

Can Healthcare Employers Require Employees to Receive the COVID-19 Vaccine?

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With COVID-19 vaccines finally receiving emergency use authorization ("EUA") from the Federal Food & Drug Administration ("FDA") and beginning to be distributed across the country, many healthcare employers are wondering whether they can require their employees to receive the vaccine to protect the health and safety of other employees and patients who are on the premises. Additionally, healthcare employers may wonder whether they can bar an employee from the premises or even terminate an employee if the person has a legitimate reason for not taking the COVID-19 vaccine. Lastly, are there liability risks in requiring employees to be vaccinated if they have a bad reaction to the vaccine?

The answers to these questions are dictated by several federal laws, including the Americans with Disabilities Act of 1990¹ ("ADA"), the Genetic Information Nondiscrimination Act ("GINA"), and Title VII of the Civil Rights Act, as well as parallel state laws. On December 16, 2020, five days after the Pfizer COVID-19 vaccine received EUA approval from the FDA, the U.S. Equal Employment Opportunity Commission ("EEOC") updated its COVID-19 guidance yet again,² this time adding a special section on COVID-19 vaccinations of employees. This article will provide an overview of this new EEOC guidance, as well as federal law and the FDA and CDC guidance on whether EUA vaccines can be mandated by employers, and what this guidance means for healthcare employers.

Background on Mandatory Vaccines

The authority to mandate vaccinations has been litigated for over 100 years. The first major pronouncement on whether states could mandate vaccines goes back to a U.S. Supreme Court case in 1905 called *Jacobson v. Massachusetts*, where the court upheld a Massachusetts ordinance requiring all adults be vaccinated against smallpox or face a fine of \$5.³ Over the years, the Supreme Court also has upheld the right of states to mandate vaccinations for school children.⁴

However, it becomes a much trickier question when private employers, rather than the state, attempt to mandate vaccination as a condition of continued employment. In general, courts have ruled that employers have such a right, provided that mandating a vaccination is necessary to

¹ Pub. L. No. 101-336, 104 Stat. 328 (1990), codified at 42 U.S.C. § 12101 et seq.

² U.S. Equal Opportunity Commission, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, <u>https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws</u> (updated Dec. 16, 2020).

³ Jacobson v. Massachusetts, 197 U.S. 11 (1905).

⁴ Zucht v. King 260 US 164 (1922).



protect safety and does not violate other laws, such as the ADA, which prohibits employment discrimination against individuals with disabilities.

One of the most recent examples of the right of employers to mandate vaccinations is the 2018 case of *Hustvet v. Allina Health Systems*, in which the Eighth Circuit ruled that an employer had the right to terminate a healthcare worker after she refused to be immunized for measles, mumps, and rubella due to her alleged chemical sensitivities and/or allergies. ⁵ The court found insufficient evidence to support that the employee's alleged conditions constituted disabilities under the ADA, but the court also found that the employer's vaccination requirement was job-related and consistent with business necessity. Many healthcare employers also require their healthcare workers to be vaccinated for the flu, and such policies are generally upheld, provided there are appropriate exceptions for disability, religious objections, and pregnancy.⁶ Notably, none of the cases cited above involved a vaccine that had received EUA approval from the FDA, rather than full approval or clearance.

The COVID-19 vaccine is merely the next phase in a long history of public and employer vaccination programs. However, with so many people reluctant to receive a COVID-19 vaccine that was developed in a fraction of the time vaccines are normally produced, healthcare employers are undoubtedly going to find many employees resistant to any policy mandating COVID-19 vaccination as a condition of continued employment. The EEOC's latest guidance on COVID-19 vaccinations by employers provides employers with a useful roadmap for navigating these tricky issues. However, it should be noted that the EEOC's guidance may be based in part on the assumption that a vaccine will help prevent one person from transmitting the virus to another, but the science on that issue is still not clear.

⁵ 283 F. Supp. 3rd 734 (8th Cir. 2018).

⁶ For example, in Rhode Island, an annual influenza vaccination is required for all healthcare workers, and each healthcare facility is required to actively track and record influenza vaccination levels. And although not required by statute in Maryland, all of Johns Hopkins Medicine entities have a mandatory vaccination policy. The policy applies across the board to all individuals, employees, faculty, staff, residents and fellows, temporary workers, trainees, volunteers, students, vendors, and voluntary medical staff, regardless of employer, who provide services to patients or work in patient care or clinical care areas, including acute and chronic care hospitals, outpatient facilities, and clinics. Similar policies are common in other healthcare workplaces. See: https://www.jdsupra.com/legalnews/can-employers-require-that-employees-53000/. See also https://www.ydsupra.com/legalnews/eeoc-provides-useful-guidance-on-mandatory-flu-vaccinations-and-reasonable-accommodations/9416/.



EEOC's Latest Vaccine Guidance

As a general rule, EEOC guidance states that an employer with a valid job-related reason can require an employee to receive a COVID-19 vaccine as a condition of returning to the work premises. But as with any general rule, there are exceptions. The two major exceptions noted by the EEOC are cases where an employee has a: 1) qualified medical disability under the ADA that would make receiving the vaccine unsafe; or 2) a sincerely held religious objection to vaccination protected by Title VII. In these two instances, and assuming there is no other feasible way to protect the safety of other workers by allowing the employee on the premises, an employer can prohibit the employee in question from coming to the work place. However, whether the employee can be terminated or instead must be allowed to work from home will require an analysis of several factors to determine if a reasonable accommodation for remote work is feasible.

a. Can I Ask the Employee Certain Pre-Vaccination Screening Questions?

As a preliminary matter, the EEOC stated that asking screening questions to ensure it is safe to administer the COVID-19 vaccination to an employee is likely to elicit disability-related information and would trigger the ADA. Thus, if the employer requires an employee to receive a vaccination that is administered by the employer, the employer must show that these disability-related screening inquiries are "job-related and consistent with business necessity." To meet this standard, an employer would need to 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 that cannot be eliminated or reduced by reasonable accommodation.

Depending on the nature of the pre-vaccination questions, they could also implicate Title II of GINA⁷, which prohibits employers from asking employees medical questions about family members. Ideally, pre-vaccination questions should entirely avoid seeking genetic information, although the EEOC admitted that the full scope of screening questions for the COVID-19 vaccine has yet to be determined. The EEOC has also stated that if the pre-vaccination questions *do* include questions about genetic information, employers may want to require employees to provide proof of vaccination by an outside party instead of administering the vaccine themselves and to ensure that such proof does not include any medical or genetic information.

b. What if the Employee Refuses to be Vaccinated Due to a Disability?

If an employer's mandatory vaccination policy screens out, or tends to screen out, an individual with a disability, the employer cannot prohibit the employee from coming to work unless the employer can show that the unvaccinated employee would pose a direct threat due to a "significant risk of substantial harm to the health or safety of the individual or others that cannot

^{7 32} U.S.C. § 2000 et seq.



be eliminated or reduced by reasonable accommodation."⁸ Employers must conduct an individualized assessment of four factors in determining whether a direct threat exists: 1) the duration of the risk; 2) the nature and severity of the potential harm; 3) the likelihood that the potential harm will occur; and 4) the imminence of the potential harm. A conclusion that there is a "direct threat" would include a determination that an unvaccinated individual could expose others to the virus at the workplace.

If an employer determines that an individual who cannot be vaccinated due to disability poses a direct threat at the workplace, and if there is no way to provide a reasonable accommodation that would eliminate or reduce this risk of direct threat without imposing an undue hardship on the employer, the employer can prohibit the employee from physically entering the workplace. For ADA purposes, an "undue hardship" is defined as a "significant difficulty or expense" in acquiring or providing the accommodation, which is a high standard to satisfy. Even if this standard is met, this does not mean the employer may automatically terminate the worker. Rather, the EEOC guidance reminds employers that the employee may still be entitled to a reasonable accommodation such as working remotely if doing so is feasible. For healthcare organizations, remote work may be a reasonable accommodation for some back office or administrative staff. It likely would not be feasible for front-line health professionals to work from home on a long-term basis unless the practice has a well-developed telemedicine practice, but another possible form of accommodation might be providing them with additional protective equipment.

Employers should remember that all employee medical information obtained in the course of its vaccination program *must* be kept confidential.

c. What if the Employee Refuses to be Vaccinated on Religious Grounds?

Once an employer is on notice that an employee's sincerely held religious belief, practice, or observance prevents the employee from receiving the vaccination, the employer must provide a reasonable accommodation unless doing so would pose an undue hardship on 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 accommodation analysis for a religious objection under Title VII is similar to that required by the ADA.

Impact of the EUA Status of COVID-19 Vaccines

The Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines have all received EUA approval from the FDA. The Federal Food, Drug and Cosmetic Act states that with respect to emergency use authorization of an unapproved product, the Secretary of Health and Human Services is required to ensure that individuals to whom the product is administered are informed

^{8 29} C.F.R. § 1630.2(r).



"of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." ⁹ The FDA's 2017 guidance on EUA drugs also requires the FDA to ensure that recipients of such drugs are informed to the extent practical that they "have the option to accept or refuse the EUA product "¹⁰

While the EUA statute and FDA guidance seem to conflict with the EEOC guidance on mandatory vaccination policies, they can be reconciled.

First, the FDA does not have direct authority over employers. In that respect the EEOC's guidance should take precedence with respect to employer vaccination policies.

Second, the EEOC guidance outlined above does not differentiate between vaccines that have only received EUA approval from the FDA versus vaccines that have received final approval. In fact, the EEOC guidance was issued knowing that the Pfizer vaccine had just been approved for emergency use and that the other anticipated vaccines would likewise be approved only for emergency use. The guidance also includes a section that specifically discusses the EUA status of the vaccine. This strongly suggests that the EEOC intended for its guidance to apply equally to vaccines that have received final approval or emergency use authorization.

Third, EUA rules can be interpreted to supplement, not conflict with the EEOC guidance. Under the EEOC guidelines, employers may require their employees to receive the COVID-19 vaccine under the circumstances outlined above and provided that reasonable accommodations are granted as legally required, while the FDA rules require employees to be informed of their right to refuse the vaccine and both the health and employment consequences of doing so.

Lastly, this conclusion is supported by the guidelines issued by the Centers for Disease Control ("CDC"), which state:

Whether an employer may require or mandate COVID-19 vaccination is a matter of state or other applicable law. If an employer requires employees to provide proof that they have received a COVID-19 vaccination from a pharmacy or their own healthcare provider, the employer cannot mandate that the employee provide any medical information as part of the proof.¹¹

The CDC guidelines also cross-reference the medical and religious exceptions set forth in the EEOC guidelines.

⁹ 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

¹⁰ See page 24 of the U.S. Department of Health and Human Services January 2017 industry guidance document entitled "Emergency Use Authorization of Medical Products and Related Authorities", found at <u>https://www.fda.gov/media/97321/download.</u>

¹¹ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/essentialworker/workplace-vaccination-program.html#Mandates.



Thus, employers can comply with both the EEOC guidelines and the FDA EUA rules by ensuring that any employees who are required to receive the COVID-19 vaccine are also informed of their right to refuse the vaccine and any health or employment consequences of such refusal. This assumes that the employer has a legitimate reason for requiring employees to receive the vaccination and has taken reasonable steps to accommodate sincerely held religious beliefs or health conditions, including possibly allowing employees to work remotely or, if feasible, enter the workplace with appropriate personal protective equipment.

Additional Liability Risks of Mandating Vaccines under State Law

In addition to bringing claims under the ADA and Title VII, employees may also challenge mandatory workplace vaccination policies under state employment and privacy laws. However, adherence to the EEOC guidelines would likely be a strong defense to any such suit. If an employee experiences severe and permanent side effects from taking a COVID-19 vaccine, there may be some liability risk under state personal injury laws for the employer that mandated the vaccine. This risk is likely to be very small, both because the employee's civil remedies may be blocked by worker's compensation laws and the risk of severe permanent side effects from the COVID-19 vaccines are very small. Additionally, many states have introduced legislation to further protect employees who refuse mandatory vaccinations or prohibit employer-mandated vaccinations outright.¹² As of the posting date of this article, no state legislation pertaining to mandatory COVID-19 vaccines has been signed into law. But, nonetheless, this is a very fluid issue and the risk of liability under state law is an additional factor that employers should consider in developing their COVID-19 vaccination policies.¹³

Other Resources

- U.S. Equal Employment Opportunity Commission, Pandemic Preparedness in the Workplace and the Americans With Disabilities Act: https://www.eeoc.gov/sites/default/files/2020-04/pandemic_flu.pdf.
- U.S. Food and Drug Administration Guidance on Emergency Use Authorization: <u>https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained</u>

¹² A 50-state survey of pending legislation pertaining to employer-mandated vaccinations can be found at <u>https://www.huschblackwell.com/newsandinsights/50-state-update-on-pending-legislation-pertaining-to-employer-mandated-vaccinations#top.</u>

¹³ Notably, a federal correctional officer in New Mexico filed a lawsuit challenging his employer's "Mandatory COVID-19 Vaccination Directive" requiring him to receive a COVID-19 vaccine as a condition of ongoing employment. However, the constitutional and state law claims in that case would likely only be relevant to actions against federal and state employers. See https://www.washingtonexaminer.com/news/new-mexico-lawsuit-coronavirus-vaccine-mandate.



 Centers for Disease Control, Workplace Vaccination Program, <u>https://www.cdc.gov/coronavirus/2019-</u> <u>ncov/vaccines/recommendations/essentialworker/workplace-vaccination-</u> <u>program.html#Mandates</u>

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