace COVID-19 vaccination policy, employers should consider any relevant legislative developments in their local jurisdictions.

IMPLICATIONS

Even though an employer *likely* will be able to require employees to get the COVID-19 vaccine after FDA approves it under a BLA, employers should weigh the employee relations concerns and potential legal challenges associated with doing so.

In fact, in its guidance on the flu vaccine, EEOC advises employers to “consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it.” In light of the potential concerns employees might have about the safety and efficacy of a COVID-19 vaccine, especially in the first few months after it becomes available, employers may wish to follow this approach. Employers could offer the vaccine at their worksites and pay for the vaccine, without requiring it. This would reduce the potential for legal challenges under the laws discussed above, as well as any potential backlash from “anti-vaxxers.”

In addition to the legal concerns outline above, there are practical difficulties that employers should consider before mandating that employees get vaccinated, such as the supply of available vaccines, pay or time off for the time an employee spends getting vaccinated, reimbursement or coverage of any cost for the vaccine, and—for employers that ultimately choose to conduct vaccinations onsite (when there is sufficient supply for this to become an option)—proper storage of the vaccine, administration of the vaccine by appropriately licensed and trained individuals, and physical side effects following vaccination.

COMPENSATION FOR INJURY

Workers' Compensation

An injury or illness occurring after the administration of a COVID-19 vaccine that has been approved by FDA under either the standard BLA process or the expedited BLA process would likely be compensable under many states' workers' compensation schemes. Even in cases where immunization was voluntary, such vaccination

would have arguably been encouraged by the employer, benefited the employer, and served a business purpose. Furthermore, if the vaccination occurred at work or was paid for by the employer, these factors also would support a finding that workers' compensation applies.

If a COVID-19 vaccine has only been approved under an EUA, an injury or illness occurring following the administration of an employer-mandated vaccine would still likely be covered by workers' compensation. However, depending on the state law, the workers' compensation exclusivity bar may be defeated if the employer engaged in gross negligence or reckless conduct.

PREP Act

Importantly, employers administering a COVID-19 vaccination program will likely be afforded another layer of immunity through the Public Readiness and Emergency Preparedness Act (PREP Act). Covered Persons, as defined therein, can include companies that administer vaccines or provide facilities for vaccine administration. The PREP Act grants liability immunity to Covered Persons against any claim of loss "caused by, arising out of, relating to, or resulting from" the distribution, administration, or use of COVID-19 vaccines approved by FDA under an EUA or BLA. The only exception to immunity is for claims involving "willful misconduct" as defined in the PREP Act.

Consequently, an employer providing a COVID-19 vaccine onsite may enjoy the liability immunity protections of the PREP Act, meaning that the employer would be immune from claims of injury or loss arising from the administration of a COVID-19 vaccine, except in instances of "willful misconduct."

Notably, on December 3, 2020, HHS [amended for the fourth time its PREP Act Declaration](#) (Fourth Amendment) to [expand civil immunity under the PREP Act](#) from tort claims related to the manufacture, distribution, administration, and nonadministration of COVID-19 countermeasures, which would include COVID-19 vaccines.

Specifically, the Fourth Amendment extends immunity to every person and entity in the public or private chain of distribution for an additional 12 months. It also expands immunity to certain licensed pharmacists who could administer COVID-19 vaccines if they have completed the immunization training required by their licensing state for pharmacists to order and administer vaccines. Thus, employers could have agreements with such pharmacists to administer COVID-19 vaccines to their employees, without losing any of the liability protections afforded by the PREP Act.

The Fourth Amendment also removes the prerequisite for employers to obtain an authorization from or agreement with the federal, state, or local government or state or local health authority to administer vaccinations. Private distribution of covered countermeasures, including COVID-19 vaccines approved by FDA, will be entitled to immunity as of December 3.

Importantly, considering the potential of COVID-19 vaccine shortages during initial distribution, the Fourth Amendment also extends immunity for employers that prioritize the vaccination of certain more vulnerable subsets of employees over others, pursuant to public health agency guidance. As noted above, these groups will likely include healthcare personnel, workers in essential and critical industries, people over the age of 65, and people with certain underlying medical conditions. Thus, if supply is limited, employers that decide not to administer COVID-19 vaccines to employees who are not part of the priority list will likely be immune from liability

under the PREP Act for potential injuries that result from that prioritization.

Note, however, that the Fourth Amendment did not change the requirement for employers to administer the vaccine in accordance with the directions for the vaccine, including ensuring it is only administered to the appropriate “population,” to obtain immunity under the PREP Act. For example, if certain groups of individuals are excluded from the approved use of the vaccine, such as pregnant individuals or persons under the age of 18, an employer would not have immunity if it administered the vaccine to an employee in the excluded group.

Finally, the PREP Act provides a “fund supplied by Congress, to compensate individuals who suffer an injury or death as a result of a COVID-19 vaccine approved under an EUA or a full FDA approval.” The fund operates as a remedy of last resort and would be offset by any health insurance or workers’ compensation payments received by the employee.

CONCLUSION

Currently, there are more questions than answers regarding COVID-19 vaccines. We expect federal and state agencies to issue more guidance in the coming months, with the issuance of an EUA for the Pfizer vaccine and the expected EUA for the Moderna vaccine. This LawFlash reflects our current analysis of potential legal issues that may emerge and is intended to help employers begin to work through these topics. Morgan Lewis has advised employers on numerous COVID-19 issues and will continue to monitor and analyze any new developments closely.

NAVIGATING THE NEXT.

Sharing insights and resources that help our clients prepare for and address evolving issues is a hallmark of Morgan Lewis. To that end, we maintain a [resource center](#) with access to tools and perspectives on timely topics driven by current events such as the global public health crisis, economic uncertainty, and geopolitical dynamics. Find resources on how to cope with the globe’s ever-changing business, social, and political landscape at [Navigating the NEXT](#), and [Coronavirus COVID-19](#) to stay up to date on developments as they unfold. [Subscribe now](#) if you would like to receive a digest of new updates to these resources.

CONTACTS

If you have any questions or would like more information on the issues discussed in this LawFlash, please contact any of the following Morgan Lewis lawyers:

Washington, DC

[Sharon Masling](#)

[Kathleen Sanzo](#)

[Jonathan Snare](#)

Houston

[Susan Feigin Harris](#)

