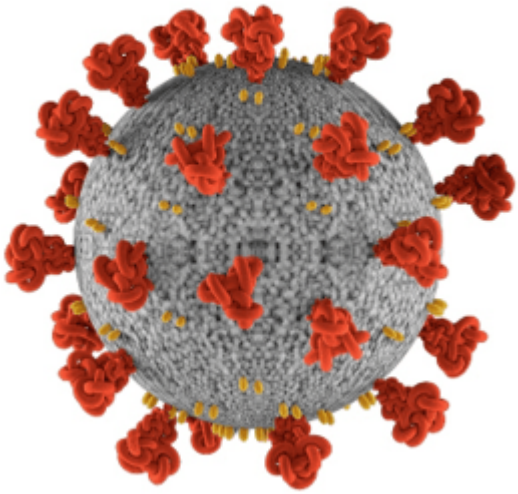
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What Employers Need to Know About Mandatory COVID-19 Vaccines

By Conn Maciel Carey's COVID-19 Task Force

With the availability of a safe, effective COVID-19 vaccine edging closer and closer, employers understandably have a number of questions regarding their role in the workplace – whether and when they can require a vaccination, what exceptions are required in a mandatory vaccination program, and whether they should require (as opposed to encourage and facilitate) the COVID-19 vaccine for employees once it becomes available.



This summer, the World Health Organization reported that nearly 200 potential vaccines were currently being developed in labs across the world, and as of mid-October, disclosed that more than 40 had advanced to clinical stage testing on humans. Drug manufacturers estimate that a vaccine will be ready and approved for general use by the end of this year, although logistically not ready for widespread distribution until mid-2021.

Indeed, just over the past couple of weeks, Pfizer and Moderna have made promising announcements regarding the results of their clinical trials. Namely, on Monday, November 9, 2020, Pfizer and BioNTech announced that a vaccine candidate against COVID-19 achieved success in the firm interim analysis from the Phase 3 study. The vaccine candidate was found to be more than 90% effective in preventing COVID-19 in participants without

evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis. According to the announcement, submission for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) is planned for soon after the required safety milestone is achieved, which is currently expected to occur this week. Additionally, as reported by the National Institutes of Health (NIH) on November 16, 2020, there have been promising interim results from a clinical trial of a NIH-Moderna COVID-19 vaccine. An independent data and safety monitoring board (DSMB) reported that the vaccine candidate was safe and well-tolerated and noted a vaccine efficacy rate of 94.5%.

As the reality of a vaccination nears, employers are inquiring whether they can and should mandate the vaccine for their employees.

1. **Can Employers Require Employees to Take the COVID-19 Vaccine?**

As a threshold matter, it should be noted that according to a member of the federal advisory panel on immunizations that will be making recommendations to the CDC on who should get the first doses, vaccines authorized under the FDA's emergency use authority, as these COVID-19 vaccinations will be at the start, *cannot* be mandated. Any COVID-19 vaccine brought to market under an EUA instead of the normal non-emergency approval process will, by necessity, lack long term safety data.

In general though, outside the context of EUA vaccine, employers *can* require vaccination as a term and condition of employment, but such practice is not without limitations, nor is it always recommended. Although the issue is only now coming to the forefront because of COVID-19, mandatory vaccinations in the workplace are not new, and have been particularly prevalent among healthcare providers for decades. Some variability exists under federal law and among federal agencies, but for the most part, mandatory vaccination programs are permissible, as long as employers consider religious accommodation requests under Title VII of the Civil Rights Act of 1964 (Title VII) and medical accommodation requests under the Americans with Disabilities Act (ADA).

OSHA has long taken the position that employers can require employees to take flu and other vaccines, but emphasizes that employees "need to be properly informed of the benefits of vaccinations." In the healthcare industry, for example, mandatory vaccination programs for employees are common. Indeed, several states have laws that require healthcare employers to offer the vaccine or to ensure that employees receive it (with certain exceptions). The CDC has long recommended that all healthcare workers get vaccinated, including all workers having direct *and indirect* patient care involvement and exposure.

However, the Americans with Disabilities Act (ADA) limits an employer's ability to make most medical-related inquires or examinations/treatments a condition of employment to certain circumstances. Specifically, to be permitted under the ADA, a medical exam or treatment would need to be job-related and consistent with business necessity. This "necessity" would need to be based on a reasonable belief that an employee's ability to perform essential job functions will be impaired by a medical condition if not treated, or the medical condition will pose a significant risk of substantial harm to workplace health or safety. The employer's belief about necessity must be based on factual information, not just subjective perceptions or irrational fears of the medical condition. Essentially, there has to be a specific and reasonable basis to believe that requiring a COVID-19 vaccine is necessary to keep the workplace safe from significant risks and/or to permit employees to be able to perform their jobs. That seems to be a hurdle that is easy and obvious to clear in the context of COVID-19 in most work circumstances.

Some of the rationale for supporting mandatory vaccinations in healthcare will apply similarly in general industry settings. That is, essential workers in public facing jobs are in communities with high community spread are at higher risk because of their exposure to the general public, and because, if an employee does not vaccinate, that creates risk of harm not just to themselves, but also risk to other employees, and to customers, etc. So, in high-risk places or work tasks, it is hard to imagine the various agencies would interfere with a mandatory vaccine program. Thus, absent a state or local law to the contrary, and outside the EUA context, private employers will very likely not be prohibited from implementing a mandatory COVID-19 vaccination program to keep the employees and the workplace safe.

2. **What Exceptions to Requiring the COVID-19 Vaccine Must Employers Permit?**

However, "mandatory" doesn't mean always mandatory. Even if a mandatory vaccination policy is permissible, employees *may* request, and must be permitted to request, reasonable accommodations from the mandatory vaccine based on a ***disability*** that prevents the employee from taking the vaccine, which under the ADA or applicable state laws, the employer would be required to grant unless it would result in undue hardship to the employer. The employee must establish a covered disability. There is a circuit split regarding whether sensitivity to vaccinations constitutes a covered disability. Under a similar set of facts, the U.S. Courts of Appeals for the Eighth and Third Circuits reached opposite conclusions—the Eighth Circuit held that alleged chemical sensitivities and allergies did *not* constitute a disability under the ADA, while the Third Circuit held that a history of allergies and anxiety related to the possible side effects of a vaccine qualified as an ADA-covered disability.

As for undue hardship, under the ADA, that is defined as "significant difficulty or expense" incurred by the employer in providing an accommodation. Under the standard established by the Supreme Court of the United States in *US Airways, Inc. v. Barnett*, to establish an undue hardship in the context of mandatory vaccinations, an employer generally "must show special (typically case-specific) circumstances demonstrating undue hardship." However, employers may be able to circumvent this problem by offering an alternative vaccine that does not contain an ingredient that could trigger an employee's medical condition (e.g., a vaccine that does not contain any egg, swine, or fetal cell products).

Similarly, under Title VII of the Civil Rights Act of 1964 and its applicable state equivalents, an employer must consider an employee's accommodation request based on a ***sincerely held religious belief***, practice, or observance, which, under relevant guidance, can be fairly broad and includes more than traditional organized religions. In *Chenzira v. Cincinnati Children's Hospital Medical Center*, the U.S. District Court for the Southern District of Ohio denied a motion to dismiss the employee's challenge to a mandatory flu vaccination because the court found "it plausible that [p]laintiff could subscribe to veganism with a sincerity equating that of traditional religious views." By comparison, in *Fallon v. Mercy Catholic Medical Center of Southeastern Pennsylvania*, the U.S. Court of Appeals for the Third Circuit affirmed the dismissal of a Title VII claim, finding that an employee's opposition to vaccines was a personal belief that did not "occupy a place in his life similar to that occupied by a more traditional faith." Personal anti-vaccination positions generally will not be sufficient to establish a sincerely held religious belief in order to be exempt from a mandatory vaccination policy.

Like with disabilities, even if an employee can establish a sincerely held religious belief, the employer may still deny an accommodation request if it poses an "undue hardship." The undue hardship analysis for Title VII religious accommodation requests includes consideration of harm to the employer, its employees, and third

parties, such as patients or customers. Federal courts are split on whether speculative harm is sufficient to establish an undue hardship, but at least one court—the U.S. District Court for the District of Massachusetts, in *Robinson v. Children's Hospital Boston*—has held that exemptions to a mandatory flu vaccine would have posed an undue hardship because allowing one employee to forgo a mandatory vaccination "could have put the health of vulnerable patients at risk."

In March of this year, the EEOC issued COVID-19 guidance specifically addressing the issue of whether employers covered by the ADA and Title VII can compel all employees to take the *flu* vaccine, and confirmed they could subject to these same two exemptions — under the ADA or Title VII. As to the rules the EEOC may set about a COVID-19 vaccine specifically, it is worth noting that since the onset of the pandemic, the EEOC has acknowledged that COVID-19 meets the ADA's "direct threat standard," which permits more extensive medical inquiries and controls in the workplace than typically allowed under the ADA. A "direct threat" finding means that having someone with COVID-19 in the workplace poses a "significant risk of substantial harm" to others. Such a finding permits employers to implement medical testing and other screening measures the ADA would usually prohibit. The forecasts likely support for mandatory COVID vaccination programs by the EEOC.

Other federal agencies have traditionally taken a more permissive stance to mandatory vaccines than the EEOC implementing the ADA. Indeed, agencies like CDC have often recommended workplace vaccination policies, especially for industries deemed critical to the economy and national infrastructure. For example, the CDC maintains a guidance document on this issue – "Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce." OSHA is also more likely to defer to employer-mandated vaccinations, although, as the agency explained in 2009, "an employee who refuses vaccination because of a reasonable belief that he or she has a medical condition that creates a real danger of serious illness or death … may be protected under Section 11(c) … whistleblower rights." Notably, OSHA is actively encouraging its inspectors to get the COVID-19 vaccination when it becomes available.



Once a COVID-19 vaccine is approved, both federal and state authorities are almost certain to issue further guidance and/or regulations governing vaccinations in the workplace. In particular, employers may want to keep an eye on developments at the state level. Any such laws could significantly alter the undue hardship analysis

under Title VII and the ADA if they mandate vaccinations to preserve the health and welfare of citizens (or subgroups, based on industry or job duties). For example, in its *Robinson* decision, the U.S. District Court for the District of Massachusetts considered a state department of health policy and guidance as support for the undue hardship defense.

So, absent undue hardship, employers will need to create exceptions to their "mandatory" policies for employees as a reasonable accommodation for the employees' disabilities or religious practices. Upon receiving an accommodation request to be relieved of a vaccination requirement due to disability or religious-related reasons, an employer must engage in an interactive process with the employee to determine if it can provide the employee with a reasonable accommodation (barring an undue hardship on the employer). An example may be asking that specific employee to wear a mask, follow social distancing rules, or take other specific precautions. As with all accommodation requests, employers need to make the determination on a case-by-case basis.

3. **Should Employers Require the Vaccine?**

Companies considering mandatory vaccination policies (either for the flu or the COVID-19 vaccine when it becomes available outside the Emergency Use context) should carefully analyze both the legal and operational elements of such a policy. The legal liability that could arise from requiring a vaccine where the vaccine goes sideways and creates harm to employees could be extraordinary. We would expect that to be limited to workers' compensation claims, but there will be efforts to bring suit against the employer and the vaccine manufacturer. And of course, there are significant practical and logistical considerations, such as who would pay for the vaccine, how the information will be collected and monitored, and whether a particular clinic should be designated for employees to receive their vaccine.

Likewise, employees may respond negatively to a vaccination requirement, and adverse reactions to the vaccine could lead to workers' compensation or tort claims, or general labor issues. In addition to the legal issues, employers may also want to consider the politicized and polarized nature of the cultural dialogue surrounding prevention of COVID-19 transmission. Imposition of a mandatory COVID-19 vaccine will almost certainly result in a slew of accommodation requests—medical, religious, personal, and ethical—fueled by mistrust of political leaders and the public health community. An August 2020 study found that one-third of Americans would refuse a COVID-19 vaccine, and if large numbers of people feel the need to be exempt from wearing a mask or face covering (which is significantly less intrusive than receiving a vaccination), then employers likely can expect an equal or greater objection to a new vaccine (which may be viewed as risky and/or ineffective).

Employer Takeaways

As a result, we have seen some advice for employers about how to prepare in anticipation of an approved vaccine outside the context of an EUA by FDA:

- Consider whether a mandatory policy is truly necessary for the business in light of other alternatives, such as remote work, physical distancing, face coverings, and other CDC-recommended steps to prevent the spread of COVID-19.
- If the company deems a mandatory vaccine policy necessary, it might consider limiting the mandate to high-risk locales, departments, and/or worksites, where alternative and similarly-effective means of limiting the contagion are not viable.

- Employers that decide to implement a mandatory policy may want to prepare in advance to review and administer numerous requests for accommodations, and create separate exemption request forms and doctor and religious leader certification forms. Potential accommodations may include increased use of personal protective equipment (PPE), modification of duties to remove at-risk activities, temporary or permanent transfers to other positions or work areas, and alternative forms of the vaccine that do not include objectionable ingredients (such as egg, swine, or fetal cell products).
- Determine if it is possible to provide the vaccinations at no or little cost to the employee and consider making them available on-site at times convenient to employees during their normal working hours.

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For additional resources on issues related to COVID-19, please visit Conn Maciel Carey's COVID-19 Resource Page for an extensive index of frequently asked questions with our answers about HR, employment law, and OSHA regulatory related developments and guidance, as well as COVID-19 recordkeeping and reporting flow charts.



Likewise, subscribe to our Employer Defense Report blog and OSHA Defense Report blog for regular updates about the Labor and Employment Law or OSHA implications of COVID-19 in the workplace. Conn Maciel Carey's COVID-19 Task Force is monitoring federal, state, and local developments closely and is continuously updating these blogs and the FAQ page with the latest news and resources for employers.