

PUBLICATION

COVID Vaccines for Long Term Care Employees: To Mandate or Not to Mandate?

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With three COVID-19 vaccines authorized by the U.S. Food and Drug Administration (FDA) for emergency use and states across the U.S. prioritizing vaccinations for essential health care workers, long term care (LTC) facilities everywhere are grappling with the same question: "May I require my employees to get vaccinated?"

It is a question that represents the most recent in a series of difficult decisions over the past year that have required LTC facilities to manage various, often competing, considerations. Understandably, in the wake of the pandemic's devastating effects on both residents and staff, LTC facilities are eager to achieve 100 percent vaccination rates among their employees and thus mitigate any further risk to these groups.

From a legal perspective, however, employer-mandated vaccinations remain untenable for the time being. Although such a requirement may be acceptable based on recently updated guidance from the Equal Employment Opportunity Commission (EEOC), other relevant authorities suggest that employers should not mandate vaccinations until the vaccine has full FDA licensure.

The EEOC has set the stage.

Recent guidance from the EEOC from December 16, 2020 indicates that neither requiring an employee to be vaccinated nor asking an employee whether he or she has been vaccinated constitutes a "medical examination" under the Americans with Disabilities Act (ADA). This guidance indicates that an employer could legally require its employees to be vaccinated, subject to certain restrictions discussed further below. However, other federal authorities strongly suggest that implementing such a requirement should be delayed until a vaccine receives full licensure by the FDA.

FDA requirements prevent employer-mandated vaccinations of non-licensed vaccines.

As most of the public is well aware, the three COVID-19 vaccines currently in circulation in the U.S. are being administered subject to an Emergency Use Authorization (EUA) from the FDA. On its [website](#), the FDA explains that EUAs "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies," subject to certain statutory criteria. In sum, to qualify for an EUA, the vaccine must have undergone sufficient testing (through Phase 3 of FDA clinical trials) to establish that its known and potential benefits outweigh its known and potential risks, but the vaccine has not yet been, and is not guaranteed to be, licensed for use by the FDA.

So long as the vaccines remain subject to an EUA rather than full FDA licensure, certain FDA guidance and statutory obstacles appear to prevent employers from requiring their employees to be vaccinated. For instance, [the Food, Drug, and Cosmetics Act](#) mandates that the U.S. Secretary of Health and Human Services (HHS) establish appropriate conditions to ensure that every individual, prior to receiving a vaccine under an EUA, is "informed . . . of the option to accept or refuse administration" of the vaccine. The fact that the Secretary of the HHS is statutorily required to ensure individuals are informed of the *option* to accept or refuse the vaccine suggests that mandates from employers are not permissible. This statutory requirement is explicitly reflected in the above-linked FDA explanation of EUAs, further underscoring the incompatibility of EUAs with employer-mandated vaccinations.

These obstacles to vaccination requirements will persist only as long as the vaccines are subject to EUAs. Once they are fully licensed by the FDA, the vaccines will not be subject to the EUA statutes and FDA guidance. While the FDA has emphasized that there is no "clock" for its clinical trial process, most sources currently project that the COVID-19 vaccines could receive full licensure sometime in the spring or summer of 2021.

Once vaccination mandates are permitted, approach with caution.

As mentioned above, the EEOC guidance published on December 16, 2020 provides several significant restrictions on any vaccination requirement from an employer. First, the EEOC explains that if the vaccine is administered by the employer or a third party contracted by the employer, the CDC-recommended pre-screening inquiries (e.g., asking vaccine recipients whether they have a history of allergic reactions to any medications, other vaccinations, etc.) are likely disability-related inquiries under the ADA. Further, asking an employee why he or she did not obtain a vaccine is likely a disability-related inquiry. The EEOC also reminds employers that, under the ADA, any such inquiries must be job-related and consistent with business necessity.

Notably, this risk could be avoided if employees are vaccinated by a third party who is not under contract with the employer (e.g., a local pharmacy chain) because the medical pre-screening inquiries are not attributed to the employer under this scenario. The employer could then require proof that the individual received a vaccination without triggering the ADA because, as explained by the EEOC, inquiry into an employee's vaccination status is not, on its own, a medical examination or inquiry under the ADA.

Be prepared to make exceptions.

Under the ADA, if an employer implements a vaccination requirement and then wants to exclude an unvaccinated employee from the workplace, the employer must 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 be eliminated or reduced by reasonable accommodation. Similarly, if an employee has a sincerely held religious belief that prevents the employee from receiving the vaccination, under Title VII of the Civil Rights Act of 1964 (Title VII), the employer must provide a reasonable accommodation unless the accommodation would pose an undue hardship.

In either situation, an unvaccinated employee would likely have a strong argument that the employer can make a reasonable accommodation that eliminates or reduces the risk of harm and does not impose an undue hardship on the employer. For instance, an unvaccinated employee could be required to continue wearing a mask, to socially distance, and to undergo daily COVID-19 testing and/or daily tests for symptoms such as fever.

Thus, while the updated EEOC guidance does allow for mandatory employee vaccinations once a vaccine has received full FDA licensure, LTC facilities should familiarize themselves with these restrictions.

Above all else, LTC facilities should be prepared to deal with employee requests for exceptions to the policy under the ADA and Title VII.

Incentives are ill-advised.

Some LTC facilities have asked whether they could offer employees incentives to get the COVID-19 vaccine, rather than implementing a mandate. While the preference for a "positive reinforcement" approach is understandable, incentive-based programs present at least as many potential legal issues as vaccination requirements. For instance, any type of incentives provided by employers to employees to encourage their obtaining the COVID-19 (or any other) vaccine could violate both the ADA and the Health Insurance Portability and Accountability Act (HIPAA) nondiscrimination rules for wellness plans under the Employee Retirement Income Security Act of 1974, as amended (ERISA).

The ADA permits employers to make medical examinations or inquiries in connection with a wellness program, but only if such a program is "voluntary," which, according to the EEOC, requires that, among other things, the program offers a reasonable accommodation to persons for whom it is medically inadvisable to participate and that incentives are "limited." As discussed above, an employee with a medical condition likely has a strong argument that the employer can provide a reasonable accommodation, so there is no guarantee of success using an incentive-based wellness program. Moreover, what constitutes a "limited" incentive is in flux. The EEOC has proposed a rule that, if approved, will set a "*de minimis*" incentive standard under which things like a water bottle or a gift card of modest value would be permissible. However, as with any legal gray area, the risk of running afoul of a law, regulation, or rule could outweigh the potential benefits of the program.

Additionally, when an employer provides or pays for employees' medical care, including a vaccination, the employer has likely created a group health plan under ERISA. Certain vaccination programs that incentivize employees to get vaccinated could create an ERISA compliance obligation. Many employers may decide to wrap the vaccine incentive programs into their existing medical plans for ERISA compliance purposes. However, if any incentive or stipend is extended to employees not enrolled in the health plan, then the employer may need to amend its health plan to provide special coverage for all employees, whether enrolled or not. Finally, the HIPAA nondiscrimination rules require that, for any wellness program that is part of or supplements a group health plan under ERISA, the employer must provide a reasonable alternative way for employees with medical conditions preventing participation to otherwise qualify for the incentive. Thus, as with reasonable accommodations under the ADA, there is no guarantee that an incentive-based program will be successful, and there are still attendant legal risks.

Where there's a will, there's a way.

The optimal way for a LTC facility to achieve a 100 percent vaccination rate among its employees is for the employees to get vaccinated voluntarily. Toward that end, the Centers for Disease Control and Prevention has created an Essential Workers COVID-19 Vaccine Toolkit that may assist LTC facilities in educating their employees on the importance and benefits of vaccination against COVID-19. As always, we urge you to consult with legal counsel to draft the policy and the appropriate forms to accompany it if your LTC facility is considering implementing any policy that will require or incentivize employees to get a COVID-19 vaccine.

[Andrew Roach](#) or the [Labor & Employment attorneys](#) at Baker Donelson are available to guide you through these matters at any time.